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 44–46 and Important Safety Information for DARZALEX® on pages 86–88. 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/30,000units

Dosing and Administration

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

Dosing and Administration

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

For subcutaneous use in the treatment of multiple myeloma[1]

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, 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
- 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 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 *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 44–46. 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 administration 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 formulation[1]

DARZALEX *FASPRO*® is a CD38-targeted monoclonal antibody in a subcutaneous formulation[1]

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 subcutaneously over ~3 to 5 minutes while DARZALEX® is given intravenously 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 1249 patients with multiple myeloma (N=1056) 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: 3.2%, Grade 3: 0.7%, Grade 4: 0.1%). Systemic administration-related reactions occurred in 7% of patients with the first injection, 0.2% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 2.9 hours (range: 5 minutes to 3.5 days). Of the 165 systemic administration-related reactions that occurred in 93 patients, 144 (87%) 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 44–46. 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/30,000units

~3 to 5 minute subcutaneous administration with every dose or each dose[1]

DARZALEX *FASPRO*® contains 30,000 units of recombinant hyaluronidase[1]

- Increases permeability of subcutaneous tissue[1]
- Enables 15 mL containing 1,800 mg of daratumumab to be absorbed into the subcutaneous tissue of the abdomen[1]
- Use an appropriate needle gauge. In the clinical trials, 23- to 25-gauge needles were used for the injection[3]
- For subcutaneous use only. DARZALEX *FASPRO*® has different dosage and administration instructions than DARZALEX® (daratumumab). Do not administer intravenously[1,2]

Pre-medication[1]

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 injection[1]

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

Post-medication[1]

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 ARRs, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) ARRs, 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 44–46. 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/30,000units

DARZALEX *FASPRO*® dosing schedule[1]

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

Indicated regimen*	Induction	Schedule
DARZALEX *FASPRO*® + VRd (bortezomib, lenalidomide, and dexamethasone) (4-week cycle)	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)
DARZALEX *FASPRO*® + VMP (bortezomib, melphalan, and prednisone) (6-week cycle)	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
DARZALEX *FASPRO*® + Vd (bortezomib and dexamethasone) (3-week cycle)	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
DARZALEX *FASPRO*® + VTd (bortezomib, thalidomide, and dexamethasone) (4-week cycle)	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)
DARZALEX *FASPRO*® + Rd **DARZALEX *FASPRO*® + Pd** **DARZALEX *FASPRO*® + Kd** **DARZALEX *FASPRO*® monotherapy** (lenalidomide, pomalidomide, or carfilzomib and dexamethasone) (4-week cycle)	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	Every 4 weeks

ARR=administration-related reaction; ASCT=autologous stem cell transplant.

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

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

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

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) + VRd dosing schedule[1]

In adult patients with newly diagnosed, transplant-eligible multiple myeloma[1]

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]

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 4; Weeks 9 to 16)

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 9 ▶

- Bortezomib 1.3 mg/m^2 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 44–46. 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/30,000units

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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

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*®.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) + VMP dosing schedule[1]

In adult patients with newly diagnosed, transplant-ineligible multiple myeloma[1]

Dosing schedule based on a randomized, active-controlled trial[2]

DARZALEX *FASPRO*® in combination with bortezomib, melphalan, and prednisone (VMP) (n=350) vs VMP alone (n=356)

Recommended dosage and schedule for DARZALEX *FASPRO*®[1]

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

2 Doses Per 6-Week Cycle — given as 1 injection **every 3 weeks** (twice per 6-week cycle; Cycles 2 to 9; Weeks 7 to 24)

1 Dose Per 4-Week Cycle — given as 1 injection **every 4 weeks** (once per 4-week cycle; Cycles 10+; Weeks 55+ until disease progression)

22 estimated Year 1 injection visits

See table on page 11 ▶

- Bortezomib was administered by subcutaneous (SC) injection at a dose of 1.3 mg/m^2 twice weekly at Weeks 1, 2, 4, and 5 for the first 6-week cycle (Cycle 1; 8 doses), followed by once weekly administrations at Weeks 1, 2, 4, and 5 for eight more 6-week cycles (Cycles 2–9; 4 doses per cycle)
- Melphalan at 9 mg/m^2 and prednisone at 60 mg/m^2 were orally administered on Days 1 to 4 of the nine 6-week cycles (Cycles 1–9)
- DARZALEX *FASPRO*® treatment was continued until disease progression or unacceptable toxicity

