

WHEN **MULTIPLE MYELOMA** IS ANYTHING BUT QUIET

NEITHER AM I

Treatment is a shared decision—talk with your doctor about
DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)

What is DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)?

DARZALEX FASPRO® is a prescription medicine used to treat adult patients with multiple myeloma:

- in combination with the medicines bortezomib, lenalidomide, and dexamethasone in newly diagnosed people who are eligible to receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines bortezomib, melphalan, and prednisone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines lenalidomide and dexamethasone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant) and in people whose multiple myeloma has come back or did not respond to treatment who have received at least one prior medicine to treat multiple myeloma
- in combination with the medicines bortezomib, thalidomide, and dexamethasone in newly diagnosed people who are eligible to receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)

- in combination with the medicines bortezomib and dexamethasone in people who have received at least one prior medicine to treat multiple myeloma
- in combination with the medicines pomalidomide and dexamethasone in people who have received at least one prior medicine, including lenalidomide and a proteasome inhibitor, to treat multiple myeloma
- in combination with the medicines carfilzomib and dexamethasone in people whose multiple myeloma has come back or did not respond to treatment who have received one to three prior medicines to treat multiple myeloma
- alone in people who have received at least three prior medicines, including a proteasome inhibitor and an immunomodulatory agent, **or** did not respond to a proteasome inhibitor and an immunomodulatory agent

It is not known if DARZALEX FASPRO® is safe and effective in children.

SELECT IMPORTANT SAFETY INFORMATION

Do not receive DARZALEX FASPRO® if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO®. See [page 52](#) for a complete list of ingredients in DARZALEX FASPRO®.

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FIND YOUR VOICE AFTER BEING DIAGNOSED WITH MULTIPLE MYELOMA

First step: Making informed decisions throughout your treatment journey

This guide will help you understand your treatment journey ahead and how a treatment option like DARZALEX FASPRO® may be right for you. It's divided into 4 chapters to help you find information that matters to you depending on where you are in your journey.

Simply click on the chapter below to learn more about:



What to Know at Diagnosis

Learn more about multiple myeloma and the need to plan ahead >



Why Choose DARZALEX FASPRO®

Learn more about DARZALEX FASPRO® and if it may be right for you >



Preparing for Treatment

Learn more about what to expect before, during, and after treatment with DARZALEX FASPRO® >



The Power of Teamwork

Learn more about the support and resources available to you >

ALWAYS REMEMBER: Treatment is a shared decision and having support from your doctor, care team, and your care partner can help you:



Stay committed to your treatment plan



Work toward your treatment goals



Have a voice when discussing treatment with your care team

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Injection site reactions.** Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX FASPRO®. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection of DARZALEX FASPRO®.

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WHAT TO KNOW AT DIAGNOSIS

A multiple myeloma diagnosis can be stressful, but knowing what to expect at the start of your journey can be helpful on your road ahead.

Key highlights from this chapter include:

✓ Multiple myeloma is a type of blood cancer

[Learn more](#)

✓ Although there is no cure for multiple myeloma at this time, there are many treatment options that may help manage it

[Learn more](#)

✓ Some key goals are for you to respond to your treatment and keep your disease from getting worse for as long as possible

[Learn more](#)

✓ Continuing a treatment that works can help to keep your multiple myeloma from getting worse

[Learn more](#)

✓ For the best results, it's important to begin multiple myeloma treatment as soon as possible, starting with the most effective treatment

[Learn more](#)

