

Dosing and Administration Guide



DARZALEX *Faspro*[®]

(daratumumab and hyaluronidase-fihj)

Injection for subcutaneous use | 1,800mg/30,000units



DARZALEX[®]

(daratumumab)

injection for intravenous infusion

100 mg/5 mL, 400 mg/20 mL

Please see Important Safety Information for DARZALEX FASPRO[®] on pages [54-56](#) and Important Safety Information for DARZALEX[®] on pages [96-97](#). Please [click here](#) for full Prescribing Information for DARZALEX FASPRO[®]. Please [click here](#) for full Prescribing Information for DARZALEX[®].

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For subcutaneous use in the treatment of multiple myeloma¹ Dosing and Administration Guide

INDICATIONS

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with bortezomib, lenalidomide, and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (PI)
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- As monotherapy in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent

DARZALEX FASPRO® as monotherapy is indicated for the treatment of adult patients with high-risk smoldering multiple myeloma.

Select Important Safety Information

CONTRAINDICATIONS

DARZALEX FASPRO® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase, or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO®.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.

DARZALEX FASPRO® benefits^{1,2}

Subcutaneous administration with DARZALEX FASPRO®



~3 to 5 minute subcutaneous injection administered by a healthcare provider



Fixed dose; no weight-based calculations



Single-dose vial, no dilution needed



Same dosing schedules as DARZALEX® (daratumumab) for approved indications*

*Split first dose option for DARZALEX® is not applicable to DARZALEX FASPRO®.



Formulated with hyaluronidase for subcutaneous administration

Select Important Safety Information

CONTRAINDICATIONS

DARZALEX FASPRO® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase, or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO®.

~3 to 5 minute administration possible with subcutaneous injection¹

DARZALEX FASPRO® is a CD38-targeted monoclonal antibody in a subcutaneous formulation¹

DARZALEX FASPRO® contains recombinant hyaluronidase, which is a substance that increases permeability of subcutaneous tissue, making it possible for 15 mL containing 1,800 mg of daratumumab to be administered in approximately 3 to 5 minutes.¹

Recombinant hyaluronidase works locally and transiently to degrade hyaluronan ([HA], a naturally occurring glycosaminoglycan found throughout the body) in the extracellular matrix of the subcutaneous space. It cleaves the linkage between the 2 sugars (N-acetylglucosamine and glucuronic acid) that comprise HA. Recombinant hyaluronidase has a half-life in skin of less than 30 minutes.¹

- The effects of hyaluronidase are reversible and permeability of the subcutaneous tissue is restored within 24 to 48 hours

DID YOU KNOW?

DARZALEX FASPRO® is administered as a subcutaneous injection over ~3 to 5 minutes while DARZALEX® is given as an intravenous infusion over 7 hours for the first infusion, 4 hours for the second infusion, and 3 hours for subsequent infusions (median).^{1,2}

Select Important Safety Information (cont)

Systemic Reactions

In a pooled safety population of 1446 patients with multiple myeloma (N=1235) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO® as monotherapy or as part of a combination therapy, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3%, Grade 3: 0.8%, Grade 4: 0.1%). In patients with high-risk smoldering multiple myeloma (N=193), systemic administration-related reactions occurred in 17% of patients in AQUILA (Grade 2: 7%, Grade 3: 1%).

In all patients (N=1639), systemic administration-related reactions occurred in 7% of patients with the first injection, 0.5% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 4 minutes to 3.5 days). Of the 283 systemic administration-related reactions that occurred in 135 patients, 240 (85%) occurred on the day of DARZALEX FASPRO® administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.

DARZALEX Faspro®
(daratumumab and hyaluronidase-fihj)
Injection for subcutaneous use | 1,800mg/50,000units

~3 to 5 minute subcutaneous administration with every dose or each dose¹

DARZALEX FASPRO[®] contains 30,000 units of recombinant hyaluronidase¹

- Increases permeability of subcutaneous tissue¹
- Enables 15 mL containing 1,800 mg of daratumumab to be absorbed into the subcutaneous tissue of the abdomen¹
- Use an appropriate needle gauge. In the clinical trials, 23- to 25-gauge needles were used for the injection³
- For subcutaneous use only. DARZALEX FASPRO[®] has different dosage and administration instructions than DARZALEX[®] (daratumumab). Do not administer intravenously^{1,2}

Pre-medication¹

Pre-medicate patients 1 to 3 hours before each dose with a histamine-1 receptor antagonist, acetaminophen, and a corticosteroid.

- Antipyretics (acetaminophen 650 to 1000 mg, oral)
- Antihistamine (diphenhydramine 25 to 50 mg or equivalent oral or IV)
- Corticosteroid (long- or intermediate-acting)
 - Methylprednisolone (100 mg, or equivalent, orally or intravenously for monotherapy). Consider reducing the dose of methylprednisolone to 60 mg (or equivalent) following the second dose of DARZALEX FASPRO[®]
 - dexamethasone (20 mg, or equivalent, orally or intravenously for combination therapy)

NOTE: When dexamethasone is the background regimen-specific corticosteroid, the dexamethasone treatment dose will also serve as pre-medication on days DARZALEX FASPRO[®] is given.

~3 to 5 minute subcutaneous injection¹



Use an appropriate needle gauge. In the clinical trials, 23- to 25-gauge needles were used for the injection.³

Post-medication¹

Consider administering corticosteroids and other medications after the administration of DARZALEX FASPRO[®], depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions (ARRs).*

NOTE: For patients with a history of chronic obstructive pulmonary disease, consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids. Following the first 4 doses of DARZALEX FASPRO[®], consider discontinuing these additional post-medications if the patient does not experience a major systemic ARR. **Please see full Prescribing Information for further guidance on post-medication.**

Monitor patients for systemic ARR, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) ARR, immediately and permanently discontinue DARZALEX FASPRO[®].

*In clinical trials of DARZALEX FASPRO[®] and DARZALEX[®], and in the Prescribing Information for DARZALEX[®], the terms "infusion reactions" and "infusion-related reactions" were used instead of "systemic administration-related reactions."

Please see Important Safety Information for DARZALEX FASPRO[®] on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO[®]. Please [click here](#) for full Prescribing Information for DARZALEX[®].



DARZALEX FASPRO[®] dosing schedules¹

Ready-to-use, single-use vial includes a fixed dose for shorter preparation and no weight-based calculations

	Indicated regimen*	Weeks	Schedule
Multiple Myeloma	DARZALEX FASPRO [®] + VRd (bortezomib, lenalidomide, and dexamethasone) for patients ineligible for ASCT	Weeks 1 to 6	Treatment weekly (total of 6 doses)
		Weeks 7 to 24 ¹	Treatment every 3 weeks (total of 6 doses)
		Week 25 onward until disease progression ¹	Treatment every 4 weeks
		Induction	Schedule
	DARZALEX FASPRO [®] + VRd (bortezomib, lenalidomide, and dexamethasone) for patients eligible for ASCT (4-week cycle)	Weeks 1 to 8	Treatment weekly (total of 8 doses)
		Weeks 9 to 16 ⁵	Treatment every 2 weeks (total of 4 doses)
		Stop for high-dose chemotherapy and ASCT	
		Consolidation	Consolidation
		Weeks 1 to 8 ¹¹	Treatment every 2 weeks (total of 4 doses)
	DARZALEX FASPRO [®] + VMP (bortezomib, melphalan, and prednisone) (6-week cycle)	Weeks	Schedule
Weeks 1 to 6		Treatment weekly (total of 6 doses)	
Weeks 7 to 54		Treatment every 3 weeks (total of 16 doses)	
Week 55 onward until disease progression		Treatment every 4 weeks	
DARZALEX FASPRO [®] + Vd (bortezomib and dexamethasone) (3-week cycle)	Weeks	Schedule	
	Weeks 1 to 9	Treatment weekly (total of 9 doses)	
	Weeks 10 to 24	Treatment every 3 weeks (total of 5 doses)	
	Week 25 onward until disease progression	Treatment every 4 weeks	
DARZALEX FASPRO [®] + VTd (bortezomib, thalidomide, and dexamethasone) (4-week cycle)	Weeks	Schedule	
	Weeks 1 to 8	Treatment weekly (total of 8 doses)	
	Weeks 9 to 16	Treatment every 2 weeks (total of 4 doses)	
	Stop for high-dose chemotherapy and ASCT		
	Consolidation	Consolidation	
	Weeks 1 to 8	Treatment every 2 weeks (total of 4 doses)	
DARZALEX FASPRO [®] + Rd DARZALEX FASPRO [®] + Pd DARZALEX FASPRO [®] + Kd DARZALEX FASPRO [®] monotherapy (lenalidomide, pomalidomide, or carfilzomib and dexamethasone) (4-week cycle)	Weeks	Schedule	
	Weeks 1 to 8	Treatment weekly (total of 8 doses)	
	Weeks 9 to 24	Treatment every 2 weeks (total of 8 doses)	
	Week 25 onward until disease progression	Treatment every 4 weeks	
High-Risk Smoldering Multiple Myeloma	Weeks	Schedule	
	Weeks 1 to 8	Treatment weekly (total of 8 doses)	
	Weeks 9 to 24 ¹	Treatment every 2 weeks (total of 8 doses)	
	Week 25 onward until diagnosis of multiple myeloma or a maximum of 3 years ⁶	Treatment every 4 weeks	

ARR=administration-related reaction; ASCT=autologous stem cell transplant.
*See the Dosage and Administration section of the full Prescribing Information for more details. When DARZALEX FASPRO[®] is administered as part of a combination therapy, see the prescribing information for dosage recommendations for the other drugs.
¹First dose of the every-3-week dosing schedule is given at Week 7.

¹First dose of the every-4-week dosing schedule is given at Week 25.

⁵First dose of the every-2-week dosing schedule is given at Week 9.

¹¹First dose of the every-2-week dosing schedule is given at Week 1 upon re-initiation of treatment following ASCT.

¹First dose of the every-2-week dosing schedule is given at Week 9.

⁶First dose of the every-4-week dosing schedule is given at Week 25.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) + VRd dosing schedule¹

In adult transplant-ineligible patients with newly diagnosed multiple myeloma¹

Dosing schedule based on a phase 3, open-label, randomized, active-controlled trial.

DARZALEX FASPRO® in combination with bortezomib, lenalidomide, and dexamethasone (VRd) (n=197) vs VRd alone (n=198).

Recommended dosage and schedule for DARZALEX FASPRO®^{1,4}

3 Doses Per 3-Week Cycle given as **once-weekly** injection (3 doses per 3-week cycle; Cycles 1* to 2; Weeks 1 to 6)

1 Dose Per 3-Week Cycle given as 1 injection **every 3 weeks** (once per 3 week cycle; Cycles 3 to 8; Weeks 7 to 24)[†]

1 Dose Per Month given as 1 injection **every 4 weeks** (once every 4-weeks; Cycles 9+; Weeks 25+ until disease progression)[‡]

19 estimated Year 1 injection visits

See table on page 9 ►

- Bortezomib was administered by subcutaneous (SC) injection at a dose of 1.3 mg/m² body surface area twice weekly (Days 1, 4, 8, and 11) of repeated 21-day (3-week) Cycles 1-8^{4*}
- Lenalidomide was administered orally at 25 mg daily on Days 1-14 during Cycles 1-8 and on Days 1-21 during Cycle 9 and beyond⁴
- Dexamethasone was administered orally at 20 mg on Days 1, 2, 4, 5, 8, 9, 11, and 12 of Cycles 1-8 and at 40 mg on Days 1, 8, 15, and 22 during Cycles 9 and beyond⁵
 - On the days of DARZALEX FASPRO® injection, the dexamethasone dose was administered orally or intravenously as a pre-injection medication

*For dosing instructions of combination agents administered with DARZALEX FASPRO®, see Clinical Studies (14.1) section of the full Prescribing Information for DARZALEX FASPRO® and the respective manufacturer's prescribing information.

[†]First dose of the every-3-week dosing schedule is given at Week 7.¹

[‡]First dose of the every-4-week dosing schedule is given at Week 25.¹

[§]Please see the full Prescribing Information for DARZALEX FASPRO® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1-2 [†] (each lasting 21 days)								Total of 6 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
DARZALEX FASPRO® weekly	●							●							●	No treatment					
bortezomib	●			●				●			●					No treatment					
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	No treatment					
dexamethasone	●	●		●	●			●	●		●	●				No treatment					

Cycles 3-8 (each lasting 21 days)								Total of 6 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
DARZALEX FASPRO® every 3 weeks	●															No treatment					
bortezomib	●			●				●			●					No treatment					
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	No treatment					
dexamethasone	●	●		●	●			●	●		●	●				No treatment					

Cycles 9 onward [‡] (each lasting 28 days)																															
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28			
DARZALEX FASPRO® every 4 weeks	●																												No treatment		
bortezomib																													No treatment		
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	No treatment	
dexamethasone	●							●							●												●		No treatment		

Continue DARZALEX FASPRO® + Rd until disease progression or unacceptable toxicity

Select Important Safety Information (cont)

Systemic Reactions (cont)

Severe reactions included hypoxia, dyspnea, hypertension, tachycardia, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritus, chills, vomiting, nausea, hypotension, and blurred vision.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen, and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX FASPRO®. Consider administering corticosteroids and other medications after the administration of DARZALEX FASPRO® depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

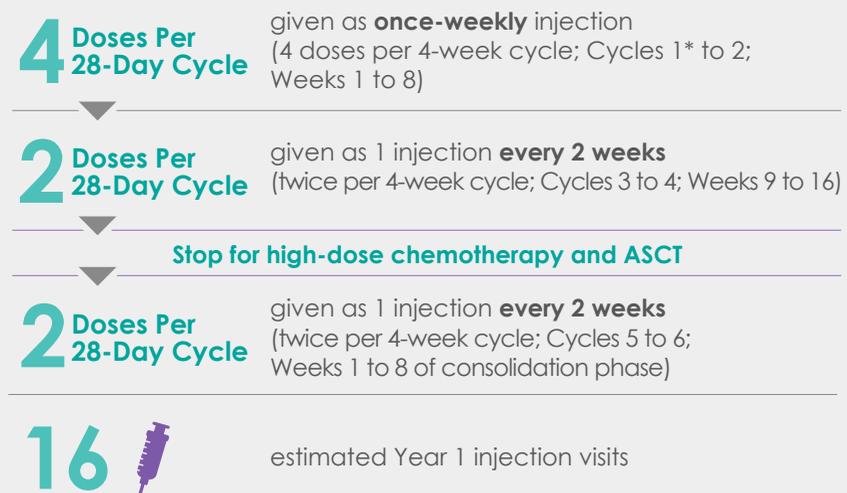
DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) + VRd dosing schedule¹

In adult transplant-eligible patients with newly diagnosed multiple myeloma¹

Dosing schedule based on a phase 3, open-label, randomized, active-controlled trial.

DARZALEX FASPRO® in combination with bortezomib, lenalidomide, and dexamethasone (VRd) (n=355) vs VRd alone (n=354).

Recommended dosage and schedule for DARZALEX FASPRO®¹



See table on page 9 ▶

- Bortezomib 1.3 mg/m² body surface area is infused on Days 1, 4, 8, and 11 of Cycles 1-6*[†]
- Lenalidomide 25 mg is given orally on Days 1-21 of Cycles 1-6[†]
- Dexamethasone 40 mg is given orally or injected on Days 1-4 and Days 9-12 of Cycles 1-6^{††}
 - On DARZALEX FASPRO® injection days, the entire dexamethasone dose was given as a pre-injection medication

ASCT=autologous stem-cell transplant.

*For dosing instructions of combination agents administered with DARZALEX FASPRO®, see Clinical Studies (14.1) section of the full Prescribing Information for DARZALEX FASPRO® and the respective manufacturer's prescribing information.

[†]Weeks 1-16 during induction phase and Weeks 1-8 during consolidation phase.¹

^{††}Please see the full Prescribing Information for DARZALEX FASPRO® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® weekly	●							●							●								●						
bortezomib	●			●				●			●																		
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
dexamethasone	●	●	●	●					●	●	●	●																	
No treatment																													

Cycles 3–4 (each lasting 28 days)															Total of 4 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 2 weeks	●														●													
bortezomib	●			●				●			●																	
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●	●	●					●	●	●	●																
No treatment																												

Stop for high-dose chemotherapy and ASCT

Cycles 5–6 (each lasting 28 days)															Total of 4 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 2 weeks	●														●													
bortezomib	●			●				●			●																	
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●	●	●					●	●	●	●																
No treatment																												

Select Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Systemic Reactions (cont)

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with daratumumab-containing products. If ocular symptoms occur, interrupt DARZALEX FASPRO® and seek immediate ophthalmologic evaluation prior to restarting DARZALEX FASPRO®.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) + VTd dosing schedule¹

In adult patients with newly diagnosed, transplant-eligible multiple myeloma¹

Dosing schedule based on an open-label, randomized, active-controlled trial

DARZALEX FASPRO® in combination with bortezomib, thalidomide, and dexamethasone (VTd) (n=543) vs VTd alone (n=542)

Recommended dosage and schedule for DARZALEX FASPRO®¹

4 Doses Per 28-Day Cycle given as **once weekly** injection (4 doses per 4-week cycle; Cycles 1* to 2; Weeks 1 to 8)

2 Doses Per 28-Day Cycle given as 1 injection **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)

Stop for high-dose chemotherapy and ASCT

2 Doses Per 28-Day Cycle given as 1 injection **every 2 weeks** (twice per 4-week cycle; Cycles 5 to 6; Weeks 1 to 8 of consolidation phase)

16  estimated Year 1 injection visits

See table on page 13 ▶

- Bortezomib 1.3 mg/m² was injected subcutaneously or IV on Days 1, 4, 8, and 11 of Cycles 1-4*
- Thalidomide 100 mg was given orally daily during 6 bortezomib cycles
- Dexamethasone 40 mg was given orally or IV on Days 1, 2, 8, 9, 15, 16, 22, and 23 of Cycles 1-2, and at 40 mg on Days 1-2, and 20 mg was administered on Days 1, 2, 8, 9, 15, 16 in Cycles 5-6†
 - On DARZALEX FASPRO® injection days, the entire dexamethasone dose was given as a pre-injection medication

ASCT=autologous stem-cell transplant.