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

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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

Cycle 1 (6-week cycles) — 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 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42
DARZALEX *FASPRO*® weekly	● ● ● ● ● ●
bortezomib	● ● ● ● ● ● ● ● ● ● ● ●
melphalan/prednisone	●●●●

Cycles 2–9 (6-week cycles) — Total of 16 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 29 30 31 32 33 34 35 36 37 38 39 40 41 42
DARZALEX *FASPRO*® every 3 weeks	● ● ●
bortezomib	● ● ● ●
melphalan/prednisone	●●●●

Continue DARZALEX *FASPRO*® until disease progression or unacceptable toxicity (dosed once every 4 weeks)

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	● ● ● ●

Select Important Safety Information

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*®.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) + VTd dosing schedule[1]

In adult patients with newly diagnosed, transplant-eligible multiple myeloma[1]

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/m^2 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 44–46. 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/30,000units

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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

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*®.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) + Rd dosing schedule[1]

In adult patients with newly diagnosed, transplant-ineligible multiple myeloma[1]

Dosing schedule based on a phase 3, randomized, active-controlled trial[2]

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.

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

Select Important Safety Information

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*®.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) + Rd dosing schedule for patients with relapsed/refractory multiple myeloma[1]

In patients at first relapse[1]

Dosing schedule based on a randomized, active-controlled trial[2]

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 44–46. 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/30,000units

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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
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	●														●													No treatment
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	●																											No treatment
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
dexamethasone	●	●						●							●							●						

Continue DARZALEX *FASPRO*® until disease progression or unacceptable toxicity

Select Important Safety Information

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*®.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) + Vd dosing schedule[1]

In patients at first relapse[1]

Dosing schedule based on a phase 3, randomized, active-controlled trial[2]

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/m^2 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 44–46. 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/30,000units

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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	●							●							●	No treatment					
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	●														No treatment						
bortezomib	●			●				●			●										
dexamethasone	●	●		●	●			●	●		●	●									

Continue DARZALEX *FASPRO*® once every 4 weeks until disease progression[2]

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

Select Important Safety Information

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*®.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) + Pd dosing schedule[1]

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

Dosing schedule based on an open-label trial[1]

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 44–46. 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/30,000units

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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
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	●														●													No treatment
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
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	●																											No treatment
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
dexamethasone	●	●						●							●							●						

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

Select Important Safety Information

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*®.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) + Kd dosing schedule[1]

In patients with 1 to 3 prior lines of therapy

Dosing schedule based on an open-label trial[1]

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 cycles†
  - — 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.

†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 44–46. 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/30,000units

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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																												
carfilzomibǁ	●	●						●	●						●	●												
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

ǁCarfilzomib 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																												
carfilzomibǁ	●	●						●	●						●	●												
dexamethasone	●	●						●	●						●	●						●						

Cycles 7 onward (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																												
carfilzomibǁ	●	●						●	●						●	●												
dexamethasone	●	●						●	●						●	●						●						

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

Select Important Safety Information

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*®.

DARZALEX *FASPRO*® monotherapy dosing schedule[1]

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[1]

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

DARZALEX *FASPRO*® dosing frequency decreases over time[1]

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.

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

Select Important Safety Information

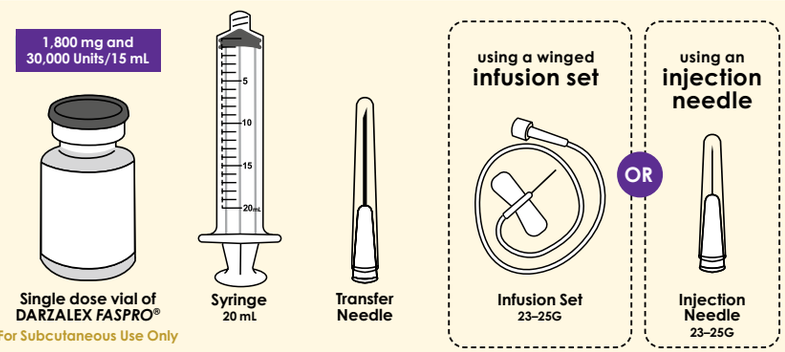
WARNINGS AND PRECAUTIONS

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*®.