ABOUT MULTIPLE MYELOMA

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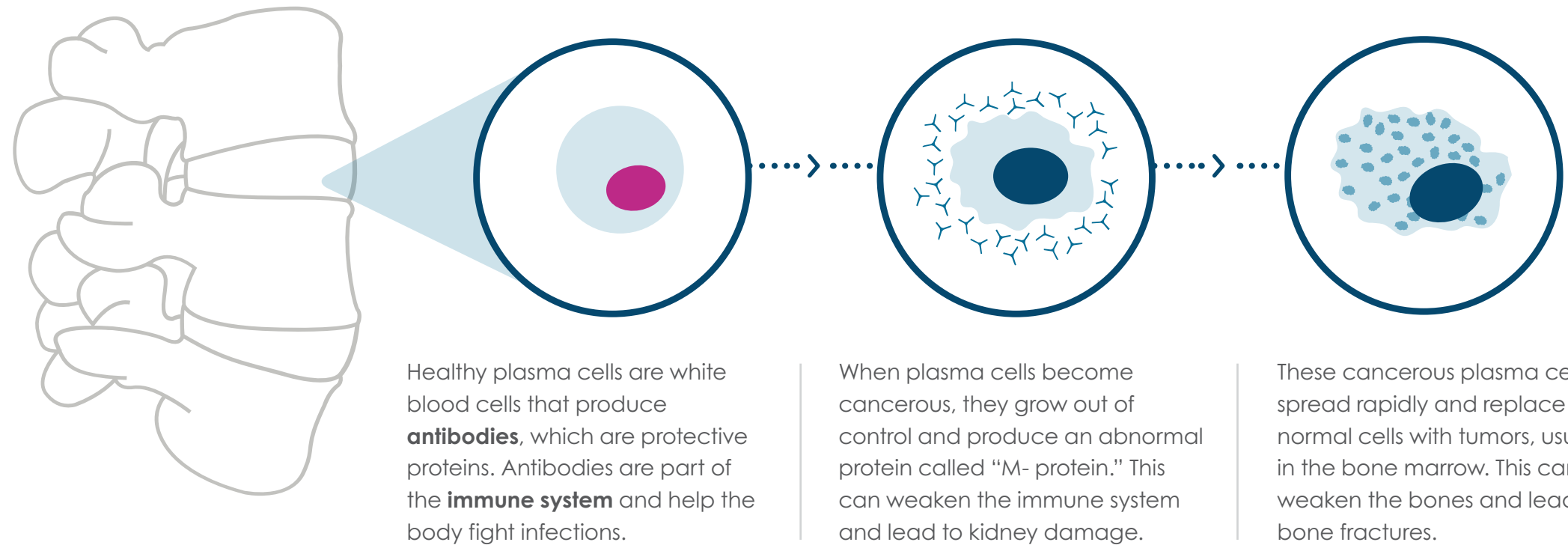
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Multiple myeloma is a blood cancer that affects a type of white blood cell called a plasma cell. These white blood cells are found mostly in bone marrow, the soft substance inside some hollow bones where blood cells are made.



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MULTIPLE MYELOMA TREATMENT OPTIONS

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There are many treatment options available. Be sure to discuss all the benefits and risks of each option you are considering with your care team.


Commonly used multiple myeloma treatments and supportive medications

 **Monoclonal antibodies** kill cancer cells and help the immune system keep them from coming back. Some monoclonal antibodies are also immunomodulatory agents


 **Immunomodulatory agents** can send signals to the immune system to destroy cancerous cells

 **Proteasome inhibitors** interfere with actions inside cancer cells that help them grow and spread

 **Chemotherapy** either kills cancer cells or stops them from spreading

 **Conditioning and stem cell transplants*** destroy cells in the blood, including cancerous cells, and replace them with healthy stem cells (cells that are still able to develop into different types of specialized cells like red blood cells, white blood cells, and platelets)

 **Steroids** help decrease inflammation and swelling

 **Bone support medications** help improve bone strength and prevent loss of bone mass



Be heard

Remember, you have a voice in your treatment plan. Speak openly about your goals and what you expect from treatment.

*Not everyone is eligible for stem cell transplant.