*For dosing instructions of combination agents administered with DARZALEX FASPRO®, see Clinical Studies (14.1) section of the full Prescribing Information for DARZALEX® and the respective manufacturer's prescribing information.

†Please see the full Prescribing Information for DARZALEX FASPRO® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® weekly	●							●							●							●							
bortezomib	●			●				●			●																		
thalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●	●						●	●						●	●						

Cycles 3–4 (each lasting 28 days)															Total of 4 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 2 weeks	●														●													
bortezomib	●			●				●			●																	
thalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

Stop for high-dose chemotherapy and ASCT

Cycles 5–6 (each lasting 28 days)															Total of 4 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 2 weeks	●														●													
bortezomib	●			●				●			●																	
thalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●	●						●	●												

Select Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Infections

DARZALEX FASPRO® can cause serious, life-threatening, or fatal infections. In patients who received DARZALEX FASPRO® in a pooled safety population including patients with smoldering multiple myeloma and light chain (AL) amyloidosis (N=1639), serious infections, including opportunistic infections, occurred in 24% of patients, Grade 3 or 4 infections occurred in 22%, and fatal infections occurred in 2.5%. The most common type of serious infection reported was pneumonia (8.5%).

Monitor patients for signs and symptoms of infection prior to and during treatment with DARZALEX FASPRO® and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) + Rd dosing schedule¹

In adult patients with newly diagnosed, transplant-ineligible multiple myeloma¹

Dosing schedule based on a phase 3, randomized, active-controlled trial²

DARZALEX FASPRO® in combination with lenalidomide and dexamethasone (Rd) (n=368) vs Rd alone (n=369)

Recommended dosage and schedule for DARZALEX FASPRO®¹

4 Doses Per 28-Day Cycle	given as once weekly injection (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
2 Doses Per 28-Day Cycle	given as 1 injection every 2 weeks (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
1 Dose Per 28-Day Cycle	given as 1 injection every 4 weeks (once per 4-week cycle; Cycle 7+; Week 25+ until disease progression)
23 	estimated Year 1 injection visits

See table on page 15 ▶

- Lenalidomide 25 mg is given orally on Days 1–21 of each cycle[†]
- Dexamethasone 40 mg is given orally or IV once a week[‡]
 - On DARZALEX FASPRO® injection days, the entire dexamethasone dose was given as a pre-injection medication

[†]For dosing instructions of combination agents administered with DARZALEX FASPRO®, see the Clinical Studies (14.2) section of the full Prescribing Information for DARZALEX FASPRO® and the respective manufacturer's prescribing information.

[‡]Please see the full Prescribing Information for DARZALEX FASPRO® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® weekly	●							●							●							●							
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
dexamethasone	●							●							●							●							
No treatment																													

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® every 2 weeks	●														●														
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
dexamethasone	●							●							●							●							
No treatment																													

Cycles 7 onward (each lasting 28 days)																													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® every 4 weeks	●																												
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
dexamethasone	●							●							●							●							
No treatment																													

Continue DARZALEX FASPRO® + Rd until disease progression or unacceptable toxicity

Select Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Neutropenia

Daratumumab may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX FASPRO® until recovery of neutrophils. In lower body weight patients receiving DARZALEX FASPRO®, higher rates of Grade 3-4 neutropenia were observed.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) + Rd dosing schedule¹

In patients at first relapse¹

Dosing schedule based on a randomized, active-controlled trial²

DARZALEX FASPRO® in combination with lenalidomide and dexamethasone (Rd) (n=286) vs Rd alone (n=283)

Recommended dosage and schedule for DARZALEX FASPRO®¹

4 Doses Per 28-Day Cycle	given as once weekly injection (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
2 Doses Per 28-Day Cycle	given as 1 injection every 2 weeks (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
1 Dose Per 28-Day Cycle	given as 1 injection every 4 weeks (once per 4-week cycle; Cycle 7+; Week 25+ until disease progression)
23 	estimated Year 1 injection visits

See table on page 17 ▶

- Lenalidomide 25 mg was given orally on Days 1–21 of each cycle[†]
- Dexamethasone 40 mg was given orally or IV once a week[†]
 - On DARZALEX FASPRO® injection days, 20 mg of the dexamethasone dose was given as a pre-injection medication and the remainder given the day after the injection
 - For patients on a reduced dexamethasone dose, the entire 20 mg dose was given as a DARZALEX FASPRO® pre-injection medication

[†]For dosing instructions of combination agents administered with DARZALEX FASPRO®, see the Clinical Studies (14.2) section of the full Prescribing Information for DARZALEX FASPRO® and the respective manufacturer's prescribing information.

[†]Please see the full Prescribing Information for DARZALEX FASPRO® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® weekly	●							●							●							●							
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●	●						●	●						●	●						

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® every 2 weeks	●														●														
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
dexamethasone	●	●						●							●	●							●						

Cycles 7 onward (each lasting 28 days)																												
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 4 weeks	●																											
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●							●	●							●					

Continue DARZALEX FASPRO® until disease progression or unacceptable toxicity

Select Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Thrombocytopenia

Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX FASPRO® until recovery of platelets.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) + Vd dosing schedule¹

In patients at first relapse¹

Dosing schedule based on a phase 3, randomized, active-controlled trial²

DARZALEX FASPRO® in combination with bortezomib and dexamethasone (Vd) (n=251) vs Vd alone (n=247)

Recommended dosage and schedule for DARZALEX FASPRO®¹

3 Doses Per 21-Day Cycle

given as **once weekly** injection (3 doses per 3-week cycle; Cycles 1 to 3; Weeks 1 to 9)

1 Dose Per 21-Day Cycle

given as 1 injection **every 3 weeks** (once per 3-week cycle; Cycles 4 to 8; Weeks 10 to 24)

1 Dose Per 4-Week Cycle

given as 1 injection **every 4 weeks** (once per 4-week cycle; Cycles 9+; Weeks 25+ until disease progression)

21

estimated Year 1 injection visits

See table on page 19 ▶

- Bortezomib 1.3 mg/m² was administered by subcutaneous injection or IV infusion on Days 1, 4, 8, and 11 of each cycle for a total of 8 cycles*
- Dexamethasone 20 mg was given orally once daily on Days 1, 2, 4, 5, 8, 9, 11, and 12 for a total of 8 cycles[†]
 - On the days of DARZALEX FASPRO® injection, 20 mg of the dexamethasone dose was administered as a pre-injection medication and was continued as a pre-medication after Vd discontinuation
 - For patients on a reduced dexamethasone dose, the entire 20 mg dose was given as a DARZALEX FASPRO® pre-injection medication

*Please refer to the bortezomib prescribing information for more detailed information about twice-weekly bortezomib dosing.

[†]Please see the full Prescribing Information for DARZALEX FASPRO® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–3 (each lasting 21 days)								Total of 9 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	
DARZALEX FASPRO® weekly	●							●							●							
bortezomib	●			●				●			●											
dexamethasone	●	●		●	●			●	●		●	●										

Cycles 4–8 (each lasting 21 days)								Total of 5 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	
DARZALEX FASPRO® every 3 weeks	●																					
bortezomib	●			●				●			●											
dexamethasone	●	●		●	●			●	●		●	●										

Continue DARZALEX FASPRO® once every 4 weeks until disease progression²

NOTE: Bortezomib and dexamethasone dosing should be stopped after 8 cycles.

Select Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX FASPRO® can cause fetal harm when administered to a pregnant woman. DARZALEX FASPRO® may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX FASPRO® and for 3 months after the last dose.

The combination of DARZALEX FASPRO® with lenalidomide, thalidomide, or pomalidomide is contraindicated in pregnant women because lenalidomide, thalidomide, and pomalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, thalidomide, or pomalidomide prescribing information on use during pregnancy.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) + Pd dosing schedule¹

In patients with ≥1 prior line of therapy including lenalidomide and a proteasome inhibitor (PI)¹

Dosing schedule based on an open-label trial¹

DARZALEX FASPRO® in combination with pomalidomide and dexamethasone (Pd) [N=103]¹

Recommended dosage and schedule for DARZALEX FASPRO®¹

4 Doses Per 28-Day Cycle	given as once weekly injection (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
2 Doses Per 28-Day Cycle	given as 1 injection every 2 weeks (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
1 Dose Per 28-Day Cycle	given as 1 injection every 4 weeks (once per 4-week cycle; Cycle 7+; Week 25+ until disease progression)
23 	estimated Year 1 injection visits

See table on page 21 ▶

- Pomalidomide 4 mg was given orally on Days 1–21 of each cycle[†]
- Dexamethasone 40 mg was given orally or IV once a week[‡]
- On DARZALEX FASPRO® injection days, 20 mg of the dexamethasone dose was given as a pre-injection medication and the remainder given the day after the injection
- For patients on a reduced dexamethasone dose, the entire 20 mg dose was given as a DARZALEX FASPRO® pre-injection medication

[†]Please refer to the pomalidomide prescribing information for more detailed information about pomalidomide dosing.

[‡]Please see the full Prescribing Information for DARZALEX FASPRO® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® weekly	●							●							●							●							
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●	●						●	●						●	●						

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® every 2 weeks	●														●														
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●							●	●							●						

Cycles 7 onward (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® every 4 weeks	●																												
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●							●	●							●						

Continue DARZALEX FASPRO® + Pd until disease progression or unacceptable toxicity

Select Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Interference With Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted.

Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX FASPRO®. Type and screen patients prior to starting DARZALEX FASPRO®.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) + Kd dosing schedule¹

In patients with 1 to 3 prior lines of therapy

Dosing schedule based on an open-label trial¹

DARZALEX FASPRO® in combination with carfilzomib and dexamethasone (Kd) [N=66]¹

Recommended dosage and schedule for DARZALEX FASPRO®¹

4 Doses Per 28-Day Cycle

given as a **once weekly** injection (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)

2 Doses Per 28-Day Cycle

given as 1 injection **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)

1 Dose Per 28-Day Cycle

given as 1 injection **every 4 weeks** (once per 4-week cycle; Cycle 7+; Week 25+ until disease progression)

23 

estimated Year 1 injection visits

See table on page 23 ►

- Carfilzomib was administered by IV infusion Days 1, 8, and 15 of each cycle for a total of 8 cycles.*
- Dexamethasone 20 mg was given orally or intravenously on Days 1, 8, and 15 and then 40 mg orally or intravenously on Day 22 for a total of 8 cycles¹
 - On DARZALEX FASPRO® injection days, 20 mg of the dexamethasone dose was given as a pre-injection medication and the remainder given the day after the injection
 - For patients on a reduced dexamethasone dose, the entire 20 mg dose was given as a DARZALEX FASPRO® pre-injection medication

*Please refer to the carfilzomib prescribing information for more detailed information about twice weekly and once weekly carfilzomib dosing.

¹Please see the full Prescribing Information for DARZALEX FASPRO® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days) with either Once-weekly or twice-weekly carfilzomib															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® weekly	●							●							●							●							
Once-weekly carfilzomib																													
carfilzomib [§]	●							●							●														
dexamethasone	●	●						●	●						●	●							●	●					
Twice-weekly carfilzomib																													
carfilzomib [¶]	●	●						●	●						●	●													
dexamethasone	●	●						●	●						●	●								●					

[§]Carfilzomib was administered intravenously once weekly at a dose of 20 mg/m² on Cycle 1 Day 1 and escalated to dose of 70 mg/m² on Cycle 1 Days 8 and 15, and Days 1, 8, and 15 of each subsequent 28-day cycle.

[¶]Carfilzomib was administered intravenously at a dose of 20 mg/m² in Cycle 1 on Days 1 and 2; at a dose of 56 mg/m² in Cycle 1 on Days 8, 9, 15, and 16; and at a dose 56 mg/m² on Days 1, 2, 8, 9, 15, and 16 of each 28-day cycle thereafter.

Cycles 3–6 (each lasting 28 days) with either Once-weekly or twice-weekly carfilzomib															Total of 8 DARZALEX FASPRO® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® weekly	●																												
Once-weekly carfilzomib																													
carfilzomib [§]	●							●							●														
dexamethasone	●	●						●	●						●	●								●					
Twice-weekly carfilzomib																													
carfilzomib [¶]	●	●						●	●						●	●													
dexamethasone	●	●						●	●						●	●								●					

Cycles 7 onward (each lasting 28 days) with either Once-weekly or twice-weekly carfilzomib																													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX FASPRO® weekly	●																												
Once-weekly carfilzomib																													
carfilzomib [§]	●							●							●														
dexamethasone	●	●						●							●										●				
Twice-weekly carfilzomib																													
carfilzomib [¶]	●	●						●	●						●	●													
dexamethasone	●	●						●	●						●	●									●				

Continue DARZALEX FASPRO® + Kd once every 4 weeks until disease progression or unacceptable toxicity

Select Important Safety Information (cont)

WARNINGS AND PRECAUTIONS

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some DARZALEX FASPRO®-treated patients with IgG kappa myeloma protein.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) monotherapy dosing schedule¹

In patients with ≥3 prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who were double-refractory to a PI and an immunomodulatory agent¹

Dosing schedule was based on an open-label, randomized, non-inferiority study (n=263)¹

Recommended dosage and schedule for DARZALEX FASPRO®¹

- 4 Doses Per 28-Day Cycle** given as **once weekly** injection (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
- 2 Doses Per 28-Day Cycle** given as 1 injection **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
- 1 Dose Per 28-Day Cycle** given as 1 injection **every 4 weeks** (once per 4-week cycle; Cycle 7+; Weeks 25+ until disease progression or unacceptable toxicity)

23  estimated Year 1 injection visits

See table on page 25 ►

- Administer DARZALEX FASPRO® only as a subcutaneous injection

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® weekly	●	No treatment						●	No treatment						●	No treatment						●	No treatment					

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 2 weeks	●	No treatment													●	No treatment												

Cycles 7 onward (each lasting 28 days)																												
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 4 weeks	●	No treatment																										

Continue DARZALEX FASPRO® until disease progression or unacceptable toxicity

For information concerning drugs given in combination with DARZALEX FASPRO®, see full Prescribing Information.

Select Important Safety Information (cont)

ADVERSE REACTIONS

In multiple myeloma, the most common adverse reaction (≥20%) with DARZALEX FASPRO® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy (≥20% for any combination) include fatigue, nausea, diarrhea, dyspnea, sleep disorder, headache, rash, renal impairment, motor dysfunction, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, musculoskeletal pain, decreased appetite, urinary tract infection, abdominal pain, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, dizziness, bruising, and COVID-19.

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) monotherapy for high-risk smoldering multiple myeloma¹

In adult patients with high-risk smoldering multiple myeloma¹

Dosing schedules based on an open-label, randomized trial.

DARZALEX FASPRO® (D) (n=194) vs active monitoring (n=196).

Recommended dosage and schedule for DARZALEX FASPRO®¹

- 4 Doses Per 28-Day Cycle** given as **once weekly** injection (4 doses per 4-week cycle; Cycles 1 to 2; Weeks 1 to 8)
- 2 Doses Per 28-Day Cycle** given as 1 injection **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
- 1 Dose Per 28-Day Cycle** given as 1 injection **every 4 weeks** (once per 4-week cycle; Cycle 7+; Weeks 25+ until 39 cycles or up to 36 months or until diagnosis of multiple myeloma)

23  estimated Year 1 injection visits

See table on page 27 ▶

- Administer DARZALEX FASPRO® only as a subcutaneous injection

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX FASPRO® dosing frequency decreases over time¹

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® weekly	●	No treatment						●	No treatment						●	No treatment						●	No treatment					

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX FASPRO® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 2 weeks	●	No treatment													●	No treatment												

Cycles 7 onward (each lasting 28 days)																												
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX FASPRO® every 4 weeks	●	No treatment																										

Continue DARZALEX FASPRO® monotherapy until diagnosis of multiple myeloma or a maximum of 3 years

For information concerning drugs given in combination with DARZALEX FASPRO®, see full Prescribing Information.

Select Important Safety Information (cont)

ADVERSE REACTIONS

The most common adverse reactions (≥20%) in patients with high-risk smoldering multiple myeloma who received DARZALEX FASPRO® monotherapy are upper respiratory tract infection, musculoskeletal pain, fatigue, diarrhea, rash, sleep disorder, sensory neuropathy, and injection site reactions.

The most common hematology laboratory abnormalities (≥40%) with DARZALEX FASPRO® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Preparation for DARZALEX FASPRO®

Before you begin, collect your supplies^{1,3*}

1,800 mg and 30,000 Units/15 mL

Single-dose vial of DARZALEX FASPRO®
For Subcutaneous Use Only

Syringe
20 mL

Regular Bevel Transfer Needle
18G-22G

using a winged infusion set
OR
using an injection needle

Infusion Set
23G or 25G

Injection Needle
23G or 25G

*Please note that the syringe volume and the gauge for the injection needle shown here were used in clinical trials.