Preparation

Before you begin, collect your supplies[1]*



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

Use Transfer Needle per institution/practice protocol.

STEP 1: Inspect and prepare the vial[1]

- 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
- 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
- Label the syringe appropriately to include the route of administration per institutional standards
- 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

DID YOU KNOW?

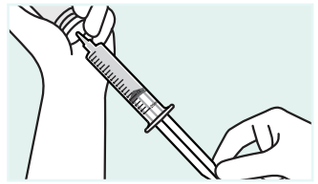
If you prefer, you may use a winged infusion set to administer DARZALEX *FASPRO*®.[3]

Select Important Safety Information

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.

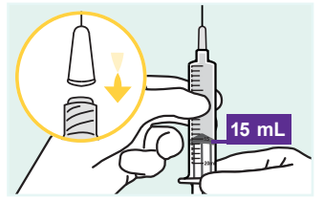
STEP 2: Attach the transfer needle and fill the syringe[1]



Prepare the dosing syringe in controlled and validated aseptic conditions.

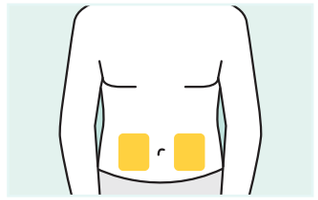
- Using the transfer needle, withdraw the full content of the vial into a 20 mL dosing syringe
- After transferring DARZALEX *FASPRO*®, inspect dosing syringe visually for particulate matter and discoloration. Do not administer if opaque particles, discoloration, or other foreign particles are present
- To avoid clogging, attach the needle to the syringe immediately prior to injection

STEP 3: Attach the injection needle and set the dose[1]



- Remove the transfer needle and attach the injection needle to the syringe
- Prime the syringe and set the dose to 15 mL

STEP 4: Choose and prepare the injection site on the abdomen[1]



- 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

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.

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

Administration

DARZALEX *FASPRO*® makes subcutaneous administration possible starting with the first dose[1]

DARZALEX *FASPRO*® is for single use only and comes in a ready-to-use vial[1]

STEP 1: Insert needle at a 45-degree angle[1,3]

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]

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

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.

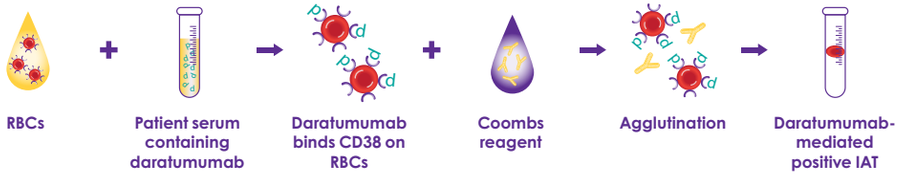
The combination of DARZALEX *FASPRO*® with lenalidomide, thalidomide, or pomalidomide is contraindicated in pregnant women because lenalidomide, thalidomide, and pomalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, thalidomide, or pomalidomide prescribing information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

Important information before administering DARZALEX *FASPRO*®

Interference with serological testing[1]

- 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 reactivation[1]

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

Handling and storage[1]

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.

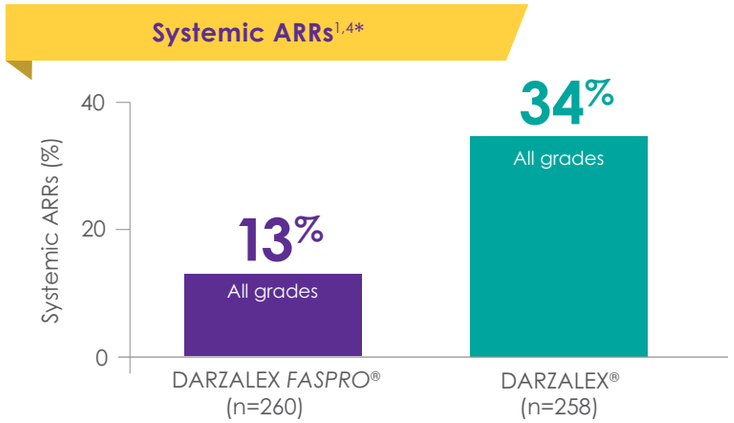
If the syringe containing DARZALEX *FASPRO*® is not used immediately, store refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours and/or at room temperature at 15°C to 25°C (59°F to 77°F) for up to 12 hours under ambient light. Discard if storage time exceeds these limits. If stored in the refrigerator,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

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

Fewer systemic administration-related reactions

Nearly 3x reduction in systemic ARRs with DARZALEX *FASPRO*® vs DARZALEX® (daratumumab) observed in the COLUMBA trial[1]



Systemic ARRs[1]

Most systemic ARRs were **Grade 1 or 2** and occurred with the first injection.