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1

Normal Bone Marrow

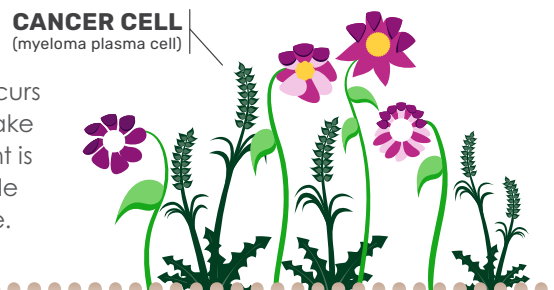
Bone marrow can be thought of as a garden. Healthy bone marrow is similar to thriving flowers without the threat of weeds.



2

Disease Diagnosis

A multiple myeloma diagnosis occurs when cancer cells begin to overtake your bone marrow. Early treatment is important. If left untreated, multiple myeloma can get worse over time.



3

Treatment Goals

Treatment aims to slow the growth of cancer cells to gain control of the disease. The goal of treatment is to control the growth of multiple myeloma cells.



4

Progression-Free Survival

Living progression-free can be thought of as the length of time that the disease does not get worse. This is a sign that the disease is under control—similar to controlling weeds in a garden.



For the best outcomes, it's important to start multiple myeloma treatment as soon as possible.

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UNDERSTANDING LEVELS OF RESPONSE

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There are many goals of multiple myeloma treatment. One goal is to live progression free. This can be thought of as the length of time that the disease does not get worse.

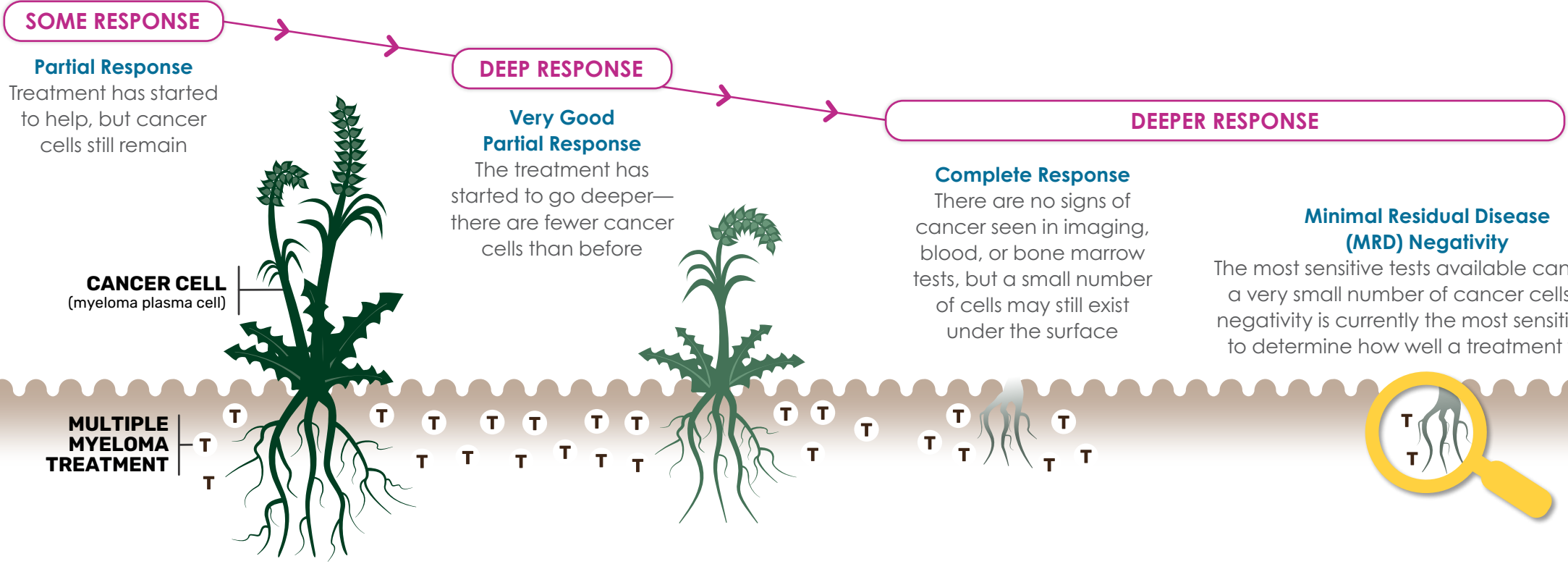
Treatment response is another key goal. This refers to how well the multiple myeloma cells in your body are being controlled by therapy. As response deepens (or gets better), fewer cancer cells remain.