STEP 1: Inspect and prepare the vial

- Remove the DARZALEX FASPRO® vial from the refrigerator and warm to room temperature. Check the liquid in the vial. Keep out of direct sunlight, and do not shake. Store the unpunctured vial at ambient temperature and ambient light for a maximum of 24 hours
- To prevent medication errors, it is important to check the vial labels to ensure that the drug being prepared and administered is DARZALEX FASPRO® for subcutaneous injection and not DARZALEX® (daratumumab)
- DARZALEX FASPRO® subcutaneous formulation is not intended for intravenous administration and should be administered via subcutaneous injection only



DID YOU KNOW?

If you prefer, you may use a winged infusion set to administer DARZALEX FASPRO®.³

Select Important Safety Information

CONTRAINDICATIONS

DARZALEX FASPRO® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase, or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

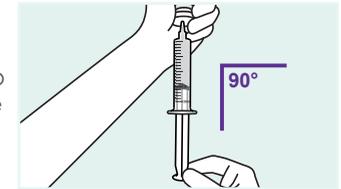
Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO®.

STEP 2: Attach the transfer needle, fill the syringe, and inspect the medication¹

Prepare the dosing syringe in controlled and validated aseptic conditions.

- Withdraw 15 mL from the vial into a syringe using an 18G to 22G transfer needle with a regular bevel. Insert the needle into the vial at a 90° angle within the ring of the stopper
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if opaque particles, discoloration or other foreign particles are present
- DARZALEX FASPRO® is compatible with polypropylene or polyethylene syringe material; polypropylene, polyethylene, or polyvinyl chloride (PVC) subcutaneous infusion sets; and stainless steel transfer and injection needles. Use the product immediately
- After the solution of DARZALEX FASPRO® is withdrawn into the syringe, replace the transfer needle with a syringe closing cap. Label the syringe appropriately to include the route of administration per institutional standards. Label the syringe with the peel-off label



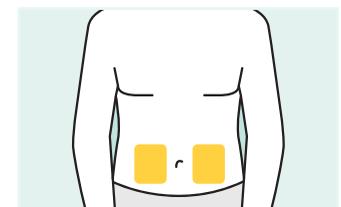
STEP 3: Attach the injection needle^{1,3}

- To avoid needle clogging, attach the hypodermic injection needle or subcutaneous infusion set to the syringe immediately prior to injection



STEP 4: Choose and prepare the injection site on the abdomen^{1,3}

- Do not inject into skin on the abdomen that is tender, bruised, red, hard, or has scars
- Wipe your chosen injection site with an alcohol swab and allow it to dry
- Rotate injection sites for each successive injection



NEED TO KNOW

To prevent medication errors, it is important to check the vial labels to ensure that the drug being prepared and administered is DARZALEX FASPRO® and not DARZALEX®.¹

Select Important Safety Information (cont)

Systemic Reactions

In a pooled safety population of 1446 patients with multiple myeloma (N=1235) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO® as monotherapy or as part of a combination therapy, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3%, Grade 3: 0.8%, Grade 4: 0.1%). In patients with high-risk smoldering multiple myeloma (N=193), systemic administration-related reactions occurred in 17% of patients in AQUILA (Grade 2: 7%, Grade 3: 1%).

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



Administration for DARZALEX FASPRO®

DARZALEX FASPRO® makes subcutaneous administration possible starting with the first dose¹

DARZALEX FASPRO® is for single use only and comes in a ready-to-use vial¹

STEP 1: Insert needle at a 45-degree angle during administration³

When you and your patient are comfortable, start the injection.

- Pinch skin at the injection site on the abdomen. It is important to pinch enough skin to inject under the skin and not into the muscle
- Insert needle with a quick, dart-like motion
- Try to limit needle and syringe movement during the injection. If needed, secure the infusion set in place with a bandage

STEP 2: Inject the dose^{1,3}

Inject 15 mL DARZALEX FASPRO® into the subcutaneous tissue of the abdomen approximately 3 inches (7.5 cm) to the right or left of the navel

- Press the plunger with a constant rate of administration for approximately 3 to 5 minutes
- If the patient feels pain, pause or slow down the rate of administration. If the patient still feels pain, consider using a different injection site on the opposite side of the abdomen to deliver the remainder of the dose
- Do not inject DARZALEX FASPRO® at other sites of the body as no data are available
- Injection sites should be rotated for successive injections
- Do not administer other medications for subcutaneous use at the same site
- DARZALEX FASPRO® subcutaneous formulation should never be injected into areas where the skin is red, bruised, tender, hard or areas where there are scars



Select Important Safety Information (cont)

Systemic Reactions

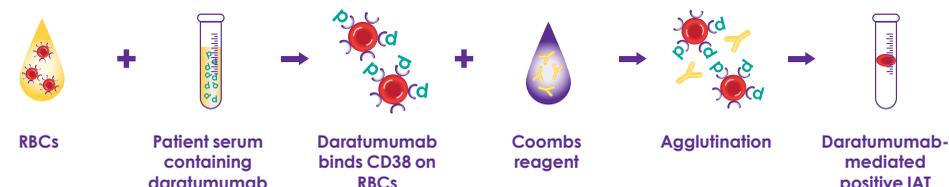
In all patients (N=1639), systemic administration-related reactions occurred in 7% of patients with the first injection, 0.5% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 4 minutes to 3.5 days). Of the 283 systemic administration-related reactions that occurred in 135 patients, 240 (85%) occurred on the day of DARZALEX FASPRO® administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Important information before administering DARZALEX FASPRO®

Interference with serological testing¹

- Daratumumab binds to CD38 found on red blood cells and results in a positive indirect antiglobulin test (indirect Coombs test) that may persist for up to 6 months after the last DARZALEX FASPRO® injection

Typical indirect antiglobulin test from a daratumumab-treated patient^{1,4}



IAT=indirect antiglobulin test; RBC=red blood cells.

Reminders

- Type and screen patients before starting DARZALEX FASPRO®
- Inform blood banks when a patient is receiving DARZALEX FASPRO®
- Identify any DARZALEX FASPRO®-treated blood samples
- Ask patients to tell other healthcare professionals that they have received DARZALEX FASPRO®

Prophylaxis for herpes zoster reactivation¹

- Initiate antiviral prophylaxis to prevent herpes zoster reactivation within 1 week after starting DARZALEX FASPRO® and continue for 3 months following the end of treatment

Handling and storage¹

Prior to administration, remove DARZALEX FASPRO® from refrigerated storage at 2°C to 8°C (36°F to 46°F) and equilibrate to ambient temperature at 15°C to 30°C (59°F to 86°F). Store the unpunctured vial at ambient temperature and ambient light for a maximum of 24 hours. Keep out of direct sunlight. Do not shake.

Liquid product (120 mg/mL) comes in a single-use, sterile vial; inspect the vial contents and expiration.

After the solution of DARZALEX FASPRO® is withdrawn into the syringe, replace the transfer needle with a syringe closing cap. Label the syringe appropriately to include the route of administration per institutional standards. Label the syringe with the peel-off label. To avoid needle clogging, attach the hypodermic injection needle or subcutaneous infusion set to the syringe immediately prior to injection.

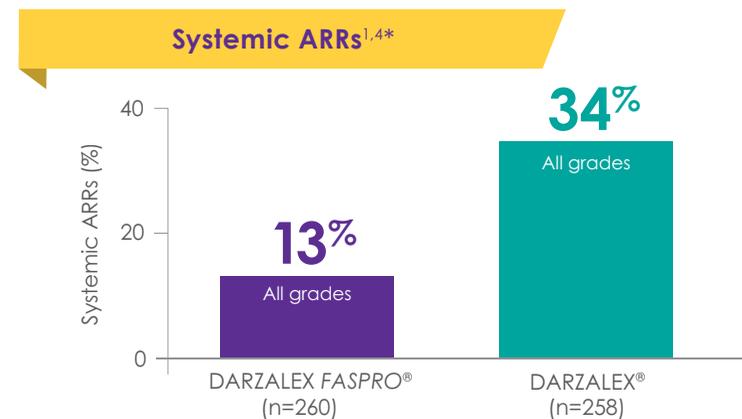
If the syringe containing DARZALEX FASPRO® is not used immediately, store refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours and/or at room temperature at 15°C to 25°C (59°F to 77°F) for up to 12 hours under ambient light. Discard if storage time exceeds these limits. If stored in the refrigerator, allow the solution to come to room temperature before administration.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.

DARZALEX Faspro®
(daratumumab and hyaluronidase-fihj)
Injection for subcutaneous use | 1,800mg/50,000units

Fewer systemic administration-related reactions with DARZALEX FASPRO® vs DARZALEX®

Nearly 3x reduction in systemic ARR^s with DARZALEX FASPRO® vs DARZALEX® (daratumumab) observed in the COLUMBA trial¹



Systemic ARR^s¹

Most systemic ARR^s were **Grade 1 or 2** and occurred with the first injection.

The most common systemic ARR^s (DARZALEX FASPRO® vs DARZALEX®) were chills (6% vs 12%), pyrexia (13% vs 13%), and dyspnea (6% vs 11%).

Grade 3 systemic ARR^s occurred in 2% of patients using DARZALEX FASPRO® vs 5% of those on DARZALEX®.

No Grade 4 systemic ARR^s were reported.

Both systemic ARR^s, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO®.¹

ARR^s=administration-related reactions.

¹Systemic ARR^s causing severe reactions included hypoxia, dyspnea, hypertension, tachycardia, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Other signs and symptoms of systemic ARR^s may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritus, chills, vomiting, nausea, hypotension, and blurred vision.¹

Hypersensitivity and administration-related reactions

Systemic reactions¹

- In a pooled safety population of 1446 patients with multiple myeloma (N=1253) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO® as monotherapy or in combination, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3%, Grade 3: 0.8%, Grade 4: 0.1%)
- In patients with high-risk smoldering multiple myeloma (N=193), systemic administration-related reactions occurred in 17% of patients in AQUILA (Grade 2: 7%, Grade 3: 1%)
- In all patients (N=1639), systemic administration-related reactions occurred in 7% of patients with the first injection, 0.5% with the second injection, and cumulatively 1% with subsequent injections
- The median time to onset was 3.2 hours (range, 4 minutes to 3.5 days). Of the 283 systemic administration-related reactions that occurred in 135 patients, 240 (85%) occurred on the day of DARZALEX FASPRO® administration
- Delayed systemic administration-related reactions have occurred in 1% of the patients

Local reactions¹

- In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 1.1%. The most frequent (>1%) injection-site reactions were injection site erythema and injection site rash
- In patients with high-risk smoldering multiple myeloma (N=193), injection-site reactions occurred in 28% of patients, including Grade 2 reactions in 3%
- These local reactions occurred a median of 6 minutes (range, 0 minutes to 6.5 days) after starting administration of DARZALEX FASPRO®. Monitor for local reactions and consider symptomatic management

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.

DARZALEX Faspro®
(daratumumab and hyaluronidase-fihj)
Injection for subcutaneous use | 1,800mg/50,000units

Safety generally consistent with DARZALEX® (daratumumab)

Adverse reactions reported in ≥10% of patients and select hematologic laboratory abnormalities worsening from baseline in patients receiving either DARZALEX FASPRO® or DARZALEX®¹

Adverse reactions	DARZALEX FASPRO® (n=260)		DARZALEX® (n=258)	
	All grades (%)	Grade ≥3 (%)	All grades (%)	Grade ≥3 (%)
Upper respiratory tract infection ^a	24	1 ^g	22	1 ^g
Pneumonia ^b	8	5	10	6 ^h
Diarrhea	15	1 ^g	11	0.4 ^g
Nausea	8	0.4 ^g	11	0.4 ^g
Fatigue ^c	15	1 ^g	16	2 ^g
Systemic ARRs ^d	13	2 ^g	34	5 ^g
Pyrexia	13	0	13	1 ^g
Chills	6	0.4 ^g	12	1 ^g
Back pain	10	2 ^g	12	3 ^g
Cough ^e	9	1 ^g	14	0
Dyspnea ^f	6	1 ^g	11	1 ^g

Systemic ARRs=systemic administration-related reactions.

^aUpper respiratory tract infection includes acute sinusitis, nasopharyngitis, pharyngitis, respiratory syncytial virus infection, respiratory tract infection, rhinitis, rhinovirus infection, sinusitis, and upper respiratory tract infection.

^bPneumonia includes lower respiratory tract infection, lung infection, pneumocystis jirovecii pneumonia, and pneumonia.

^cFatigue includes asthenia and fatigue.

^dSystemic ARRs includes terms determined by investigators to be related to infusion. In clinical trials of DARZALEX FASPRO® and DARZALEX®, and in the Prescribing Information for DARZALEX®, the terms "infusion reactions" and "infusion-related reactions" were used instead of "systemic ARRs."

^eCough includes cough and productive cough.

^fDyspnea includes dyspnea and dyspnea exertional.

^gOnly Grade 3 adverse reactions occurred.

^hGrade 5 adverse reactions occurred.

Laboratory abnormalities	DARZALEX FASPRO® (n=260) ^a		DARZALEX® (n=258) ^a	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
Decreased leukocytes	65	19	57	14
Decreased lymphocytes	59	36	56	36
Decreased neutrophils	55	19	43	11
Decreased platelets	43	16	45	14
Decreased hemoglobin	42	14	39	16

^aDenominator is based on the safety population treated with DARZALEX FASPRO® (n=260) or with DARZALEX® (n=258).

In the treatment of transplant-ineligible patients with newly diagnosed multiple myeloma¹
Types of adverse reactions seen with DARZALEX FASPRO® + VRd were similar to those observed with VRd¹

Adverse reactions reported in ≥20% of patients who received DARZALEX FASPRO® + VRd

Adverse reaction	DARZALEX FASPRO® + VRd (n=197)		VRd (n=195)	
	All grades (%)	Grade 3 or 4 (%)	All grades (%)	Grade 3 or 4 (%)
Infections				
Upper respiratory tract infection ^a	75	4 [#]	63	3 [#]
COVID-19 ^b	39 [@]	9	25 [@]	3
Pneumonia ^c	31 [@]	16	26 [@]	15
Urinary tract infection ^b	24	4 [#]	17	3 [#]
Nervous system disorders				
Sensory neuropathy ^d	72	12 [#]	72	10
Motor dysfunction ^e	44	11 [#]	37	7 [#]
Dizziness ^b	26	2 [#]	26	1 [#]
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain ^b	62	9 [#]	61	7 [#]
Gastrointestinal disorders				
Diarrhea ^b	57	12 [#]	59	9 [#]
Constipation	38	2 [#]	42	3 [#]
Nausea	25	0	25	2 [#]
Abdominal pain ^b	23 [@]	1	17	2 [#]
General disorders and administration site conditions				
Fatigue ^b	56	14 [#]	53	11 [#]
Edema ^b	54	4 [#]	46	2 [#]
Pyrexia ^b	24	1 [#]	16	1 [#]
Skin and subcutaneous tissue disorders				
Rash ^b	50	8 [#]	47	7
Psychiatric disorders				
Sleep disorder ^b	33	3 [#]	33	2 [#]
Respiratory, thoracic, and mediastinal disorders				
Cough ^b	32	1 [#]	21	1 [#]
Dyspnea ^b	21 [@]	2	17	1 [#]
Renal and urinary disorders				
Renal impairment ^f	26	7	25	6
Metabolism and nutrition disorders				
Decreased appetite	21	1 [#]	20	3 [#]
Injury, poisoning, and procedural complications				
Bruising ^b	20	0	12	0

VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

^aUpper respiratory tract infection includes acute sinusitis, influenza, influenza-like illness, laryngitis, nasal congestion, nasopharyngitis, parainfluenzae virus infection, pharyngitis, pharyngitis streptococcal, respiratory syncytial virus infection, respiratory tract infection, respiratory tract infection bacterial, respiratory tract infection viral, rhinitis, rhinovirus infection, sinus congestion, sinus disorder, sinusitis, tonsillitis, tracheitis, upper respiratory tract infection, upper respiratory tract inflammation, and viral upper respiratory tract infection.

^bIncludes other related terms.

^cPneumonia includes bronchopulmonary aspergillosis, COVID-19 pneumonia, lower respiratory tract infection, pneumocystis jirovecii pneumonia, pneumonia, pneumonia aspiration, pneumonia bacterial, pneumonia cryptococcal, pneumonia influenzal, pneumonia klebsiella, pneumonia legionella, pneumonia pneumococcal, pneumonia respiratory syncytial viral, pneumonia viral, and tuberculosis.

^dSensory neuropathy includes anosmia, burning sensation, dysesthesia, hyperesthesia, hyperesthesia teeth, hypoesthesia, hypoesthesia oral, neuralgia, neuropathy peripheral, oral dysesthesia, palmar-plantar erythrodysesthesia syndrome, paresthesia, paresthesia oral, peripheral sensorimotor neuropathy, peripheral sensory neuropathy, polyneuropathy, and skin burning sensation.

^eMotor dysfunction includes balance disorder, essential tremor, extrapyramidal disorder, facial paralysis, gait disturbance, hypotonia, mobility decreased, motor dysfunction, muscle contractions involuntary, muscle contracture, muscle spasms, muscular weakness, myopathy, paraparesis, peripheral motor neuropathy, peroneal nerve palsy, pharyngeal paraesthesia, and tremor.

^fRenal impairment includes acute kidney injury, blood creatinine increased, chronic kidney disease, creatinine renal clearance decreased, glomerular filtration rate decreased, prerenal failure, renal failure, renal impairment, and renal injury.