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

Grade 3 systemic ARRs occurred in 2% of patients using DARZALEX *FASPRO*® vs 5% of those on DARZALEX®.

No Grade 4 systemic ARRs were reported.

Both systemic ARRs, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX *FASPRO*®.[1]

ARRs=administration-related reactions.

*Systemic ARRs 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 ARRs 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]

In a pooled safety population of 1249 patients with multiple myeloma (N=1056) 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: 3.2%, Grade 3: 0.7%, Grade 4: 0.1%).[1]

- Systemic administration-related reactions occurred in 7% of patients with the first injection, 0.2% with the second injection, and cumulatively 1% with subsequent injections
- The median time to onset was 2.9 hours (range: 5 minutes to 3.5 days). Of the 165 systemic administration-related reactions that occurred in 93 patients, 144 (87%) occurred on the day of DARZALEX *FASPRO*® administration
- Delayed systemic administration-related reactions have occurred in 1% of the patients

Local reactions[1]

- In this pooled safety population, injection-site reactions occurred in 7% of patients, including Grade 2 reactions in 0.8%. The most frequent (>1%) injection-site reaction was injection-site erythema
- These local reactions occurred a median of 5 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX *FASPRO*®. Monitor for local reactions and consider symptomatic management

Select Important Safety Information

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.

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

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]

	DARZALEX *FASPRO*® (n=260)		DARZALEX® (n=258)	
Adverse reactions	**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]

[a]Upper respiratory tract infection includes acute sinusitis, nasopharyngitis, pharyngitis, respiratory syncytial virus infection, respiratory tract infection, rhinitis, rhinovirus infection, sinusitis, and upper respiratory tract infection.
[b]Pneumonia includes lower respiratory tract infection, lung infection, pneumocystis jirovecii pneumonia, and pneumonia.
[c]Fatigue includes asthenia and fatigue.
[d]Systemic 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."
[e]Cough includes cough and productive cough.
[f]Dyspnea includes dyspnea and dyspnea exertional.
[g]Only Grade 3 adverse reactions occurred.
[h]Grade 5 adverse reactions occurred.

	DARZALEX *FASPRO*® (n=260)[a]		DARZALEX® (n=258)[a]	
Laboratory abnormalities	**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

[a]Denominator is based on the safety population treated with DARZALEX *FASPRO*® (n=260) or with DARZALEX® (n=258).

ADVERSE REACTIONS

Serious adverse reactions occurred in 26% of patients who received DARZALEX *FASPRO*® vs 29% who received DARZALEX®. Fatal adverse reactions occurred in 5% of patients receiving DARZALEX *FASPRO*®. Fatal adverse reactions occurring in more than 1 patient were general physical health deterioration, septic shock, and respiratory failure. Fatal adverse reactions occurred in 7% of patients receiving DARZALEX®.[1,4]

Systemic ARRs=systemic administration-related reactions.

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

Demonstrated safety profile through post-transplant consolidation for frontline DARZALEX *FASPRO*® + VRd[1]

Adverse reactions reported in ≥10% of patients who received DVRd through post-transplant consolidation[1]

	DARZALEX *FASPRO*® + VRd (n=351)		VRd (n=347)	
Adverse reaction	**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, hepatoxicity, 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 consolidation[1]

	DARZALEX *FASPRO*® + VRd (n=350)**		VRd (n=345)**	
Laboratory abnormality	**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 DVRd[1]:

- 37% experienced serious adverse reactions
- >5% experienced most frequent serious adverse reactions: 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 sepsis.[1]

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.