You can think of response like weeds being treated in a garden. The weeds begin to disappear as treatment becomes more effective.

Achieving the deepest response for as long as possible is one goal of treatment



A multiple myeloma diagnosis can feel overwhelming, but you and your care team are in this together. If you have questions about your treatment goals, be sure to ask your team.



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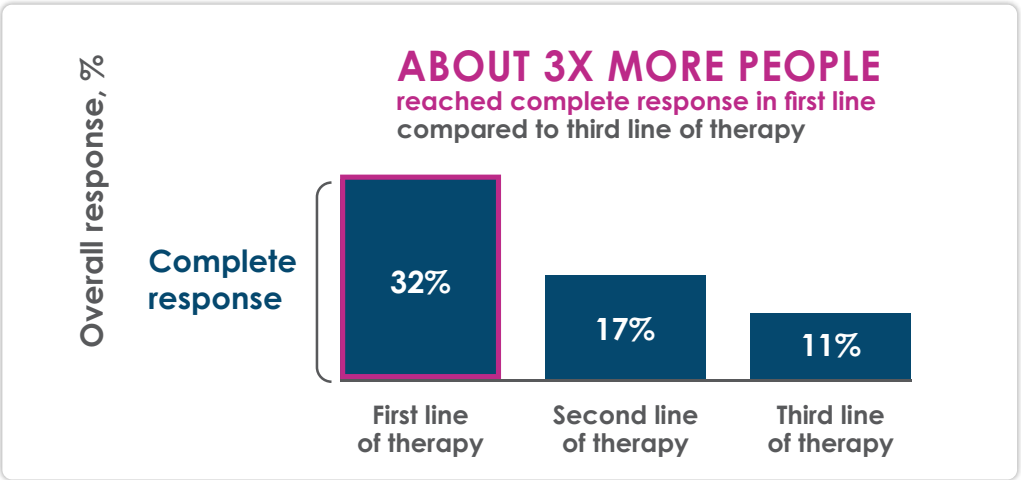
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IMPORTANCE OF YOUR FIRST TREATMENT CHOICE

A treatment plan that includes one or more medications is called a line of therapy. It may also include a stem cell transplant.

A change in treatment is considered a new line of therapy. This may happen if one or more treatments stop working or cause side effects. **You and your care team will work together to determine the right treatment for you.**

Research has shown that your best chance at deeper response occurs with your first line of therapy*



*In a retrospective study of 4997 patient charts from 7 European countries.

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WHY CHOOSE DARZALEX FASPRO®

Learning about which treatments are available to you is an important step in deciding with your doctor which one is right for you. One treatment option is DARZALEX FASPRO®. It is a prescription medicine that can be used to treat adults who have newly diagnosed multiple myeloma or adults who have received previous multiple myeloma treatment.



Key highlights in this chapter:



DARZALEX FASPRO® is not chemotherapy. It is an immunotherapy that works with your immune system to fight disease

[Learn more](#)



Daratumumab, the main ingredient in DARZALEX FASPRO®, kills multiple myeloma cells and/or allows your immune system to identify and destroy them. Because of the way daratumumab works, it may also affect normal cells

[Learn more](#)



In a clinical study, patients on DARZALEX FASPRO® experienced results comparable to those receiving DARZALEX® (daratumumab) when used as monotherapy (by itself). **DARZALEX® (IV version) and DARZALEX FASPRO® (injection under the skin) both contain the medicine daratumumab and are given differently**

[Learn more](#)



DARZALEX® has been used to treat multiple myeloma since 2015. DARZALEX FASPRO® became available in 2020. Combined, the two products have been studied in 12 clinical trials and have extensive data to support their use.