[#]Only Grade 3 adverse reactions occurred.

[@]Fatal adverse reactions occurred for abdominal pain: n=1 (1%) in the DARZALEX FASPRO®-VRd arm; COVID-19: n=7 (4%) in the DARZALEX FASPRO®-VRd arm and n=5 (3%) in the VRd arm; pneumonia: n=8 (4%) in the DARZALEX FASPRO®-VRd arm and n=5 (3%) in the VRd arm; dyspnea: n=1 (1%) in the DARZALEX FASPRO®-VRd arm.

In the treatment of transplant-ineligible patients with newly diagnosed multiple myeloma¹

Most frequent laboratory abnormalities and serious adverse reactions in this study^{1*}

Select laboratory abnormalities (≥30%) that worsened from baseline in patients who received DARZALEX FASPRO® + VRd^{1*}

Laboratory abnormality	DARZALEX FASPRO® + VRd ^a		VRd ^a	
	All grades (%)	Grade 3 or 4 (%)	All grades (%)	Grade 3 or 4 (%)
Hematology				
Decreased leukocytes	93	39	77	15
Decreased neutrophils	89	49	75	35
Decreased lymphocytes	87	55	72	38
Decreased platelets	81	31	73	23
Decreased hemoglobin	53	14	52	16
Chemistry				
Increased alanine aminotransferase (ALT)	66	7	61	3
Increased creatinine	54	5	56	3
Decreased potassium	53	19	36	12
Decreased sodium	48	16	40	13
Increased aspartate aminotransferase (AST)	43	3	46	3
Increased alkaline phosphatase	43	2	31	1
Decreased corrected calcium	32	5	26	5

- Serious adverse reactions occurred in 72% of patients who received DARZALEX FASPRO® + VRd. The most frequent serious adverse reactions in >5% of patients who received DARZALEX FASPRO® + VRd were pneumonia (19%), COVID-19 (12%), thromboembolism (7%), and diarrhea (6%)¹
- Fatal adverse reactions occurred in 16.8% of patients who received DARZALEX FASPRO® + VRd¹
 - Fatal adverse reactions that occurred in more than 1 patient included pneumonia (4%), COVID-19 (4%), and myocardial infarction (2%)

ALT=alanine aminotransferase; AST=aspartate aminotransferase; DVRd=DARZALEX FASPRO® (D) + bortezomib (V) + lenalidomide (R) + dexamethasone (d); VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

*A total of 395 patients (with transplant-ineligible disease or who refused transplant as initial therapy) with newly diagnosed multiple myeloma were enrolled between December 11, 2018, and October 7, 2019, with a clinical cutoff date of May 7, 2024. This time period coincided with the World Health Organization's International Health Regulation Emergency Committee declaring the 2019 novel coronavirus outbreak a Public Health Emergency of International Concern (PHEIC) in January 2020.^{4,5}

^aDenominator is based on number of subjects with a baseline and post-baseline laboratory value for each laboratory test: N=197 for DARZALEX FASPRO® + VRd and N=194 for VRd.¹

In the treatment of transplant-eligible patients with newly diagnosed multiple myeloma¹

Demonstrated safety profile through post-transplant consolidation for frontline DARZALEX FASPRO® + VRd¹

Adverse reactions reported in ≥10% of patients who received DVRd through post-transplant consolidation¹

Adverse reaction	DARZALEX FASPRO® + VRd (n=351)		VRd (n=347)	
	All grades (%)	Grade 3 or 4 (%)	All grades (%)	Grade 3 or 4 (%)
Peripheral neuropathy*	52	5	54	4
Paraesthesia	11	<1 [†]	11	<1 [†]
Fatigue [†]	35	3 [†]	37	5 [†]
Edema [†]	22	1	21	1 [†]
Pyrexia	21	2 [†]	22	3 [†]
Upper respiratory tract infection [‡]	32	1 [†]	26	2 [†]
Pneumonia [§]	14	9	10	6 [#]
Constipation	31	2 [†]	30	2 [†]
Diarrhea	23	3 [†]	25	5 [†]
Nausea	16	1 [†]	12	1 [†]
Abdominal pain [†]	11	0	12	0
Musculoskeletal pain [†]	26	1 [†]	23	1 [†]
Muscle spasm	12	0	9	<1 [†]
Insomnia	26	2 [†]	16	2 [†]
Rash [†]	25	3 [†]	31	5
Hepatotoxicity	16	6 [†]	16	5
Cough [†]	12	<1 [†]	8	0

DVRd=DARZALEX FASPRO® (D) + bortezomib (V) + lenalidomide (R) + dexamethasone (d); VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

*Peripheral neuropathy includes neuropathy peripheral, peripheral motor neuropathy, peripheral sensorimotor neuropathy, and peripheral sensory neuropathy.

[†]Includes other related terms.

[‡]Upper respiratory tract infection includes fungal pharyngitis, h1n1 influenza, influenza, influenza-like illness, laryngitis, nasopharyngitis, oral candidiasis, oropharyngeal candidiasis, parainfluenzae virus infection, pharyngitis, respiratory moniliasis, respiratory syncytial virus infection, respiratory tract infection, respiratory tract infection viral, rhinitis, rhinovirus infection, sinusitis, tonsillitis, upper respiratory tract infection, viral tonsillitis, and viral upper respiratory tract infection.

[§]Pneumonia includes bronchopulmonary aspergillosis, lower respiratory tract infection, pneumocystis jirovecii pneumonia, pneumonia, pneumonia bacterial, pneumonia cytomegaloviral, pneumonia influenzal, pneumonia klebsiella, pneumonia legionella, and pneumonia streptococcal.

^{||}Hepatotoxicity includes alanine aminotransferase increased, aspartate aminotransferase increased, hepatic cytolysis, hepatic failure, hepatic function abnormal, hepatotoxicity, hyperbilirubinemia, hypertransaminasemia, and liver disorder.

[†]Only Grade 3 adverse reactions occurred.

[#]Fatal adverse reactions included pneumonia: n=1 (0.3%) in the VRd arm.

Select laboratory abnormalities (≥30%) that worsened from baseline in patients who received DVRd through post-transplant consolidation¹

Laboratory abnormality	DARZALEX FASPRO® + VRd (n=351)**		VRd (n=346)**	
	All grades (%)	Grade 3 or 4 (%)	All grades (%)	Grade 3 or 4 (%)
Hematology				
Decreased platelets	89	34	78	25
Decreased lymphocytes	87	69	69	43
Decreased leukocytes	78	47	56	22
Decreased neutrophils	67	52	47	34
Decreased hemoglobin	39	7	43	6
Chemistry				
Increased alanine aminotransferase (ALT)	52	7	48	5
Decreased sodium	40	5	25	5
Increased alkaline phosphatase	39	0	36	1
Decreased potassium	30	6	24	3

The most common adverse reactions (≥20%) were peripheral neuropathy, fatigue, edema, pyrexia, upper respiratory infection, constipation, diarrhea, musculoskeletal pain, insomnia, and rash.¹

In patients who received DVRd¹:

- 37% experienced serious adverse reactions
- >5% experienced most frequent serious adverse reaction: pneumonia (6%)
- 1.7% experienced fatal adverse reactions
- 2% experienced permanent treatment discontinuation due to an adverse reaction
 - An adverse reaction which resulted in permanent discontinuation of DVRd in more than 1 patient included sepsis¹

ALT=alanine aminotransferase; DVRd=DARZALEX FASPRO® (D) + bortezomib (V) + lenalidomide (R) + dexamethasone (d); VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

**Based on number of patients with a baseline and post-baseline laboratory value for each laboratory test.

In adult patients with newly diagnosed, transplant-ineligible multiple myeloma
Safety results demonstrated in combination with VMP

Adverse reactions (≥10%) and select hematologic laboratory abnormalities worsening from baseline in patients receiving DARZALEX FASPRO® in combination with bortezomib, melphalan, and prednisone¹

Adverse reactions	DARZALEX FASPRO® + VMP (n=67)	
	Any grade (%)	Grade ≥3 (%)
Upper respiratory tract infection ^a	39	0
Bronchitis	16	0
Pneumonia ^b	15	7 ^g
Constipation	37	0
Nausea	36	0
Diarrhea	33	3 ^g
Vomiting	21	0
Abdominal pain ^c	13	0
Fatigue ^d	36	3
Pyrexia	34	0
Edema peripheral ^e	13	1 ^g
Peripheral sensory neuropathy	34	1 ^g
Dizziness	10	0
Cough ^f	24	0
Insomnia	22	3 ^g
Back pain	21	3 ^g
Musculoskeletal chest pain	12	0
Decreased appetite	15	1 ^g
Rash	13	0
Pruritus	12	0
Hypertension	13	6 ^g
Hypotension	10	3 ^g

VMP=bortezomib (V) + melphalan (M) + prednisone (P).
^aUpper respiratory tract infection includes nasopharyngitis, respiratory syncytial virus infection, respiratory tract infection, rhinitis, tonsillitis, upper respiratory tract infection, and viral pharyngitis.
^bPneumonia includes lower respiratory tract infection, lung infection, pneumocystis jirovecii pneumonia, pneumonia, and pneumonia bacterial.
^cAbdominal pain includes abdominal pain and abdominal pain upper.
^dFatigue includes asthenia and fatigue.
^eEdema peripheral includes edema, edema peripheral, and peripheral swelling.
^fCough includes cough and productive cough.
^gOnly Grade 3 adverse reactions occurred.

The most common adverse reactions (≥20%) were upper respiratory tract infection, constipation, nausea, fatigue, pyrexia, peripheral sensory neuropathy, diarrhea, cough, insomnia, vomiting, and back pain.¹

Laboratory abnormalities	DARZALEX FASPRO® + VMP ^a	
	Any grade (%)	Grades 3 or 4 (%)
Decreased leukocytes	96	52
Decreased lymphocytes	93	84
Decreased platelets	93	42
Decreased neutrophils	88	49
Decreased hemoglobin	48	19

DVMP=DARZALEX FASPRO® (D) + bortezomib (V) + melphalan (M) + prednisone (P).
^aDenominator is based on the safety population treated with DVMP (n=67).

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



In patients with relapsed/refractory multiple myeloma
Safety results demonstrated in combination with Rd

Adverse reactions (≥10%) and select hematologic laboratory abnormalities worsening from baseline in patients receiving DARZALEX FASPRO® in combination with lenalidomide and dexamethasone¹

Adverse reactions	DARZALEX FASPRO® + Rd (n=65)	
	Any grade (%)	Grade ≥3 (%)
Fatigue ^a	52	5 ^g
Pyrexia	23	2 ^g
Edema peripheral	18	3 ^g
Diarrhea	45	5 ^g
Constipation	26	2 ^g
Nausea	12	0
Vomiting	11	0
Upper respiratory tract infection ^b	43	3 ^g
Pneumonia ^c	23	17
Bronchitis ^d	14	2 ^g
Urinary tract infection	11	0
Muscle spasms	31	2 ^g
Back pain	14	0
Dyspnea ^e	22	3
Cough ^f	14	0
Peripheral sensory neuropathy	17	2 ^g
Insomnia	17	5 ^g
Hyperglycemia	12	9 ^g
Hypocalcemia	11	0

^aFatigue includes asthenia and fatigue.

^bUpper respiratory tract infection includes nasopharyngitis, pharyngitis, respiratory tract infection viral, rhinitis, sinusitis, upper respiratory tract infection, and upper respiratory tract infection bacterial.

^cPneumonia includes lower respiratory tract infection, lung infection, and pneumonia.

^dBronchitis includes bronchitis and bronchitis viral.

^eDyspnea includes dyspnea and dyspnea exertional.

^fCough includes cough and productive cough.

^gOnly Grade 3 adverse reactions occurred.

The most common adverse reactions (≥20%) were fatigue, diarrhea, upper respiratory tract infection, muscle spasms, constipation, pyrexia, pneumonia, and dyspnea.¹

Laboratory abnormalities	DARZALEX FASPRO® + Rd ^a	
	Any grade (%)	Grades 3 or 4 (%)
Decreased leukocytes	94	34
Decreased lymphocytes	82	58
Decreased platelets	86	9
Decreased neutrophils	89	52
Decreased hemoglobin	45	8

^aDenominator is based on the safety population treated with DRd (n=65).

In patients with relapsed/refractory multiple myeloma
Safety results demonstrated in combination with Kd

Adverse reactions (≥10%) and select laboratory abnormalities (≥30%) worsening from baseline in patients receiving DARZALEX FASPRO® in combination with carfilzomib and dexamethasone¹

Adverse reactions	DARZALEX FASPRO® + Kd (n=66)	
	Any grade (%)	Grade ≥3 (%)
Upper respiratory tract infection ^a	52	0
Bronchitis ^b	12	2 ^h
Fatigue ^c	39	2 ^h
Pyrexia	21	2 ^h
Edema peripheral ^d	20	0
Insomnia	33	6 ^h
Hypertension ^e	32	21 ^h
Diarrhea	29	0
Nausea	21	0
Vomiting	15	0
Cough ^f	24	0
Dyspnea ^g	23	2 ^h
Headache	23	0
Peripheral sensory neuropathy	11	0
Back pain	17	2 ^h
Musculoskeletal chest pain	11	0

Kd=carfilzomib (K) + dexamethasone (d).

^aUpper respiratory tract infection includes nasopharyngitis, pharyngitis, respiratory tract infection, respiratory tract infection viral, rhinitis, sinusitis, tonsillitis, upper respiratory tract infection, viral pharyngitis, and viral upper respiratory tract infection.

^bBronchitis includes bronchitis and bronchitis viral.

^cFatigue includes asthenia and fatigue.

^dEdema peripheral includes generalized edema, edema peripheral, and peripheral swelling.

^eHypertension includes blood pressure increased and hypertension.

^fCough includes cough and productive cough.

^gDyspnea includes dyspnea and dyspnea exertional.

^hOnly Grade 3 adverse reactions occurred.

Clinically relevant adverse reactions in <10% of patients who received DARZALEX FASPRO® with carfilzomib and dexamethasone include¹:

- **Gastrointestinal disorders:** abdominal pain, constipation, pancreatitis
- **Infection and infestations:** pneumonia, influenza, urinary tract infection, herpes zoster, sepsis
- **Metabolism and nutrition disorders:** hyperglycemia, decreased appetite, hypocalcemia
- **Musculoskeletal and connective tissue disorders:** muscle spasms, arthralgia
- **Nervous system disorders:** paresthesia, dizziness, syncope
- **General disorders and administration site conditions:** injection site reaction, infusion-related reactions, chills
- **Skin and subcutaneous tissue disorders:** rash, pruritus
- **Cardiac disorders:** cardiac failure
- **Vascular disorders:** hypotension

Laboratory abnormalities	DARZALEX FASPRO® + Kd ^a	
	Any grade (%)	Grades 3 or 4 (%)
Decreased platelets	88	18
Decreased lymphocytes	83	50
Decreased leukocytes	68	18
Decreased neutrophils	55	15
Decreased hemoglobin	47	6
Decreased corrected calcium	45	2
Increased alanine aminotransferase (ALT)	35	5

^aDenominator is based on the safety population treated with DKd (n=66).

DKd=DARZALEX FASPRO® (D) + carfilzomib (K) + dexamethasone (d).

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.

DARZALEX Faspro®
 (daratumumab and hyaluronidase-fihj)
 Injection for subcutaneous use | 1,800mg/50,000units

In patients with relapsed/refractory multiple myeloma
Safety results demonstrated in combination with Pd

Adverse reactions reported in ≥10% of patients and with at least a 5% greater frequency in the DARZALEX FASPRO® + Pd arm and select hematologic laboratory abnormalities worsening from baseline in APOLLO¹

Adverse reactions	DARZALEX FASPRO® + Pd (n=149)		Pd (n=150)	
	All grades (%)	Grade ≥3 (%)	All grades (%)	Grade ≥3 (%)
Fatigue ^a	46	13	39	5 ^f
Pyrexia	19	0	14	0
Edema peripheral ^b	15	0	9	0
Pneumonia ^c	38	23 ^g	27	17 ^g
Upper respiratory infection ^d	36	1 ^f	22	2 ^f
Diarrhea	22	5 ^f	14	1 ^f
Cough ^e	13	0	8	0

^aFatigue includes asthenia and fatigue.

^bEdema peripheral includes edema, edema peripheral, and peripheral swelling.

^cPneumonia includes atypical pneumonia, lower respiratory tract infection, pneumonia, pneumonia aspiration, pneumonia bacterial, and pneumonia respiratory syncytial viral.

^dUpper respiratory tract infection includes nasopharyngitis, pharyngitis, respiratory syncytial virus infection, respiratory tract infection, respiratory tract infection viral, rhinitis, sinusitis, tonsillitis, upper respiratory tract infection, and viral upper respiratory tract infection.

^eCough includes cough and productive cough.

^fOnly grade 3 adverse reactions occurred.

^gGrade 5 adverse reactions occurred, n=34 (2.0%) in the DARZALEX FASPRO® + Pd arm and n=2 (1.3%) in the Pd arm.

- The most common adverse reactions (≥20%) were fatigue, pneumonia, upper respiratory tract infection, and diarrhea¹
- Serious adverse reactions occurred in 50% of patients who received DARZALEX FASPRO® + Pd. The most frequent serious adverse reactions in >5% of patients who received DARZALEX FASPRO® + Pd were pneumonia (15%) and lower respiratory tract infection (12%). Fatal adverse reactions occurred in 7% of patients who received DARZALEX FASPRO® + Pd¹
- Permanent treatment discontinuation due to an adverse reaction occurred in 2% of patients who received DARZALEX FASPRO® + Pd¹

Pd=pomalidomide (P) + dexamethasone (d).