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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 VMP

Adverse reactions (≥10%) and select hematologic laboratory abnormalities worsening from baseline in patients receiving DARZALEX *FASPRO*® in combination with bortezomib, melphalan, and prednisone[1]

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]

[a]Upper respiratory tract infection includes nasopharyngitis, respiratory syncytial virus infection, respiratory tract infection, rhinitis, tonsillitis, upper respiratory tract infection, and viral pharyngitis.
[b]Pneumonia includes lower respiratory tract infection, lung infection, pneumocystis jirovecii pneumonia, pneumonia, and pneumonia bacterial.
[c]Abdominal pain includes abdominal pain and abdominal pain upper.
[d]Fatigue includes asthenia and fatigue.
[e]Edema peripheral includes edema, edema peripheral, and peripheral swelling.
[f]Cough includes cough and productive cough.
[g]Only 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]

VMP=bortezomib (V) + melphalan (M) + prednisone (P).

Laboratory abnormalities	DARZALEX *FASPRO*®[a] + VMP 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

[a]Denominator is based on the safety population treated with DVMP (n=67).

DVMP=DARZALEX *FASPRO*® (D) + bortezomib (V) + melphalan (M) + prednisone (P).

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

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 dexamethasone[1]

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

[a]Fatigue includes asthenia and fatigue.
[b]Upper respiratory tract infection includes nasopharyngitis, pharyngitis, respiratory tract infection viral, rhinitis, sinusitis, upper respiratory tract infection, and upper respiratory tract infection bacterial.
[c]Pneumonia includes lower respiratory tract infection, lung infection, and pneumonia.
[d]Bronchitis includes bronchitis and bronchitis viral.
[e]Dyspnea includes dyspnea and dyspnea exertional.
[f]Cough includes cough and productive cough.
[g]Only Grade 3 adverse reactions occurred.

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

[a]Denominator is based on the safety population treated with DRd (n=65).

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

Rd=lenalidomide (R) + dexamethasone (d).

DRd=DARZALEX *FASPRO*® (D) + lenalidomide (R) + dexamethasone (d).

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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/30,000units

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 dexamethasone[1]

	DARZALEX *FASPRO*® + Kd (n=66)	
Adverse reactions	**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

[a]Upper 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.
[b]Bronchitis includes bronchitis and bronchitis viral.
[c]Fatigue includes asthenia and fatigue.
[d]Edema peripheral includes generalized edema, edema peripheral, and peripheral swelling.
[e]Hypertension includes blood pressure increased and hypertension.
[f]Cough includes cough and productive cough.
[g]Dyspnea includes dyspnea and dyspnea exertional.
[h]Only Grade 3 adverse reactions occurred.

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

Clinically relevant adverse reactions in <10% of patients who received DARZALEX *FASPRO*® with carfilzomib and dexamethasone include[1]:

- **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

	DARZALEX *FASPRO*® + Kd[a]	
Laboratory abnormalities	**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

[a]Denominator 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 44–46. 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/30,000units

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 APOLLO[1]

	DARZALEX *FASPRO*® + Pd (n=149)		Pd (n=150)	
Adverse reactions	**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

[a]Fatigue includes asthenia and fatigue.
[b]Edema peripheral includes edema, edema peripheral, and peripheral swelling.
[c]Pneumonia includes atypical pneumonia, lower respiratory tract infection, pneumonia, pneumonia aspiration, pneumonia bacterial, and pneumonia respiratory syncytial viral.
[d]Upper 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.
[e]Cough includes cough and productive cough.
[f]Only grade 3 adverse reactions occurred.
[g]Grade 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 diarrhea[1]
- 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*® + Pd[1]
- Permanent treatment discontinuation due to an adverse reaction occurred in 2% of patients who received DARZALEX *FASPRO*® + Pd[1]

	DARZALEX *FASPRO*® + Pd[a]		Pd[a]	
Laboratory abnormalities	**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

[a]Denominator 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.

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

Please see Important Safety Information for DARZALEX *FASPRO*® on pages 44–46. 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 *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, 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

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 1249 patients with multiple myeloma (N=1056) 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: 3.2%, Grade 3: 0.7%, Grade 4: 0.1%). Systemic administration-related reactions occurred in 7% of patients with the first injection, 0.2% with the second injection, and cumulatively 1% with subsequent injections. The median time to onset was 2.9 hours (range: 5 minutes to 3.5 days). Of the 165 systemic administration-related reactions that occurred in 93 patients, 144 (87%) 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, injection-site reactions occurred in 7% of patients, including Grade 2 reactions in 0.8%. The most frequent (>1%) injection-site reaction was injection-site erythema. These local reactions occurred a median of 5 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX *FASPRO*®. Monitor for local reactions and consider symptomatic management.