Discover how effectively DARZALEX FASPRO® and DARZALEX® fight multiple myeloma:

- For newly diagnosed, transplant-eligible patients
- For newly diagnosed, transplant-ineligible patients
- For patients who have been previously treated

[Learn more](#)

[Learn more](#)

[Learn more](#)

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO®.

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ABOUT DARZALEX FASPRO®

DARZALEX FASPRO® is used to treat adult patients with multiple myeloma. It is not chemotherapy. It's a type of immunotherapy called a monoclonal antibody and is given as an injection under the skin. This means it works with your immune system to fight disease for as long as you're taking it.

It is made up of 2 main parts:



Daratumumab (pronounced da-ra-tu-mu-mab) is the ingredient that treats multiple myeloma. It directly kills multiple myeloma cells and/or helps your immune system find and destroy them.

Daratumumab attaches itself to a protein (called CD38) on the surface of multiple myeloma cells, as well as other cell types such as red blood cells. Because of the way daratumumab works, it may also affect normal cells.



Hyaluronidase (pronounced hy-a-lur-on-i-dase) helps daratumumab to be injected into the skin and absorbed into the body.

DARZALEX® (daratumumab) and DARZALEX FASPRO® both contain the medicine daratumumab, but DARZALEX® is given as an IV infusion with a needle inserted into a vein of your arm.

IV=intravenous.

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SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:









- **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX FASPRO® if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX FASPRO®.
 - shortness of breath or trouble breathing
 - dizziness or lightheadedness (hypotension)
 - cough
 - wheezing
 - heart beating faster than usual
 - low oxygen in the blood (hypoxia)
 - throat tightness or irritation
 - runny or stuffy nose
 - headache
 - itching
 - high blood pressure
 - eye pain
 - nausea
 - vomiting
 - chills
 - fever
 - chest pain
 - blurred vision

- For newly diagnosed, transplant-eligible patients
- For newly diagnosed, transplant-ineligible patients
- For previously treated patients

WHO DARZALEX FASPRO® IS FOR



DARZALEX FASPRO® is used with other medicines, with or without a stem cell transplant or by itself, depending on your doctor's treatment plan. It's given under the skin in the stomach area by your healthcare provider. The injection takes about 3 to 5 minutes.* **Treatment options with DARZALEX FASPRO® include:**

For newly diagnosed, transplant-eligible patients	For patients who have been previously treated
<div> DARZALEX FASPRO® + VRd (bortezomib, lenalidomide, and dexamethasone) ></div>	<div> DARZALEX FASPRO® + Rd (lenalidomide and dexamethasone) ></div>
<div> DARZALEX FASPRO® + VTd (bortezomib, thalidomide, and dexamethasone) ></div>	<div> DARZALEX FASPRO® + Vd (bortezomib and dexamethasone) ></div>
	<div> DARZALEX FASPRO® + Pd (pomalidomide and dexamethasone) ></div>
	<div> DARZALEX FASPRO® + Kd (carfilzomib and dexamethasone) ></div>
<div> DARZALEX FASPRO® + VMP (bortezomib, melphalan, and prednisone) ></div>	<div> DARZALEX FASPRO® by itself (also called monotherapy) ></div>

*This refers to the injection administration time and does not account for all aspects of treatment.

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Decreases in blood cell counts.** DARZALEX FASPRO® can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX FASPRO® but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX FASPRO®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.