Laboratory abnormalities	DARZALEX FASPRO® + Pd ^a		Pd ^a	
	All grades (%)	Grades 3-4 (%)	All grades (%)	Grades 3-4 (%)
Decreased neutrophils	97	84	84	63
Decreased leukocytes	95	64	82	40
Decreased lymphocytes	93	59	79	33
Decreased platelets	75	19	60	19
Decreased hemoglobin	51	16	57	15

^aDenominator is based on number of subjects with a baseline and post-baseline laboratory value for each laboratory test: n=148 for DARZALEX FASPRO® + Pd and n=149 for Pd.

Please see Important Safety Information for DARZALEX FASPRO® on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.

DARZALEX Faspro®
 (daratumumab and hyaluronidase-fihj)
 Injection for subcutaneous use | 1,800mg/50,000units

In patients with high-risk smoldering multiple myeloma Safety results as a monotherapy¹

Adverse reactions reported in ≥10% of patients with high-risk smoldering multiple myeloma and with at least a 5% greater frequency in the DARZALEX FASPRO[®] arm in AQUILA

Adverse reaction	DARZALEX FASPRO [®] (n=193)		ACTM (n=196)	
	All grades (%)	Grade 3 or 4 (%)	All grades (%)	Grade 3 or 4 (%)
Infections				
Upper respiratory tract infection ^a	66	1 [#]	27	0
Pneumonia ^b	16	7 [@]	8	3 [#]
Rhinitis ^c	10	0	2	0
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain ^d	59	1 [#]	42	3 [#]
General disorders and administration site conditions				
Fatigue ^e	42	3 [#]	21	1 [#]
Injection site reactions ^f	20	0	0	0
Infusion-related reactions ^g	17	1 [#]	0	0
Pyrexia	17	0	3	1 [#]
Edema ^h	15	1	5	1 [#]
Gastrointestinal disorders				
Diarrhea	27	2 [#]	5	1 [#]
Nausea	19	0	5	0
Abdominal pain ⁱ	17	1 [#]	7	2 [#]
Skin and subcutaneous tissue disorders				
Rash ^j	27	1 [#]	6	1 [#]

ACTM=active monitoring.

^aUpper respiratory tract infection includes acute sinusitis, adenoviral upper respiratory infection, catarrh, influenza, influenza like illness, laryngitis, metapneumovirus infection, nasal congestion, nasopharyngitis, parainfluenzae virus infection, pharyngitis, respiratory tract congestion, respiratory tract infection, respiratory tract infection viral, sinus congestion, sinusitis, throat irritation, tonsillitis, tracheitis, upper respiratory tract congestion, upper respiratory tract infection, upper respiratory tract infection bacterial, upper-airway cough syndrome, and viral upper respiratory tract infection.

^bPneumonia includes covid-19 pneumonia, lower respiratory tract infection, organizing pneumonia, pneumonia, pneumonia bacterial, pneumonia pneumococcal, pneumonia streptococcal, and pneumonia viral.

^cRhinitis includes rhinitis, rhinitis atrophic, rhinorrhea, rhinovirus infection, and viral rhinitis.

^dMusculoskeletal pain includes arthralgia, axillary pain, back pain, breast pain, chest pain, facial spasm, fibromyalgia, flank pain, groin pain, muscle fatigue, muscle rupture, muscle spasms, muscle strain, muscle tightness, muscular weakness, musculoskeletal chest pain, musculoskeletal pain, musculoskeletal stiffness, myalgia, neck pain, non-cardiac chest pain, pain, pain in extremity, pain in jaw, periarthritis, radicular pain, rotator cuff syndrome, spinal pain, spinal stenosis, and tendon pain.

^eFatigue includes asthenia, fatigue, and malaise.

^fInjection site reaction includes injection site discoloration, injection site erythema, injection site hemorrhage, injection site induration, injection site edema, injection site pain, injection site pruritus, injection site rash, injection site swelling, injection site urticaria, injection site vesicles, and injection site warmth.

^gInfusion-related reactions includes terms determined by investigators to be related to infusion.

^hEdema includes brain edema, eye swelling, eyelid edema, generalized edema, joint swelling, laryngeal edema, localized edema, edema, edema peripheral, peripheral swelling, post procedural edema, post procedural swelling, swelling face, and swelling of eyelid.

ⁱAbdominal pain includes abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper, abdominal tenderness, epigastric discomfort, and gastrointestinal pain.

^jRash includes acne, dermatitis, dermatitis allergic, dermatitis bullous, dermatitis contact, drug eruption, drug hypersensitivity, eczema, eczema asteatotic, eczema infected, erysipelas, erythema, erythema multiforme, rash, rash erythematous, rash maculopapular, rash papular, rash pruritic, seborrheic dermatitis, seborrheic keratosis, skin lesion, skin reaction, skin ulcer, and urticaria.

^kSleep disorder includes insomnia, restless legs syndrome, sleep apnea syndrome, sleep deficit, and sleep disorder.

^lSensory neuropathy includes allodynia, anosmia, burning sensation, carpal tunnel syndrome, cervical radiculopathy, cervicobrachial syndrome, dysesthesia, hypoesthesia, hypoesthesia oral, paresthesia, paresthesia oral, peripheral sensorimotor neuropathy, peripheral sensory neuropathy, pharyngeal paresthesia, polyneuropathy, and sensory disturbance.

^mHeadache includes headache, migraine, and vascular headache.

DARZALEX FASPRO[®]
(n=193)

ACTM
(n=196)

Adverse reaction	DARZALEX FASPRO [®] (n=193)		ACTM (n=196)	
	All grades (%)	Grade 3 or 4 (%)	All grades (%)	Grade 3 or 4 (%)
Psychiatric disorders				
Sleep disorder ^k	24	1 [#]	5	0
Nervous system disorders				
Sensory neuropathy ^l	20	0	8	0
Headache ^m	18	1 [#]	8	0
Dizziness ⁿ	12	0	5	0
Respiratory, thoracic and mediastinal disorders				
Cough ^o	19	0	7	0
Dyspnea ^p	18	1 [#]	6	1

ⁿDizziness includes dizziness and dizziness postural.

^oCough includes cough and productive cough.

^pDyspnea includes dyspnea and dyspnea exertional.

[#]Only Grade 3 adverse reactions occurred.

[@]Fatal adverse reactions occurred for Pneumonia: n=1 (1%) in the DARZALEX FASPRO[®] arm.

The most common adverse reactions (≥20%) were upper respiratory tract infection, musculoskeletal pain, fatigue, diarrhea, rash, sleep disorder, sensory neuropathy, and injection site reactions.

Select laboratory abnormalities (≥20%) that worsened from baseline in patients with high-risk smoldering multiple myeloma who received DARZALEX FASPRO[®] in AQUILA

Laboratory abnormality	DARZALEX FASPRO ^{®a}		ACTM ^c	
	All grades (%)	Grade 3 or 4 (%)	All grades (%)	Grade 3 or 4 (%)
Hematology				
Decreased lymphocytes	47	6	12	3
Decreased hemoglobin	42	0	44	2
Decreased leukocytes	34	3	27	2
Decreased neutrophils	34	6	29	4
Decreased platelets	19	1	9	1
Chemistry				
Decreased albumin	28	0	15	1
Increased alanine aminotransferase (ALT)	25	1	13	1
Decreased sodium	24	3	19	2
Increased creatinine	20	0	13	1
Increased aspartate aminotransferase (AST)	20	0	12	1

ACTM=active monitoring.

^aDenominator is based on number of subjects with a baseline and post-baseline laboratory value for each laboratory test: N=191 for DARZALEX FASPRO[®] and N=191 for ACTM.

Please see Important Safety Information for DARZALEX FASPRO[®] on pages 54-56. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO[®]. Please [click here](#) for full Prescribing Information for DARZALEX[®].

DARZALEX Faspro[®]
(daratumumab and hyaluronidase-fihj)
Injection for subcutaneous use | 1,800mg/50,000units

Indications and Important Safety Information for DARZALEX FASPRO®

INDICATIONS

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with bortezomib, lenalidomide, and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (PI)
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- As monotherapy in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent

DARZALEX FASPRO® as monotherapy is indicated for the treatment of adult patients with high-risk smoldering multiple myeloma.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX FASPRO® is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase, or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Hypersensitivity and Other Administration Reactions

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO®.

Systemic Reactions

In a pooled safety population of 1446 patients with multiple myeloma (N=1235) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO® as monotherapy or as part of a combination therapy, 7% of patients experienced a systemic administration-related reaction (Grade 2: 3%, Grade 3: 0.8%, Grade 4: 0.1%). In patients with high-risk smoldering multiple myeloma (N=193), systemic administration-related reactions occurred in 17% of patients in AQUILA (Grade 2: 7%, Grade 3: 1%).

In all patients (N=1639), systemic administration-related reactions occurred in 7% of patients with the first injection, 0.5% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 3.2 hours (range: 4 minutes to 3.5 days). Of the 283 systemic administration-related reactions that occurred in 135 patients, 240 (85%) occurred on the day of DARZALEX FASPRO® administration. Delayed systemic administration-related reactions have occurred in 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension, tachycardia, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Other signs and symptoms of systemic administration-related reactions may include respiratory

symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritus, chills, vomiting, nausea, hypotension, and blurred vision.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen, and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX FASPRO®. Consider administering corticosteroids and other medications after the administration of DARZALEX FASPRO® depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with daratumumab-containing products. If ocular symptoms occur, interrupt DARZALEX FASPRO® and seek immediate ophthalmologic evaluation prior to restarting DARZALEX FASPRO®.

Local Reactions

In this pooled safety population of 1446 patients with multiple myeloma (N=1253) or light chain amyloidosis (N=193), injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 1.1%. The most frequent (>1%) injection-site reactions were injection site erythema and injection site rash. In patients with high-risk smoldering multiple myeloma (N=193), injection-site reactions occurred in 28% of patients, including Grade 2 reactions in 3%. These local reactions occurred a median of 6 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX FASPRO®. Monitor for local reactions and consider symptomatic management.

Infections

DARZALEX FASPRO® can cause serious, life-threatening, or fatal infections. In patients who received DARZALEX FASPRO® in a pooled safety population including patients with smoldering multiple myeloma and light chain (AL) amyloidosis (N=1639), serious infections, including opportunistic infections, occurred in 24% of patients, Grade 3 or 4 infections occurred in 22%, and fatal infections occurred in 2.5%. The most common type of serious infection reported was pneumonia (8.5%).

Monitor patients for signs and symptoms of infection prior to and during treatment with DARZALEX FASPRO® and treat appropriately. Administer prophylactic antimicrobials according to guidelines.

Neutropenia

Daratumumab may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX FASPRO® until recovery of neutrophils. In lower body weight patients receiving DARZALEX FASPRO®, higher rates of Grade 3-4 neutropenia were observed.

Thrombocytopenia

Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX FASPRO® until recovery of platelets.

Continued on next page

 **DARZALEX Faspro®**
(daratumumab and hyaluronidase-fihj)
Injection for subcutaneous use | 1,800mg/30,000units

Important Safety Information for DARZALEX FASPRO® (cont)

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX FASPRO® can cause fetal harm when administered to a pregnant woman. DARZALEX FASPRO® may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX FASPRO® and for 3 months after the last dose.

The combination of DARZALEX FASPRO® with lenalidomide, thalidomide, or pomalidomide is contraindicated in pregnant women because lenalidomide, thalidomide, and pomalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, thalidomide, or pomalidomide prescribing information on use during pregnancy.

Interference With Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab administration. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted.

Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX FASPRO®. Type and screen patients prior to starting DARZALEX FASPRO®.

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some DARZALEX FASPRO®-treated patients with IgG kappa myeloma protein.

ADVERSE REACTIONS

In multiple myeloma, the most common adverse reaction ($\geq 20\%$) with DARZALEX FASPRO® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy ($\geq 20\%$ for any combination) include fatigue, nausea, diarrhea, dyspnea, sleep disorder, headache, rash, renal impairment, motor dysfunction, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, musculoskeletal pain, decreased appetite, urinary tract infection, abdominal pain, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, dizziness, bruising, and COVID-19.

The most common adverse reactions ($\geq 20\%$) in patients with high-risk smoldering multiple myeloma who received DARZALEX FASPRO® monotherapy are upper respiratory tract infection, musculoskeletal pain, fatigue, diarrhea, rash, sleep disorder, sensory neuropathy, and injection site reactions.

The most common hematology laboratory abnormalities ($\geq 40\%$) with DARZALEX FASPRO® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Please [click here](#) to read full Prescribing Information for DARZALEX FASPRO®.

cp-552204v3

References: 1. DARZALEX FASPRO® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. DARZALEX® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 3. Data on file. RF-136620. Janssen Biotech, Inc. 4. Usmani SZ, Facon T, Hungria V, et al. Daratumumab plus bortezomib, lenalidomide and dexamethasone for transplant-ineligible or transplant-deferred newly diagnosed multiple myeloma: the randomized phase 3 CEPHEUS trial. *Nat Med.* 2025;31(4):1195-1202. 5. World Health Organization. COVID 19 Public Health Emergency of International Concern (PHEIC) Global research and innovation forum: towards a research roadmap. Presented February 11-12, 2020.

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For the treatment of adult patients with multiple myeloma Dosing and Administration Guide

INDICATIONS

DARZALEX® (daratumumab) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
- As monotherapy in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

Select Important Safety Information

CONTRAINDICATIONS

DARZALEX® is contraindicated in patients with a history of severe hypersensitivity (eg, anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.

DARZALEX[®] mechanism of action

DARZALEX[®] is a first-in-class monoclonal antibody that targets CD38²

- CD38 is expressed on hematopoietic cells, other cell types and tissues, and is highly expressed on multiple myeloma cells²
- DARZALEX[®] inhibits tumor cell growth through immune-mediated, direct on-tumor, and immunomodulatory actions. DARZALEX[®] may also have an effect on normal cells²

DID YOU KNOW?

DARZALEX FASPRO[®] makes subcutaneous injection possible, starting with the first dose. DARZALEX[®] patients can also be switched to DARZALEX FASPRO[®] at any point in approved DARZALEX FASPRO[®] indications only.^{1,4}

How DARZALEX[®] is supplied²



Dosage form and strengths²

DARZALEX[®] is a colorless to pale yellow, preservative-free solution for intravenous (IV) infusion.

- DARZALEX[®] is supplied in single-use vials



100 mg/5 mL
(20 mg/mL)



400 mg/20 mL
(20 mg/mL)



Storage²

- Store in a refrigerator at 2°C to 8°C (36°F to 46°F)
- Do not freeze or shake. Protect from light. This product contains no preservative

DID YOU KNOW?

DARZALEX[®] is given intravenously over 7 hours for the first infusion, 4 hours for the second infusion, and 3 hours for subsequent infusions (median). DARZALEX FASPRO[®] (daratumumab and hyaluronidase-fihj) is administered subcutaneously over ~3 to 5 minutes.^{1,2}

Select Important Safety Information

CONTRAINDICATIONS

DARZALEX[®] is contraindicated in patients with a history of severe hypersensitivity (eg, anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

DARZALEX[®] can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination; N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4 infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX[®]. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension, and blurred vision.

Select Important Safety Information

Interference With Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab infusion. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type is not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX[®]. Type and screen patients prior to starting DARZALEX[®].

Please see Important Safety Information for DARZALEX[®] on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO[®]. Please [click here](#) for full Prescribing Information for DARZALEX[®].

 **DARZALEX[®]**
(daratumumab)
injection for intravenous infusion
100 mg/5 mL, 400 mg/20 mL

DARZALEX® is indicated for use in various regimens

Indicated regimen*	Weeks	Schedule
In combination with lenalidomide or pomalidomide and dexamethasone (4-week cycle) (DRd)(DPd) ; or for monotherapy	Weeks 1–8	Treatment weekly (total of 8 doses)
	Weeks 9–24	Treatment every 2 weeks (total of 8 doses)
	Week 25 onward until disease progression	Treatment every 4 weeks
With carfilzomib and dexamethasone (4-week cycle) (DKd)	Week 1 (8 mg/kg)	Treatment Days 1 and 2 (total of 2 doses)
	Weeks 2–8 (16 mg/kg)	Treatment weekly (total of 7 doses)
	Weeks 9–24 (16 mg/kg)	Treatment every 2 weeks (total of 8 doses)
	Week 25 onward until disease progression (16 mg/kg)	Treatment every 4 weeks
With bortezomib, melphalan, and prednisone (6-week cycle) (DVMP)	Weeks 1–6	Treatment weekly (total of 6 doses)
	Weeks 7–54	Treatment every 3 weeks (total of 16 doses)
	Week 55 onward until disease progression	Treatment every 4 weeks

*See dosage and administration section of the full Prescribing Information for more detail. When DARZALEX® is administered as part of a combination therapy, see the prescribing information for dosage recommendations for the other drugs.

Select Important Safety Information

Neutropenia and Thrombocytopenia

DARZALEX® may increase neutropenia and thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer’s prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX® until recovery of neutrophils or for recovery of platelets.