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 (≥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, insomnia, headache, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, upper respiratory tract infection, peripheral neuropathy, peripheral sensory neuropathy, constipation, pneumonia, edema, peripheral edema, musculoskeletal pain, and rash.

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

Please click here to see the full Prescribing Information for DARZALEX *FASPRO*®.

cp-143279v9

References: 1. DARZALEX *FASPRO*® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** DARZALEX® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **3.** Data on file. Janssen Biotech, Inc. **4.** Mateos M-V, Nahi H, Legiec W, et al. Subcutaneous versus intravenous daratumumab in patients with relapsed or refractory multiple myeloma (COLUMBA): a multicentre, open-label, non-inferiority, randomised, phase 3 trial. *Lancet Haematol*. 2020;7(5):e370-e380.

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

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 86–88.
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 CD38[2]

- CD38 is expressed on hematopoietic cells, other cell types and tissues, and is highly expressed on multiple myeloma cells[2]
- DARZALEX® inhibits tumor cell growth through immune-mediated, direct on-tumor, and immunomodulatory actions. DARZALEX® may also have an effect on normal cells[2]

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.[1,5]

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.

How DARZALEX® is supplied[2]

Dosage form and strengths[2]

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)

Storage[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

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

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 86–88. 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® dosing schedules[2]

DARZALEX® is indicated for use in 7 different 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
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
With bortezomib, thalidomide, and dexamethasone (4-week cycle) **(DVTd)**	**Induction**	**Induction**
	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

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.

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 86–88. 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® + VMP dosing schedule[2]

In adult patients with newly diagnosed, transplant-ineligible multiple myeloma[2]

Dosing schedule based on a randomized, active-controlled trial

DARZALEX® in combination with bortezomib and melphalan and prednisone (VMP) (n=350) vs VMP alone (n=356)

Recommended dosage and schedule for DARZALEX®[2]

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

2 Doses Per 6-Week Cycle — given as 1 infusion **every 3 weeks** (twice per 6-week cycle; Cycles 2 to 9; Weeks 7 to 54)

1 Doses Per 4-Week Cycle — given as 1 infusion **every 4 weeks** (once per 4-week cycle; Cycles 10+; Weeks 55+ until disease progression)

22 estimated Year 1 infusion visits

See table on page 53 ▶

- Bortezomib was administered by subcutaneous (SC) injection at a dose of 1.3 mg/m^2 twice weekly at Weeks 1, 2, 4, and 5 for the first 6-week cycle (Cycle 1; 8 doses), followed by once weekly administrations at Weeks 1, 2, 4, and 5 for eight more 6-week cycles (Cycles 2–9; 4 doses per cycle)†
- Melphalan at 9 mg/m^2 and prednisone at 60 mg/m^2 were orally administered on Days 1 to 4 of the nine 6-week cycles (Cycles 1–9)
- DARZALEX® treatment was continued until disease progression or unacceptable toxicity

*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 Important Safety Information for DARZALEX® on pages 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

DARZALEX® dosing frequency decreases over time[2]

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

Cycle 1 (6-week cycles) — Total of 6 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 29 30 31 32 33 34 35 36 37 38 39 40 41 42
DARZALEX® weekly	●‡ ● ● ● ● ● ●
bortezomib	● ● ● ● ● ● ● ●
melphalan/prednisone	●●●●

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

Cycles 2–9 (6-week cycles) — Total of 16 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 29 30 31 32 33 34 35 36 37 38 39 40 41 42
DARZALEX® every 3 weeks	●§ ● ●
bortezomib	● ● ● ●
melphalan/prednisone	●●●●

Continue DARZALEX® until disease progression or unacceptable toxicity (dosed once every 4 weeks)

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	●

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® + Rd dosing schedule[2]

In adult patients with newly diagnosed, transplant-ineligible multiple myeloma[2]

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 55 ▶

- 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 (14.2) 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.

DARZALEX® dosing frequency decreases over time[2]

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	●							●							●							●						

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	●														●													
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
dexamethasone	●							●							●							●						

No treatment

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	●							●							●							●						

No treatment

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.