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DARZALEX FASPRO® vs DARZALEX®



DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) (injection under the skin) has been evaluated in a clinical trial to show that it can work as well as DARZALEX® (daratumumab) (IV version) when treating multiple myeloma. Both contain the medicine daratumumab and are given differently. In the clinical trial of 522 patients, DARZALEX FASPRO® (injection under the skin) provided comparable results with DARZALEX® (IV version) when treating for multiple myeloma. Patients who participated in this trial had been treated with at least 3 prior medicines or had not responded to a proteasome inhibitor or an immunomodulatory agent.

DARZALEX FASPRO® and DARZALEX® were shown to provide consistent results



41% of patients responded to
treatment with **DARZALEX FASPRO®**
(108 out of 263)



37% of patients responded to
treatment with **DARZALEX®**
(96 out of 259)



DARZALEX®, the IV version, has been used to treat multiple myeloma since 2015. DARZALEX FASPRO® became available in 2020. Combined, the two products have been studied in 12 clinical trials and have extensive data to support their use.

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Changes in blood tests.** DARZALEX FASPRO® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX FASPRO®.

Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO® before receiving blood transfusions.

Do not receive DARZALEX® if you have a history of a severe allergic reaction to daratumumab or any of the ingredients in DARZALEX®. See [page 55](#) for a complete list of ingredients.

Please [click here](#) to see the Product Information. Please [click here](#) to see full Important Safety Information.

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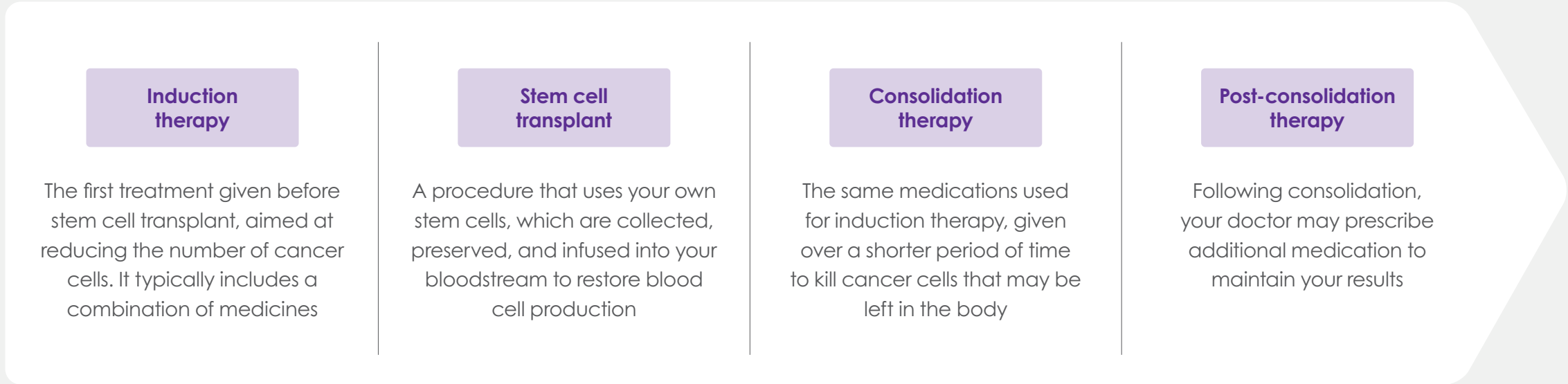
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For patients eligible for a type of transplant that uses their own stem cells, first-line therapy may include different treatment phases



SELECT IMPORTANT SAFETY INFORMATION (cont)

The most common side effects of DARZALEX FASPRO® when used in combination therapy include:

- | | | | | |
|-----------------------|-----------------|--------------------------------|--|-----------------------------------|
| • tiredness | • headache | • back pain | • cold-like symptoms (upper respiratory infection) | • lung infection (pneumonia) |
| • nausea | • rash | • vomiting | • nerve damage causing tingling, numbness, or pain | • swollen hands, ankles, or feet |
| • diarrhea | • fever | • high blood pressure | • constipation | • decreased red blood cell counts |
| • shortness of breath | • cough | • muscle, bone, and joint pain | | |
| • trouble sleeping | • muscle spasms | | | |

These are not all of the possible side effects of DARZALEX FASPRO®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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Clinical Study: DARZALEX FASPRO® + VRd

In a clinical trial, DARZALEX FASPRO® was studied in combination with bortezomib, lenalidomide, and dexamethasone (**DARZALEX FASPRO® + VRd**) in induction and consolidation, compared to treatment with VRd.