Indicated regimen*	Weeks	Schedule
With bortezomib and dexamethasone (3-week cycle) (DVd)	Weeks 1–9	Treatment weekly (total of 9 doses)
	Weeks 10–24	Treatment every 3 weeks (total of 5 doses)
	Week 25 onward until disease progression	Treatment every 4 weeks
	Induction	Induction
With bortezomib, thalidomide, and dexamethasone (4-week cycle) (DVTd)	Weeks 1-8	Treatment weekly (total of 8 doses)
	Weeks 9-16	Treatment every 2 weeks (total of 4 doses)
	Stop for high-dose chemotherapy and ASCT	
	Consolidation	Consolidation
	Weeks 1-8	Treatment every 2 weeks (total of 4 doses)

*See dosage and administration section of the full Prescribing Information for more detail. When DARZALEX® is administered as part of a combination therapy, see the prescribing information for dosage recommendations for the other drugs.

ASCT=autologous stem cell transplant.

Select Important Safety Information

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



DARZALEX® + Rd dosing schedule²

In adult patients with newly diagnosed, transplant-ineligible multiple myeloma²

Dosing schedule based on a randomized, active-controlled trial

DARZALEX® in combination with lenalidomide and dexamethasone (Rd) (n=368) vs Rd alone (n=369)

Recommended dosage and schedule for DARZALEX®²

4 Doses Per 28-Day Cycle given as **once weekly** infusion (4 doses per 4-week cycle; Cycles 1* to 2; Weeks 1 to 8)

2 Doses Per 28-Day Cycle given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)

1 Dose Per 28-Day Cycle given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycle 7; Week 25+ until disease progression)

23  estimated Year 1 infusion visits

See table on page 59 ▶

- Lenalidomide 25 mg was given orally on Days 1–21 of each cycle[†]
- Dexamethasone 40 mg was given orally or IV once a week[‡]
 - On DARZALEX® infusion days, the entire dexamethasone dose was given as a pre-infusion medication

*The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

[†]For dosing instructions of combination agents administered with DARZALEX®, see the Clinical Studies (14.1) section of the full Prescribing Information for DARZALEX® and the respective manufacturer's prescribing information.

[‡]Please see the full Prescribing Information for DARZALEX® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX®. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®.



DARZALEX® dosing frequency decreases over time²

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® weekly	● [§]							●							●							●							
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●							●							●							●							

[§]The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® every 2 weeks	●														●														
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●							●							●							●							

Cycles 7 onward (each lasting 28 days)															Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® every 4 weeks	●																												
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●							●							●							●							

Continue DARZALEX® + Rd until disease progression or unacceptable toxicity

Infusion reactions of any grade or severity may be managed by interruption, modification, and/or discontinuation of the infusion. DARZALEX® should be permanently discontinued upon the third occurrence of a Grade 3 infusion reaction and upon any occurrence of a Grade 4 infusion reaction.

No dose reductions of DARZALEX® are recommended. Dose delay may be required to allow recovery of blood cell counts in the event of myelosuppression [see *Warnings and Precautions* (5.3, 5.4)]. For information concerning drugs given in combination with DARZALEX®, see manufacturer's prescribing information.

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions.

DARZALEX® + VTd dosing schedule²

In adult patients with newly diagnosed, transplant-eligible multiple myeloma²

Dosing schedule based on an open-label, randomized, active-controlled trial

DARZALEX® in combination with bortezomib, thalidomide, and dexamethasone (VTd) (n=543) vs VTd alone (n=542)

Recommended dosage and schedule for DARZALEX®²

4 Doses Per 28-Day Cycle

given as **once weekly** infusion (4 doses per 4-week cycle; Cycles 1* to 2; Weeks 1 to 8)

2 Doses Per 28-Day Cycle

given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 16)

Stop for high-dose chemotherapy and ASCT

2 Doses Per Cycle

given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycles 5 to 6; Weeks 1 to 8 of consolidation phase)

16



estimated Year 1 infusion visits

See table on page 61 ▶

- Bortezomib 1.3 mg/m² was injected subcutaneously or IV on Days 1, 4, 8, and 11 of Cycles 1-4*
- Thalidomide 100 mg was given orally daily during 6 bortezomib cycles
- Dexamethasone 40 mg was given orally or IV on Days 1, 2, 8, 9, 15, 16, 22, and 23 of Cycles 1-2, and at 40 mg on Days 1-2 and 20 mg was administered on Days 1, 2, 8, 9, 15, 16 in Cycles 5-6†
 - On DARZALEX® infusion days, the entire dexamethasone dose was given as a pre-infusion medication

ASCT=autologous stem-cell transplant.

*For dosing instructions of combination agents administered with DARZALEX®, see Clinical Studies (14.1) section of the full Prescribing Information for DARZALEX® and the respective manufacturer's prescribing information.

†Please see the full Prescribing Information for DARZALEX® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX®. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®.



DARZALEX® dosing frequency decreases over time²

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)														Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® weekly	●							§																				
bortezomib	●			●				●			●																	
thalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●	●						●	●						●	●					

§The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

Cycles 3–4 (each lasting 28 days)														Total of 4 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® every 2 weeks	●															●												
bortezomib	●			●				●			●																	
thalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

Stop for high-dose chemotherapy and ASCT

Cycles 5–6 (each lasting 28 days)														Total of 4 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® every 2 weeks	●															●												
bortezomib	●			●				●			●																	
thalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●	●						●	●							●	●				

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions.

DARZALEX® + Rd dosing schedule²

In patients at first relapse²

Dosing schedule based on a randomized, active-controlled trial

DARZALEX® in combination with lenalidomide and dexamethasone (Rd) (n=286) vs Rd alone (n=283)

Recommended dosage and schedule for DARZALEX®²

4 Doses Per 28-Day Cycle

given as **once weekly** infusion (4 doses per 4-week cycle; Cycles 1* to 2; Weeks 1 to 8)

2 Doses Per 28-Day Cycle

given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)

1 Dose Per 28-Day Cycle

given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycle 7+; Week 25+ until disease progression)

23



estimated Year 1 infusion visits

See table on page 63 ▶

- Lenalidomide 25 mg was given orally on Days 1–21 of each cycle[†]
- Dexamethasone 40 mg was given orally or IV once a week[‡]
 - On DARZALEX® infusion days, 20 mg of the dexamethasone dose was given as a pre-infusion medication and the remainder given the day after the infusion
 - For patients on a reduced dexamethasone dose, the entire 20 mg dose was given as a DARZALEX® pre-infusion medication

*The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

[†]For dosing instructions of combination agents administered with DARZALEX®, see the Clinical Studies (14.2) section of the full Prescribing Information for DARZALEX® and the respective manufacturer's prescribing information.

[‡]Please see the full Prescribing Information for DARZALEX® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX®. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®.



DARZALEX® dosing frequency decreases over time²

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® weekly	●							§																					
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●	●							●	●						●	●					

[§]The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® every 2 weeks			●													●													
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
dexamethasone	●	●						●								●	●						●						

Cycles 7 onward (each lasting 28 days)															Total of 8 DARZALEX® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® every 4 weeks																●												
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●								●							●					

Continue DARZALEX® + Rd until disease progression or unacceptable toxicity

Infusion reactions of any grade or severity may be managed by interruption, modification, and/or discontinuation of the infusion. DARZALEX® should be permanently discontinued upon the third occurrence of a Grade 3 infusion reaction and upon any occurrence of a Grade 4 infusion reaction.

No dose reductions of DARZALEX® are recommended. Dose delay may be required to allow recovery of blood cell counts in the event of myelosuppression [see Warnings and Precautions (5.3, 5.4)]. For information concerning drugs given in combination with DARZALEX®, see manufacturer's prescribing information.

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions.

DARZALEX® + Vd dosing schedule²

In patients at first relapse²

Dosing schedule based on a randomized, active-controlled trial

DARZALEX® in combination with bortezomib and dexamethasone (Vd) (n=251) vs Vd alone (n=247)

Recommended dosage and schedule for DARZALEX®²

3 Doses Per 21-Day Cycle

given as **once weekly** infusion (3 doses per 3-week cycle; Cycles 1* to 3; Weeks 1 to 9)

1 Doses Per 21-Day Cycle

given as 1 infusion **every 3 weeks** (once per 3-week cycle; Cycles 4 to 8; Weeks 10 to 24)

1 Doses Per 4-Week Cycle

given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycles 9+; Weeks 25+ until disease progression)

21



estimated Year 1 infusion visits

See table on page 65 ▶

- Bortezomib 1.3 mg/m² was administered by subcutaneous injection or IV infusion on Days 1, 4, 8, and 11 of each cycle for a total of 8 cycles[†]
- Dexamethasone 20 mg was given orally once daily on Days 1, 2, 4, 5, 8, 9, 11, and 12 for a total of 8 cycles[‡]
 - On the days of DARZALEX® infusion, 20 mg of the dexamethasone dose was administered as a pre-infusion medication and was continued as a pre-medication after Vd discontinuation
 - For patients on a reduced dexamethasone dose, the entire 20 mg dose was given as a DARZALEX® pre-infusion medication

*The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

†Please refer to the bortezomib prescribing information for more detailed information about twice-weekly bortezomib dosing.

‡Please see the full Prescribing Information for DARZALEX® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX®. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®.



DARZALEX® dosing frequency decreases over time²

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–3 (each lasting 21 days)								Total of 9 DARZALEX® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
DARZALEX® weekly	● [§]							●							●	No treatment					
bortezomib	●			●				●			●					No treatment					
dexamethasone	●	●		●	●			●	●		●	●				No treatment					

[§]The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

Cycles 4–8 (each lasting 21 days)								Total of 5 DARZALEX® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
DARZALEX® every 3 weeks	●															No treatment					
bortezomib	●			●				●			●					No treatment					
dexamethasone	●	●		●	●			●	●		●	●				No treatment					

Continue DARZALEX® once every 4 weeks until disease progression²

NOTE: Bortezomib and dexamethasone dosing should be stopped after 8 cycles.

Infusion reactions of any grade or severity may be managed by interruption, modification, and/or discontinuation of the infusion. DARZALEX® should be permanently discontinued upon the third occurrence of a Grade 3 infusion reaction and upon any occurrence of a Grade 4 infusion reaction.

No dose reductions of DARZALEX® are recommended. Dose delay may be required to allow recovery of blood cell counts in the event of myelosuppression [see Warnings and Precautions (5.3, 5.4)]. For information concerning drugs given in combination with DARZALEX®, see manufacturer's prescribing information.

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions.

DARZALEX® + Pd dosing schedule²

In patients with ≥2 prior lines of therapy including lenalidomide and a proteasome inhibitor (PI)²

Dosing schedule based on an open-label trial

DARZALEX® in combination with pomalidomide and dexamethasone (Pd) [N=103]²

Recommended dosage and schedule for DARZALEX®²

4 Doses Per 28-Day Cycle given as **once weekly** infusion (4 doses per 4-week cycle; Cycles 1* to 2; Weeks 1 to 8)

2 Doses Per 28-Day Cycle given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)

1 Dose Per 28-Day Cycle given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycle 7+; Week 25+ until disease progression)

23  estimated Year 1 infusion visits

See table on page 67 ▶

- Pomalidomide 4 mg was given orally on Days 1–21 of each cycle[†]
- Dexamethasone 40 mg was given orally or IV once a week[‡]
 - On DARZALEX® infusion days, 20 mg of the dexamethasone dose was given as a pre-infusion medication and the remainder given the day after the infusion
 - For patients on a reduced dexamethasone dose, the entire 20 mg dose was given as a DARZALEX® pre-infusion medication

*The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

[†]Please refer to the pomalidomide prescribing information for more detailed information about pomalidomide dosing.

[‡]Please see the full Prescribing Information for DARZALEX® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX®. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®.



DARZALEX® dosing frequency decreases over time²

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® weekly	● [§]								●							●							●						
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●	●							●	●						●	●					

[§]The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® every 2 weeks		●														●												
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●								●	●						●					

Cycles 7 onward (each lasting 28 days)															Total of 8 DARZALEX® doses													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® every 4 weeks		●																										
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
dexamethasone	●	●						●								●							●					

Continue DARZALEX® + Pd until disease progression

Infusion reactions of any grade or severity may be managed by interruption, modification, and/or discontinuation of the infusion. DARZALEX® should be permanently discontinued upon the third occurrence of a Grade 3 infusion reaction and upon any occurrence of a Grade 4 infusion reaction.

No dose reductions of DARZALEX® are recommended. Dose delay may be required to allow recovery of blood cell counts in the event of myelosuppression [see Warnings and Precautions (5.3, 5.4)]. For information concerning drugs given in combination with DARZALEX®, see manufacturer's prescribing information.

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions.

DARZALEX® + Kd dosing schedule²

In patients with 1 to 3 prior lines of therapy

Dosing schedule based on a randomized, open-label trial

DARZALEX® in combination with carfilzomib and dexamethasone (Kd) [n=466]²

Recommended dosage and schedule for DARZALEX®²

5 Doses Per 28-Day Cycle

given as **once weekly** infusion (5 doses per 4-week cycle; Cycles 1* to 2; Weeks 1 to 4)

4 Doses Per 28-Day Cycle

given as **once weekly** infusion (4 doses per 4-week cycle; Cycle 2; Weeks 5 to 8)

2 Doses Per 28-Day Cycle

given as 1 infusion **every 2 weeks** (twice per 4-week cycle; Cycle 3 to 6; Weeks 9 to 24 until disease progression)

1 Dose Per 28-Day Cycle

given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycle 7+; Week 25+ until disease progression)

24

estimated Year 1 infusion visits

See table on page 69 ▶

- Carfilzomib was administered by IV infusion Days 1 and 2, 8, 9, 15, and 16 of each cycle for a total of 8 cycles.[‡]
- Dexamethasone 20 mg was given orally or intravenously on Days 1, 2, 8, 9, 15 and 16 and then 40 mg orally or intravenously on Day 22 for a total of 8 cycles[‡]
 - On DARZALEX® infusion days, 20 mg of the dexamethasone dose was given as a pre-infusion medication and the remainder given the day after the infusion
 - For patients on a reduced dexamethasone dose, the entire 20 mg dose was given as a DARZALEX® pre-infusion medication

*The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

[†]Please refer to the carfilzomib prescribing information for more detailed information about twice weekly and once-weekly carfilzomib dosing.

[‡]Please see the full Prescribing Information for DARZALEX® for more information regarding dexamethasone dosage and administration.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX®. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®.



DARZALEX® dosing frequency decreases over time²

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days) with either Once-weekly or Twice-weekly carfilzomib														Total of 9 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® weekly	● [§]							●							●							●						
Once-weekly carfilzomib																												
carfilzomib [†]	●							●							●								●					
dexamethasone	●	●						●	●						●	●							●	●				
Twice-weekly carfilzomib																												
carfilzomib [†]	●	●						●	●						●	●												
dexamethasone	●	●						●	●						●	●							●					

[§]The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

[†]Carfilzomib was administered intravenously once weekly at a dose of 20 mg/m² on Cycle 1 Day 1 and escalated to dose of 70 mg/m² on Cycle 1 Days 8 and 15, and Days 1, 8, and 15 of each subsequent 28-day cycle

[‡]Carfilzomib was administered intravenously at a dose of 20 mg/m² in Cycle 1 on Days 1 and 2; at a dose of 56 mg/m² in Cycle 1 on Days 8, 9, 15, and 16; and at a dose 56 mg/m² on Days 1, 2, 8, 9, 15, and 16 of each 28-day cycle thereafter

Cycles 3–6 (each lasting 28 days) with either Once-weekly or twice-weekly carfilzomib														Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® weekly	●																											
Once-weekly carfilzomib																												
carfilzomib	●							●							●													
dexamethasone	●	●						●	●						●	●								●				
Twice-weekly carfilzomib																												
carfilzomib	●	●						●	●						●	●												
dexamethasone	●	●						●	●						●	●								●				

Cycles 7 onward (each lasting 28 days) with either Once-weekly or twice-weekly carfilzomib														Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
DARZALEX® weekly	●																											
Once-weekly carfilzomib																												
carfilzomib	●							●							●													
dexamethasone	●	●						●							●										●			
Twice-weekly carfilzomib																												
carfilzomib	●	●						●	●						●	●												
dexamethasone	●	●						●	●						●	●									●			

Continue DARZALEX® + Kd once every 4 weeks until disease progression or unacceptable toxicity

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions.

DARZALEX® monotherapy dosing schedule²

In patients with ≥ 3 prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who were double-refractory to a PI and an immunomodulatory agent

Dosing schedule based on a single-agent trial (N=106)

Recommended dosage and schedule for DARZALEX®²

4 Doses Per 28-Day Cycle	given as 1 weekly infusion (4 doses per 4-week cycle; Cycles 1* to 2; Weeks 1 to 8)
2 Doses Per 28-Day Cycle	given as 1 infusion every 2 weeks (twice per 4-week cycle; Cycles 3 to 6; Weeks 9 to 24)
1 Dose Per 28-Day Cycle	given as 1 infusion every 4 weeks (once per 4-week cycle; Cycles 7+; Weeks 25+ until disease progression)

23  estimated Year 1 infusion visits

See table on page 71 ►

- Administer DARZALEX® only as an IV infusion after dilution

*The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

DARZALEX® dosing frequency decreases over time²

See the ● marks below to follow along with the suggested dosing schedules for each cycle.

Cycles 1–2 (each lasting 28 days)															Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® weekly	●																												
No treatment									●																				
No treatment																													
No treatment																													
No treatment																													

[§]The first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days.