Please see Important Safety Information for DARZALEX® on pages 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

DARZALEX® + VTd dosing schedule[2]

In adult patients with newly diagnosed, transplant-eligible multiple myeloma[2]

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 57 ▶

- Bortezomib 1.3 mg/m^2 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 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

DARZALEX® dosing frequency decreases over time[2]

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 schedule for patients with relapsed/refractory multiple myeloma[2]

In patients at first relapse[2]

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 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, 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 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

DARZALEX® dosing frequency decreases over time[2]

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	●	●						●	●						●	●						●	●					

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	●														●													
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® every 4 weeks	●																											
lenalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
dexamethasone	●	●						●							●							●						

No treatment

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 schedule[2]

In patients at first relapse[2]

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 61 ▶

- Bortezomib 1.3 mg/m^2 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.

DARZALEX® dosing frequency decreases over time[2]

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	●			●				●			●										
dexamethasone	●	●		●	●			●	●		●	●									

§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	●			●				●			●										
dexamethasone	●	●		●	●			●	●		●	●									

Continue DARZALEX® once every 4 weeks until disease progression[2]

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.

Please see Important Safety Information for DARZALEX® on pages 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

DARZALEX® + Pd dosing schedule[2]

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 63 ▶

- 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 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

DARZALEX® dosing frequency decreases over time[2]

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	●	●						●	●						●	●						●	●					

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	●														●													
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
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® every 4 weeks	●																											
pomalidomide	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							
dexamethasone	●	●						●							●							●						

No treatment

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 schedule[2]

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 65 ▶

- 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 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

DARZALEX® dosing frequency decreases over time[2]

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 schedule[2]

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 67 ▶

- 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 time[2]

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												

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 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

Preparation for DARZALEX® administration[2]

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
- 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

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.

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 86–88. Please click here for full Prescribing Information for DARZALEX *FASPRO*®. Please click here for full Prescribing Information for DARZALEX®.

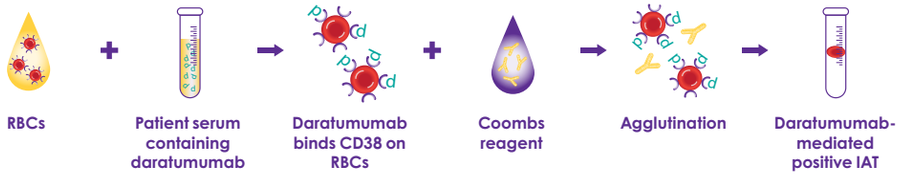
DARZALEX® (daratumumab) injection for intravenous infusion 100 mg/5 mL, 400 mg/20 mL

Important information before administering DARZALEX®

Interference with serological testing[2]

- 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

Typical indirect antiglobulin test from a DARZALEX® patient[2,4]



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 reactivation[2]

- 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 storage[2]

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 86–88. 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

Infusion rates for DARZALEX®

Slower rate of infusion for the first DARZALEX® dose is recommended, as infusion-related reactions are more likely to occur with the first infusion[2]

		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, respectively[2] (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.[18]
‖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 39)[2]

In clinical trials (monotherapy and combination treatments; N=2066)

Most infusion-related reactions occurred during the first infusion[2]

- 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 infusions[2]
- 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 vision[2]
- 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 reactions[2]
- 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 86–88. 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

Management of infusion-related reactions

Infusion-related reactions of any grade or severity may be managed by interruption, modification, and/or discontinuation of the infusion[2]

- 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 reactions[2]

Infusion-related reaction grade	Dose interruptions/modifications
Grades 1 & 2 (mild to moderate)	Once symptoms resolve: • Resume the infusion at no more than half the rate at which the reaction occurred If the patient does not experience any further reaction symptoms: • Infusion rate escalation may resume at increments and intervals as clinically appropriate up to the maximum rate of 200 mL/hour
Grade 3 (severe)	Once symptoms resolve: • Consider restarting infusion at no more than half the rate at which the reaction occurred If the patient does not experience additional symptoms: • Resume infusion rate escalation at increments and intervals as appropriate In the event of recurrence of Grade 3 symptoms: • Repeat the procedure above If the patient experiences a third occurrence of a Grade 3 or higher infusion-related reaction: • 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 medications[2]

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 medications[2]

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 86–88. 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

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]*

	DARZALEX® + Rd (n=364)			Rd (n=365)		
Adverse reactions	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 ≥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).