Cycles 3–6 (each lasting 28 days)															Total of 8 DARZALEX® doses														
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® every 2 weeks	●																												
No treatment																													
No treatment																													
No treatment																													

Cycles 7 onward (each lasting 28 days)																													
Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	
DARZALEX® every 4 weeks	●																												
No treatment																													

Continue DARZALEX® until disease progression or unacceptable toxicity

Infusion reactions of any grade or severity may be managed by interruption, modification, and/or discontinuation of the infusion. DARZALEX® should be permanently discontinued upon the third occurrence of a Grade 3 infusion reaction and upon any occurrence of a Grade 4 infusion reaction.

No dose reductions of DARZALEX® are recommended. Dose delay may be required to allow recovery of blood cell counts in the event of myelosuppression [see *Warnings and Precautions* (5.3, 5.4)]. For information concerning drugs given in combination with DARZALEX®, see manufacturer's prescribing information.

Select Important Safety Information

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX®. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®.





Prepare the solution for infusion using aseptic technique as follows:

- Calculate the dose (mg), total volume (mL) of DARZALEX® solution required, and the number of DARZALEX® vials needed based on the patient's actual body weight
- Check that the DARZALEX® solution is colorless to pale yellow. Do not use if opaque particles, discoloration, or foreign particles are present
- Remove a volume of 0.9% Sodium Chloride Injection, USP, from the infusion bag/container that is equal to the required volume of DARZALEX® solution
- Withdraw necessary amount of DARZALEX® solution and dilute to appropriate volume by adding to the infusion bag/container containing 0.9% Sodium Chloride Injection, USP. Infusion bags/containers must be made of either polyvinylchloride (PVC), polypropylene (PP), polyethylene (PE), or polyolefin blend (PP+PE). Dilute under appropriate conditions. Discard any unused portion left in the vial
- Gently invert the bag/container to mix the solution. Do not shake



NEED TO KNOW

To prevent medication errors, it is important to check the vial labels to ensure that the drug being prepared and administered is DARZALEX® and not DARZALEX FASPRO®.¹

Select Important Safety Information

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX® can cause fetal harm when administered to a pregnant woman. DARZALEX® may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX® and for 3 months after the last dose.

The combination of DARZALEX® with lenalidomide, pomalidomide, or thalidomide is contraindicated in pregnant women because lenalidomide, pomalidomide, and thalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, pomalidomide, or thalidomide prescribing information on use during pregnancy.

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The diluted solution may develop very small, translucent to white proteinaceous particles, as daratumumab is a protein. Do not use if visibly opaque particles, discoloration, or foreign particles are observed
- Since DARZALEX® does not contain a preservative, administer the diluted solution immediately at room temperature, 15°C to 25°C (59°F to 77°F), and in room light. Diluted solution may be kept at room temperature for a maximum of 15 hours (including infusion time)
- If not used immediately, the diluted solution can be stored prior to administration for up to 24 hours at refrigerated conditions, 2°C to 8°C (36°F to 46°F), and protected from light. Do not freeze

Select Important Safety Information

ADVERSE REACTIONS

The most frequently reported adverse reactions (incidence ≥20%) were upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia. The most common hematologic laboratory abnormalities (≥40%) with DARZALEX® are neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

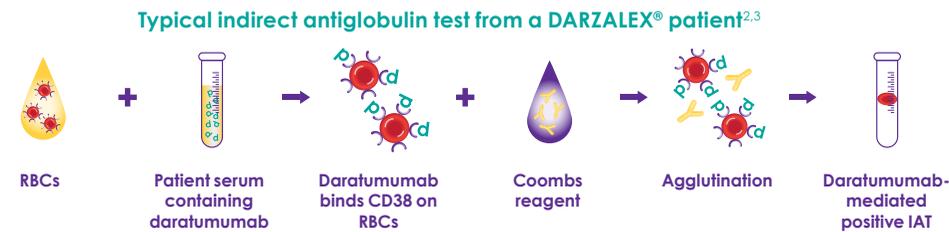
Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



Important information before administering DARZALEX®

Interference with serological testing²

- Daratumumab binds to CD38 found on red blood cells and results in a positive indirect antiglobulin test (indirect Coombs test) that may persist for up to 6 months after the last DARZALEX® infusion



IAT=indirect antiglobulin test; RBC=red blood cells.

Reminders

- Type and screen patients before starting DARZALEX®
- Inform blood banks when a patient is receiving DARZALEX®
- Identify any DARZALEX®-treated blood samples
- Ask patients to tell other healthcare professionals that they have received DARZALEX®

Prophylaxis for herpes zoster reactivation²

- Initiate antiviral prophylaxis to prevent herpes zoster reactivation within 1 week of starting DARZALEX® and continue for 3 months following treatment

Hereditary Fructose Intolerance (HFI)²

- DARZALEX® contains sorbitol. Advise patients with HFI of the risks related to sorbitol, which is a source of fructose. Patients with HFI cannot break down fructose, which may cause serious side effects.

Select Important Safety Information

CONTRAINDICATIONS

DARZALEX® is contraindicated in patients with a history of severe hypersensitivity (eg, anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported.

Handling and storage²



How to store DARZALEX®²

- Store in a refrigerator at 2°C to 8°C (36°F to 46°F)
- Do not freeze or shake. Protect from light. This product contains no preservative
- If stored in the refrigerator, allow the solution to come to room temperature. Administer diluted solution by intravenous (IV) infusion using an infusion set fitted with a flow regulator and with an in-line, sterile, nonpyrogenic, low protein-binding polyethersulfone (PES) filter (pore size 0.22 or 0.2 micrometer). Administration sets must be made of either polyurethane (PU), polybutadiene (PBD), PVC, PP, or PE
- Do not store any unused portion of the infusion solution for reuse. Any unused product or waste material should be disposed of in accordance with local requirements
- Do not infuse DARZALEX® concomitantly in the same IV line with other agents

Select Important Safety Information

Interference With Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab infusion. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type is not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX®. Type and screen patients prior to starting DARZALEX®.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.


DARZALEX®
(daratumumab)
injection for intravenous infusion
100 mg/5 mL, 400 mg/20 mL

Slower rate of infusion for the first DARZALEX® dose is recommended, as infusion-related reactions are more likely to occur with the first infusion²

		Dilution volume	Initial rate (first hour)	Rate increment*	Maximum rate	
Week 1 infusion	Option 1 (single-dose infusion)	Week 1 Day 1 (16 mg/kg)	1000 mL	50 mL/hour	50 mL/hour every hour*	200 mL/hour
	Option 2 (split-dose infusion)	Week 1 Day 1 (8 mg/kg)	500 mL	50 mL/hour	50 mL/hour every hour*	200 mL/hour
		Week 1 Day 2 (8 mg/kg)	500 mL	50 mL/hour	50 mL/hour every hour*	200 mL/hour
Week 2 (16 mg/kg) infusion [†]		500 mL	50 mL/hour	50 mL/hour every hour*	200 mL/hour	
Subsequent (Week 3 onward, 16 mg/kg) infusions [‡]		500 mL	100 mL/hour	50 mL/hour every hour*	200 mL/hour	

*Consider incremental escalation of the infusion rate only in the absence of infusion-related reactions.

[†]Use a dilution volume of 500 mL for the 16 mg/kg dose only if there were no infusion-related reactions the previous week. Otherwise, use a dilution volume of 1000 mL.

[‡]Use a modified initial rate (100 mL/hour) for subsequent infusions (ie, Week 3 onward) only if there were no infusion-related reactions during the previous infusion. Otherwise, use instructions indicated in the table for the Week 2 infusion rate.

- To facilitate administration, the first prescribed 16 mg/kg dose at Week 1 may be split over 2 consecutive days, ie, 8 mg/kg on Day 1 and Day 2, respectively² (see above table)

Median durations[§] of 16 mg/kg infusions decreased after the first infusion across all trials (N=2066)²

- First week infusion was 7 hours
- Second week infusion was 4 hours
- Subsequent infusions were 3 hours^{||}

[§]When the first dose was administered as 2 infusions over 2 days (split dose) in the EQUULEUS study (n=97), the median durations of infusions were 4.2 hours for Week 1 Day 1, 4.2 hours for Week 1 Day 2, 4.2 hours for Week 2, and 3.4 hours for the subsequent infusions.^{||}

^{||}Median infusion length for subsequent infusions (Week 2+ in aggregate). Administer the Week 2 (16 mg/kg) infusion according to the infusion rates outlined in Table 6 of the DARZALEX® full Prescribing Information.

Administration of pre- and post-infusion medications is recommended to reduce the risk of infusion-related reactions (see page 79)²

In clinical trials (monotherapy and combination treatments; N=2066)
Most infusion-related reactions occurred during the first infusion²

- For 37% of patients, infusion-related reactions (any grade) occurred with the first infusion, 2% of patients with the second infusion, and cumulatively, 6% of patients with subsequent infusions²
- The median time to onset of an infusion-related reaction was 1.5 hours (range: 0 to 73 hours)²
- Incidence of infusion modification due to reactions was 36%²
- DARZALEX® can cause severe infusion-related reactions. Severe infusion-related reactions included bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Other adverse infusion-related reactions included respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension, and blurred vision²
- For infusion-related reactions of any grade/severity, immediately interrupt the DARZALEX® infusion and manage symptoms. Management of infusion-related reactions may further require reduction in the rate of infusion, or permanent discontinuation of DARZALEX® for Grade 4 reactions²
- Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with DARZALEX® infusion. If ocular symptoms occur, interrupt DARZALEX® infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX®²

Select Important Safety Information

Neutropenia and Thrombocytopenia

DARZALEX® may increase neutropenia and thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX® until recovery of neutrophils or for recovery of platelets.

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



Management of infusion-related reactions

Infusion-related reactions of any grade or severity may be managed by interruption, modification, and/or discontinuation of the infusion²

- For infusion-related reactions of any grade/severity, immediately interrupt the DARZALEX[®] infusion and manage symptoms. Management of infusion-related reactions may further require reduction in the rate of infusion or treatment discontinuation of DARZALEX[®] as outlined below

Recommended management of infusion-related reactions²

Infusion-related reaction grade	Dose interruptions/modifications
Grades 1 & 2 (mild to moderate)	<p>Once symptoms resolve:</p> <ul style="list-style-type: none"> Resume the infusion at no more than half the rate at which the reaction occurred <p>If the patient does not experience any further reaction symptoms:</p> <ul style="list-style-type: none"> Infusion rate escalation may resume at increments and intervals as clinically appropriate up to the maximum rate of 200 mL/hour
Grade 3 (severe)	<p>Once symptoms resolve:</p> <ul style="list-style-type: none"> Consider restarting infusion at no more than half the rate at which the reaction occurred <p>If the patient does not experience additional symptoms:</p> <ul style="list-style-type: none"> Resume infusion rate escalation at increments and intervals as appropriate <p>In the event of recurrence of Grade 3 symptoms:</p> <ul style="list-style-type: none"> Repeat the procedure above <p>If the patient experiences a third occurrence of a Grade 3 or higher infusion-related reaction:</p> <ul style="list-style-type: none"> Permanently discontinue DARZALEX[®]
Grade 4 (life-threatening)	Permanently discontinue DARZALEX [®]

Select Important Safety Information

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

Pre- and post-infusion medications for DARZALEX[®]

Pre-infusion medications²

To reduce the risk of infusion-related reactions, administer to all patients approximately 1 to 3 hours prior to every infusion as follows:

- Dexamethasone 20 mg prior to every DARZALEX[®] infusion. When dexamethasone is the background regimen-specific corticosteroid, the dexamethasone treatment dose will also serve as pre-medication on DARZALEX[®] infusion days*
- During monotherapy, methylprednisolone 100 mg, or equivalent, administered intravenously. Following the second infusion, the dose of corticosteroid may be reduced (oral or intravenous methylprednisolone 60 mg)
- Oral antipyretics (acetaminophen 650 to 1000 mg), plus
- Oral or IV antihistamine (diphenhydramine 25 to 50 mg or equivalent)

*Dexamethasone is given intravenously prior to the first DARZALEX[®] infusion and oral administration may be considered prior to subsequent infusions. Additional background regimen-specific corticosteroids (eg, prednisone) should not be taken on DARZALEX[®] infusion days when patients receive dexamethasone (or equivalent) as pre-medication.

Post-infusion medications²

Post-infusion medications are recommended

To reduce the risk of delayed infusion-related reactions, administer the day after every infusion as follows:

- Oral corticosteroid (≤ 20 mg methylprednisolone or equivalent); however, if a background regimen-specific corticosteroid (eg, dexamethasone, prednisone) is administered the day after the DARZALEX[®] infusion, additional post-infusion medications may not be needed
- During monotherapy, administer oral corticosteroid (20 mg methylprednisolone or equivalent dose of an intermediate-acting or long-acting corticosteroid in accordance with local standards) on each of the 2 days following all DARZALEX[®] infusions (beginning the day after the infusion)

NOTE: For patients with a history of chronic obstructive pulmonary disease, consider including short- and long-acting bronchodilators and inhaled corticosteroids. Following the first 4 infusions, if the patient experiences no major infusion-related reactions, these additional inhaled post-infusion medications may be discontinued.

Select Important Safety Information

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX[®] can cause fetal harm when administered to a pregnant woman. DARZALEX[®] may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX[®] and for 3 months after the last dose.

Please see Important Safety Information for DARZALEX[®] on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO[®]. Please [click here](#) for full Prescribing Information for DARZALEX[®].



Safety results demonstrated in combination with Rd

Most frequent adverse reactions and hematologic laboratory abnormalities reported in $\geq 20\%$ of patients and with at least a 5% greater frequency in the DARZALEX® + Rd arm^{2*}

Adverse reactions	DARZALEX® + Rd (n=364)			Rd (n=365)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Diarrhea	57	7	0	46	4	0
Upper respiratory tract infection	52	2	<1	36	2	<1
Infusion-related reactions	41	2	<1	0	0	0
Constipation	41	1	<1	36	<1	0
Peripheral edema	41	2	0	33	1	0
Fatigue	40	8	0	28	4	0
Back pain	34	3	<1	26	3	<1
Asthenia	32	4	0	25	3	<1
Nausea	32	1	0	23	1	0
Dyspnea	32	3	<1	20	1	0
Cough	30	<1	0	18	0	0
Bronchitis	29	3	0	21	1	0
Muscle spasms	29	1	0	22	1	0
Pneumonia	26	14	1	14	7	1
Peripheral sensory neuropathy	24	1	0	15	0	0
Pyrexia	23	2	0	18	2	0
Decreased appetite	22	1	0	15	<1	<1

*Adverse reactions that occurred with a frequency of $\geq 10\%$ and $<20\%$, and with at least a 5% greater frequency in the DARZALEX® + Rd arm were headache, urinary tract infection, hyperglycemia, hypocalcemia, vomiting, chills, paresthesia, and hypertension.

Serious adverse reactions (ARs) with at least a 2% greater incidence in the DRd arm compared to the Rd arm were pneumonia (DRd 15% vs Rd 8%), bronchitis (DRd 4% vs Rd 2%), and dehydration (DRd 2% vs Rd $<1\%$).¹

DRd=DARZALEX® (D) + lenalidomide (R) + dexamethasone (d); Rd=lenalidomide (R) + dexamethasone (d).

Laboratory abnormalities	DARZALEX® + Rd (n=364)			Rd (n=365)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Neutropenia	91	39	17	77	28	11
Leukopenia	90	30	5	82	20	4
Lymphopenia	84	41	11	75	36	6
Thrombocytopenia	67	6	3	58	7	4
Anemia	47	13	0	57	24	0

Additional safety results

- Discontinuation rates due to ARs: 7% with DRd vs 16% with Rd²
- Infusion-related reactions (IRRs) with DRd occurred in 41% of patients; 2% were Grade 3 and $<1\%$ were Grade 4²
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion²
- Most IRRs occurred during the first infusion²

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



In adult patients with newly diagnosed, transplant-eligible multiple myeloma
Safety results demonstrated in combination with VTd

Most frequent adverse reactions and hematologic laboratory abnormalities reported in ≥20% of patients and with at least a 5% greater frequency in the DARZALEX® + VTd arm^{2*}

Adverse reactions	DARZALEX® + VTd (n=536)			VTd (n=538)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Infusion-related reactions	35	3	<1	0	0	0
Nausea	30	4	0	24	2	<1
Upper respiratory tract infection	27	1	0	17	1	0
Pyrexia	26	2	<1	21	2	0
Bronchitis	20	1	0	13	1	0

*Adverse reactions that occurred with a frequency of ≥10% and <20%, and with at least a 5% greater frequency in the DARZALEX® + VTd arm were cough, vomiting, and hypertension.

Serious ARs with a 2% greater incidence in the DVTd arm compared with the VTd arm were bronchitis (DVTd 2% vs VTd <1%) and pneumonia (DVTd 6% vs VTd 4%).²

Laboratory abnormalities	DARZALEX® + VTd (n=536)			VTd (n=538)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Lymphopenia	95	44	15	91	37	10
Leukopenia	82	14	10	57	6	9
Thrombocytopenia	81	9	5	58	8	3
Neutropenia	63	19	14	41	10	9
Anemia	36	4	0	35	5	0

Additional safety results

- Discontinuation rates due to any adverse event: 7% with DVTd vs 8% with VTd²
- IRRs with DVTd occurred in 35% of patients; 3% were Grade 3 and <1% were Grade 4²
- Most IRRs occurred during the first infusion²
 - 27% of patients had IRRs with the first infusion²
 - 11% of patients had IRRs with the first post-transplant infusion²
- Grade 3/4 infections were similar between study arms: 22% vs 20% with DVTd vs VTd alone, respectively²

AR=adverse reaction; DVTd=DARZALEX® (D) + bortezomib (V) + thalidomide (T) + dexamethasone (d); VTd=bortezomib (V) + thalidomide (T) + dexamethasone (d).

In adult patients with newly diagnosed, transplant-ineligible multiple myeloma
Safety results demonstrated in combination with VMP

Most frequent adverse reactions and hematologic laboratory abnormalities reported in ≥10% of patients and with at least a 5% greater frequency in the DARZALEX® + VMP arm²

Adverse reactions	DARZALEX® + VMP (n=346)			VMP (n=354)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Upper respiratory tract infection	48	5	0	28	3	0
Infusion-related reactions	28	4	1	0	0	0
Peripheral edema	21	1	<1	14	1	0
Pneumonia	16	12	<1	6	5	<1
Cough	16	<1	0	8	<1	0
Dyspnea	13	2	1	5	1	0
Hypertension	10	4	<1	3	2	0

Serious ARs with at least a 2% greater incidence in the DVMP arm compared to the VMP arm were pneumonia (DVMP 11% vs VMP 4%), upper respiratory tract infection (DVMP 5% vs VMP 1%), and pulmonary edema (DVMP 2% vs VMP 0%).²

Laboratory abnormalities	DARZALEX® + VMP (n=346)			VMP (n=354)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Anemia	47	18	0	50	21	0
Thrombocytopenia	88	27	11	88	26	16
Neutropenia	86	34	10	87	32	11
Lymphopenia	85	46	12	83	44	9

- Discontinuation rates due to any adverse event: 4.9% with DVMP vs 9.3% with VMP alone²
- IRRs with DARZALEX® + VMP occurred in 28% of patients; 4% were Grade 3 and 1% were Grade 4²

Additional safety results

- Grade 3 or 4 infections were 23% with DVMP vs 15% with VMP alone²
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion²
- Most IRRs occurred during the first infusion²

DVMP=DARZALEX® (D) + bortezomib (V) + melphalan (M) + prednisone (P); VMP=bortezomib (V) + melphalan (M) + prednisone (P).

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



In patients with relapsed/refractory multiple myeloma
Safety results demonstrated in combination with Rd

Most frequent adverse reactions and hematologic laboratory abnormalities reported in ≥20% of patients and with at least a 5% greater frequency in the DARZALEX® + Rd arm^{2*}

Adverse reactions	DARZALEX® + Rd (n=283)			Rd (n=281)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Upper respiratory tract infection	65	6	<1	51	4	0
Infusion-related reactions	48	5	0	0	0	0
Diarrhea	43	5	0	25	3	0
Fatigue	35	6	<1	28	2	0
Cough	30	0	0	15	0	0
Muscle spasms	26	1	0	19	2	0
Nausea	24	1	0	14	0	0
Dyspnea	21	3	<1	12	1	0
Pyrexia	20	2	0	11	1	0

*Adverse reactions that occurred with a frequency of ≥10% and <20%, and with at least a 5% greater frequency in the DARZALEX® + Rd arm were vomiting and headache.

Serious ARs with at least a 2% greater incidence in the DRd arm compared to the Rd arm were pneumonia (DRd 12% vs Rd 10%), upper respiratory tract infection (DRd 7% vs Rd 4%), influenza, and pyrexia (DRd 3% vs Rd 1% for each).²

Laboratory abnormalities	DARZALEX® + Rd (n=283)			Rd (n=281)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Anemia	52	13	0	57	19	0
Thrombocytopenia	73	7	6	67	10	5
Neutropenia	92	36	17	87	32	8
Lymphopenia	95	42	10	87	32	6

Additional safety results

- Discontinuation rates due to ARs with DRd were similar to Rd alone (7% vs 8%, respectively)²
- IRRs with DRd occurred in 48% of patients; 5% were Grade 3 and 0% were Grade 4²
- Grade 3/4 infections between study arms: 28% vs 23% with DRd and Rd, respectively²
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion²
- Most IRRs occurred during the first infusion²

DRd=DARZALEX® (D) + lenalidomide (R) + dexamethasone (d); Rd=lenalidomide (R) + dexamethasone (d).

In patients with relapsed/refractory multiple myeloma
Safety results demonstrated in combination with Vd

Most frequent adverse reactions and hematologic laboratory abnormalities reported in ≥20% of patients and with at least a 5% greater frequency in the DARZALEX® + Vd arm^{2*}

Adverse reactions	DARZALEX® + Vd (n=243)			Vd (n=237)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Peripheral sensory neuropathy	47	5	0	38	6	<1
Infusion-related reactions	45	9	0	0	0	0
Upper respiratory tract infection	44	6	0	30	3	<1
Diarrhea	32	3	<1	22	1	0
Cough	27	0	0	14	0	0
Peripheral edema	22	1	0	13	0	0
Dyspnea	21	4	0	11	1	0

*Adverse reactions that occurred with a frequency of ≥10% and <20%, and with at least a 5% greater frequency in the DARZALEX® + Vd arm were pyrexia and vomiting.

Serious ARs with at least a 2% greater incidence in the DVd arm compared with the Vd arm were upper respiratory tract infection (DVd 5% vs Vd 2%), diarrhea, and atrial fibrillation (DVd 2% vs Vd 0% for each).²

Laboratory abnormalities	DARZALEX® + Vd (n=243)			Vd (n=237)		
	Any grade (%)	Grade 3 (%)	Grade 4 (%)	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Anemia	48	13	0	56	14	0
Thrombocytopenia	90	28	19	85	22	13
Neutropenia	58	12	3	40	5	<1
Lymphopenia	89	41	7	81	24	3

Additional safety results

- Discontinuation rates due to ARs with DVd were similar to Vd alone (7% vs 9%, respectively)²
- IRRs with DVd occurred in 45% of patients; 9% were Grade 3 and 0% were Grade 4²
- Grade 3/4 infections were similar between study arms: 21% vs 19% with DVd vs Vd alone, respectively²
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion²
- Most IRRs occurred during the first infusion²

DVd=DARZALEX® (D) + bortezomib (V) + dexamethasone (d); Vd=bortezomib (V) + dexamethasone (d).

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



In patients with relapsed/refractory multiple myeloma
Safety results demonstrated in combination with Kd

Most frequent adverse reactions reported in ≥15% of patients who received DARZALEX® + twice-weekly Kd^{2*}

Adverse reactions (CANDOR)	DARZALEX® + Kd (n=308)		Kd (n=153)	
	All grades (%)	Grades 3 or 4 (%)	All grades (%)	Grades 3 or 4 (%)
Infusion-related reactions	41	12	28	5
Respiratory tract infection	40 [†]	7	29	3.3
Thrombocytopenia	37	25	30	16
Anemia	33	17	31	14
Fatigue	32	11	28	8
Diarrhea	32	3.9	14	0.7
Hypertension	31	18	28	13
Cough	21	0	21	0
Pyrexia	20	1.9	15	0.7
Dyspnea	20	3.9	22	2.6
Pneumonia	18 [†]	13	12	9
Nausea	18	0	13	0.7
Insomnia	18	3.9	11	2
Bronchitis	17	2.6	12	1.3
Back pain	16	1.9	10	1.3

*The most frequent serious adverse reactions reported in the DKd arm as compared with the Kd arm were pneumonia (DKd 14% vs Kd 9%), pyrexia (DKd 4.2% vs Kd 2.0%), influenza (DKd 3.9% vs Kd 1.3%), sepsis (DKd 3.9% vs Kd 1.3%), anemia (DKd 2.3% vs Kd 0.7%), bronchitis (DKd 1.9% vs Kd 0%), and diarrhea (DKd 1.6% vs Kd 0%).
[†]Includes fatal adverse reactions.

Fatal ARs within 30 days of the last dose of any study treatment occurred in 10% of 308 patients who received DKd vs 5% of 153 patients who received Kd. The most frequent fatal AR was infection (4.5% vs 2.6%).²

DKd=DARZALEX® (D) + carfilzomib (K) + dexamethasone (d); Kd=carfilzomib (K) + dexamethasone (d).

Additional safety results

- Discontinuation rates due to ARs with DKd were similar to Kd alone (22% vs 25%, respectively)²
- IRRs that occurred on the day of administration of any DARZALEX® dose or on the next day occurred in 18% of patients and that occurred on the day of administration of the first DARZALEX® dose or the next day occurred in 12%²
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion²

Most frequent adverse reactions reported in ≥15% of patients who received DARZALEX® + once-weekly Kd²

Adverse reactions (EQUULEUS)	DARZALEX® + Kd (n=85)	
	All grades (%)	Grades 3 or 4 (%)
Thrombocytopenia	68	32
Fatigue	54	18
Infusion-related reactions	53	12
Respiratory tract infection	53	3.5
Anemia	52	21
Nausea	42	1.2
Vomiting	40	1.2
Diarrhea	38	2.4
Pyrexia	37	1.2
Dyspnea	35	3.5
Cough	33	0
Hypertension	33	20
Insomnia	33	4.7
Neutropenia	31	21
Lymphopenia	29	25
Headache	27	1.2
Back pain	25	0
Bronchitis	19	0
Nasopharyngitis	18	0
Influenza	17	3.5
Constipation	17	0
Pain in extremity	15	0

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



In patients with relapsed/refractory multiple myeloma
Safety results demonstrated in combination with Pd

Most frequent adverse reactions and hematologic laboratory abnormalities reported in ≥20% of patients^{2*}

DARZALEX® + Pd (n=103)			
Adverse reactions	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Fatigue	50	10	0
Upper respiratory tract infection	50	4	1
Infusion-related reactions	50	4	0
Cough	43	1	0
Diarrhea	38	3	0
Dyspnea	33	6	1
Constipation	33	0	0
Nausea	30	0	0
Muscle spasms	26	1	0
Back pain	25	6	0
Pyrexia	25	1	0
Insomnia	23	2	0
Arthralgia	22	2	0
Vomiting	21	2	0
Dizziness	21	2	0
Chills	20	0	0

*Adverse reactions that occurred with a frequency of ≥10% and <20% were tremor, headache, edema peripheral, hypokalemia, nasal congestion, asthenia, noncardiac chest pain, pneumonia, pain in extremity, bone pain, hyperglycemia, musculoskeletal chest pain, anxiety, pain, and decreased appetite.

The overall incidence of serious ARs was 49%. Serious ARs reported in ≥5% of patients included pneumonia (7%).²

DARZALEX® + Pd (n=103)			
Laboratory abnormalities	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Anemia	57	30	0
Thrombocytopenia	75	10	10
Neutropenia	95	36	46
Lymphopenia	94	45	26

Additional safety results

- Discontinuation rate due to ARs with DPd was 13%²
- Infusion-related reactions (IRRs) with DPd occurred in 50% of patients; 4% were Grade 3 and 0% were Grade 4²
- Grade 3/4 infections were reported in 28% of patients treated with DPd²
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion²
- Most IRRs occurred during the first infusion²

DPd=DARZALEX® (D) + pomalidomide (P) + dexamethasone (d); Pd=pomalidomide (P) + dexamethasone (d).

In patients with relapsed/refractory multiple myeloma
Safety results demonstrated with DARZALEX® monotherapy

Most frequent adverse reactions and hematologic laboratory abnormalities reported in ≥20% of patients^{2*}

DARZALEX® (n=156)			
Adverse reactions	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Infusion-related reactions	48	3	0
Fatigue	39	2	0
Nausea	27	0	0
Back pain	23	2	0
Cough	21	0	0
Pyrexia	21	1	0
Upper respiratory tract infection	20	1	0

*Adverse reactions that occurred with a frequency of ≥10% and <20% were arthralgia, nasal congestion, diarrhea, decreased appetite, nasopharyngitis, constipation, pain in extremity, dyspnea, vomiting, headache, musculoskeletal chest pain, pneumonia, chills, and hypertension.

Serious ARs were reported in 33% of patients. The most frequent serious ARs were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%).²

DARZALEX® (n=156)			
Laboratory abnormalities	Any grade (%)	Grade 3 (%)	Grade 4 (%)
Anemia	45	19	0
Thrombocytopenia	48	10	8
Neutropenia	60	17	3
Lymphopenia	72	30	10

Additional safety results

- Discontinuation rate due to any adverse event: 4%²
- IRRs with DARZALEX® occurred in 48% of patients; 3% were Grade 3 and 0% were Grade 4²
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion²
- Most IRRs occurred during the first infusion²

Please see Important Safety Information for DARZALEX® on pages 96-97. Please [click here](#) for full Prescribing Information for DARZALEX FASPRO®. Please [click here](#) for full Prescribing Information for DARZALEX®.



Indications and Important Safety Information for DARZALEX®

INDICATIONS

DARZALEX® (daratumumab) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
- As monotherapy in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX® is contraindicated in patients with a history of severe hypersensitivity (eg, anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. These reactions can be life-threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4 infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX®. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension, and blurred vision.

When DARZALEX® dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX®, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX® following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1%) with those reported in previous studies at Week 2 or subsequent infusions. In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days, ie, 8 mg/kg on Day 1 and Day 2, respectively. The incidence of any grade infusion-related reactions was 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt DARZALEX® infusion for reactions of any severity and institute medical management as needed. Permanently discontinue DARZALEX®

therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion-related reactions, administer oral corticosteroids to all patients following DARZALEX® infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with DARZALEX® infusion. If ocular symptoms occur, interrupt DARZALEX® infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX®.

Interference With Serological Testing

Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive indirect antiglobulin test (indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab infusion. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type is not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX®. Type and screen patients prior to starting DARZALEX®.

Neutropenia and Thrombocytopenia

DARZALEX® may increase neutropenia and thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX® until recovery of neutrophils or for recovery of platelets.

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (IgG) kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE) and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX® can cause fetal harm when administered to a pregnant woman. DARZALEX® may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX® and for 3 months after the last dose.

The combination of DARZALEX® with lenalidomide, pomalidomide, or thalidomide is contraindicated in pregnant women because lenalidomide, pomalidomide, and thalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, pomalidomide, or thalidomide prescribing information on use during pregnancy.

ADVERSE REACTIONS

The most frequently reported adverse reactions (incidence ≥20%) were upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia. The most common hematologic laboratory abnormalities (≥40%) with DARZALEX® are neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

Please [click here](#) to see the full Prescribing Information.

cp-60862v8

References: 1. DARZALEX FASPRO® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2. DARZALEX® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 3. Chapuy C, Nicholson R, Aguad M, et al. Resolving the daratumumab interference with blood compatibility testing. *Transfusion*. 2015;55:1545-1554. 4. Mateos M-V, Nahi W, Grosicki S, et al. Subcutaneous versus intravenous daratumumab in patients with relapsed or refractory multiple myeloma (COLUMBA): a multicentre, open-label, non-inferiority, randomized, phase 3 trial. *Lancet Haematol*. 2020;7(10):e710.


DARZALEX®
(daratumumab)
injection for intravenous infusion
100 mg/5 mL, 400 mg/20 mL



Introducing J&J withMe



Once you have made the clinical decision to prescribe DARZALEX® or DARZALEX FASPRO®, Johnson & Johnson has resources to help you support your patients.

Access and Affordability Resources Plus Personalized Support for Your Patients

At Johnson & Johnson, we are committed to helping people in their fight against cancer. Our J&J withMe program is here at every step to provide personalized support to help patients start and stay on their J&J medicines.

J&J withMe is your single source for access, affordability, and treatment support programs from Johnson & Johnson. Your patients will be connected to DARZALEX withMe

- Access Support—to help navigate payer processes
- Affordability Resources—to help patients discover ways to afford their medicine from J&J
- Dedicated, free 1-on-1 Care Navigator Support for Your Patients—offered through DARZALEX withMe to support the nonclinical needs that may arise while on treatment

Get your patient connected to J&J withMe support by asking them to enroll at DarzalexwithMe.com

Please [click here](#) for full Prescribing Information for DARZALEX® (daratumumab).
Please [click here](#) for full Prescribing Information for DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj).

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SUPPORT

Dedicated, free 1-on-1 support for your patients throughout their treatment journey

Each patient's treatment journey is unique. We're here to help by providing personalized 1-on-1 support from Care Navigators – oncology-trained nurses* who can help patients:

- Understand their disease and learn more about DARZALEX® or DARZALEX FASPRO®
- Find health and wellness resources for living with cancer
- Explore cost support options regardless of their insurance type
- Help them find online or in-person patient-to-patient support
- Connect them with transportation-related services in their community

Patients will partner with their Care Navigator to schedule phone calls during key milestones throughout their treatment journey. They can also contact them as needs arise Monday through Friday, 8:00 AM to 8:00 PM ET.

Get started with J&J withMe

- Visit [Portal.JNJwithMe.com](https://portal.jnjwithme.com) to investigate insurance coverage for your patients, enroll your patients in savings, or sign them up for Care Navigator support
- Visit [JNJwithMe.com/hcp/](https://jnjwithme.com/hcp/) for access and affordability information for the J&J medicine you prescribed
- Questions? Call **833-JNJ-wMe1** (833-565-9631), Monday through Friday, 8:00 AM to 8:00 PM ET

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe a J&J medicine.

*Care Navigators do not provide medical advice.

Please [click here](#) for full Prescribing Information for DARZALEX® (daratumumab).
Please [click here](#) for full Prescribing Information for DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj).

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DARZALEX Faspro[®]
(daratumumab and hyaluronidase-fihj)
Injection for subcutaneous use | 1,800mg/30,000units



DARZALEX[®]
(daratumumab)
injection for intravenous infusion
100 mg/5 mL, 400 mg/20 mL

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