	DARZALEX® + Rd (n=364)			Rd (n=365)		
Laboratory abnormalities	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 Rd[2]
- Infusion-related reactions (IRRs) with DRd occurred in 41% of patients; 2% were Grade 3 and <1% were Grade 4[2]
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion[2]
- Most IRRs occurred during the first infusion[2]

Please see Important Safety Information for DARZALEX® on pages 86–88. 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

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]*

	DARZALEX® + VTd (n=536)			VTd (n=538)		
Adverse reactions	**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]

	DARZALEX® + VTd (n=536)			VTd (n=538)		
Laboratory abnormalities	**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 VTd[2]
- IRRs with DVTd occurred in 35% of patients; 3% were Grade 3 and <1% were Grade 4[2]
- Most IRRs occurred during the first infusion[2]
  - 27% of patients had IRRs with the first infusion[2]
  - 11% of patients had IRRs with the first post-transplant infusion[2]
- Grade 3/4 infections were similar between study arms: 22% vs 20% with DVTd vs VTd alone, respectively[2]

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

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 arm[2]

	DARZALEX® + VMP (n=346)			VMP (n=354)		
Adverse reactions	**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]

	DARZALEX® + VMP (n=346)			VMP (n=354)		
Laboratory abnormalities	**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 alone[2]
- IRRs with DARZALEX® + VMP occurred in 28% of patients; 4% were Grade 3 and 1% were Grade 4[2]

Additional safety results

- Grade 3 or 4 infections were 23% with DVMP vs 15% with VMP alone[2]
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion[2]
- Most IRRs occurred during the first infusion[2]

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 86–88. 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

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*]

	DARZALEX® + Rd (n=283)			Rd (n=281)		
Adverse reactions	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]

	DARZALEX® + Rd (n=283)			Rd (n=281)		
Laboratory abnormalities	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 4[2]
- Grade 3/4 infections between study arms: 28% vs 23% with DRd and Rd, respectively[2]
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion[2]
- Most IRRs occurred during the first infusion[2]

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*]

	DARZALEX® + Vd (n=243)			Vd (n=237)		
Adverse reactions	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]

	DARZALEX® + Vd (n=243)			Vd (n=237)		
Laboratory abnormalities	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 4[2]
- Grade 3/4 infections were similar between study arms: 21% vs 19% with DVd vs Vd alone, respectively[2]
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion[2]
- Most IRRs occurred during the first infusion[2]

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

Please see Important Safety Information for DARZALEX® on pages 86–88. 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

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]*

	DARZALEX® + Kd (n=308)		Kd (n=153)	
Adverse reactions (CANDOR)	**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).

Please see Important Safety Information for DARZALEX® on pages 86–88. Please click here for full Prescribing Information for DARZALEX®. Please click here for full Prescribing Information for DARZALEX *FASPRO*®.

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

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 infusion[2]

Most frequent adverse reactions reported in ≥15% of patients who received DARZALEX® + once-weekly Kd[2]

	DARZALEX® + Kd (n=85)	
Adverse reactions (EQUULEUS)	**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

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]*

Adverse reactions	DARZALEX® + Pd (n=103) 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]

Laboratory abnormalities	DARZALEX® + Pd (n=103) 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 4[2]
- Grade 3/4 infections were reported in 28% of patients treated with DPd[2]
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion[2]
- Most IRRs occurred during the first infusion[2]

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]*

Adverse reactions	DARZALEX® (n=156) 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]

Laboratory abnormalities	DARZALEX® (n=156) 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 4[2]
- IRRs of any grade or severity may require management by interruption, modification, and/or discontinuation of the infusion[2]
- Most IRRs occurred during the first infusion[2]

Please see Important Safety Information for DARZALEX® on pages 86–88. 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

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®.

Continued on next page

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

Important Safety Information for DARZALEX® (cont)

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

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

References: 1. DARZALEX *FASPRO*® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** DARZALEX® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **3.** Data on file. **4.** Chapuy C, Nicholson R, Aguad M, et al. Resolving the daratumumab interference with blood compatibility testing. *Transfusion*. 2015;55:1545-1554. **5.** 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.