Who participated?

-  709 people
-  Newly diagnosed with multiple myeloma
-  Eligible to receive a type of stem cell transplant that uses the patient's own stem cells*

What were the goals of the study?

-  The main goal was to measure how long patients lived without their multiple myeloma getting worse
-  A second goal was to measure response to treatment using markers in blood, urine, and bone marrow

R=lenalidomide; VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).
*A doctor determined transplant eligibility for each patient.
†Treatment restarted at week 1 after recovery from stem cell transplant.

SELECT IMPORTANT SAFETY INFORMATION (cont)

The most common side effects of DARZALEX FASPRO® when used alone include cold-like symptoms (upper respiratory infection) and decreased red blood cell counts.

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What treatments were compared?

DARZALEX FASPRO® + VRd Group	VS	VRd Group
Induction therapy DARZALEX FASPRO® + VRd	Weeks 1 to 16	Induction therapy VRd
Stem cell transplant		Stem cell transplant
Consolidation therapy DARZALEX FASPRO® + VRd	Weeks 1 to 8†	Consolidation therapy VRd
Investigational post-consolidation therapy DARZALEX FASPRO® + R (DR) <i>This phase was investigational and not set up to determine the effect of DR. Therefore, treatment effectiveness post consolidation has not been proven.</i>		Post-consolidation therapy R

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Clinical Study: DARZALEX FASPRO® + VRd (cont)

In the DARZALEX FASPRO® + VRd group, more people lived progression-free*

Disease progression was 60% less likely with DARZALEX FASPRO® + VRd compared with VRd alone

85% in the DARZALEX FASPRO® + VRd group lived without their disease getting worse after 48 months[†]



compared with 67% in the VRd treatment group[†]

MRD=minimal residual disease; R=lenalidomide; VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO®.

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In people who received DARZALEX FASPRO® + VRd for induction and consolidation:

45% achieved complete response or better
(158 out of 355)

vs 35% (123 out of 354) in the VRd group

58% achieved MRD negativity
(204 out of 355)

vs 33% (115 out of 354) in the VRd group

In people who achieved complete response or better during induction and consolidation, **77% (121 out of 158) on DARZALEX FASPRO® + VRd also achieved MRD negativity**, compared with 59% (72 out of 123) treated with VRd alone

*Living progression free refers to the length of time a patient lived without having their disease getting worse, or passing away.

[†]48-month estimate based on a median follow-up of 47.5 months for the DARZALEX FASPRO® + VRd and VRd groups.

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Clinical Study: DARZALEX® + VTd

DARZALEX® (daratumumab) (IV version) and DARZALEX FASPRO® (injection under the skin) both contain the medicine daratumumab and are given differently.



In a clinical trial, DARZALEX®, the IV version, was studied in combination with bortezomib, thalidomide, and dexamethasone (DARZALEX® + VTd), in induction and consolidation, compared to treatment with VTd alone.

Who participated?

-  1085 people
-  Newly diagnosed with multiple myeloma
-  Eligible to receive a type of stem cell transplant that uses the patient's own stem cells*

*A doctor determined transplant eligibility for each patient.
VTd=bortezomib (V) + thalidomide (T) + dexamethasone (d).

What were the goals of the study?

-  The main goal was to measure stringent complete response, a deeper measure of complete response
-  A second goal was to measure how long patients lived without their multiple myeloma getting worse or passing away from any cause

Study Results

In the DARZALEX® + VTd group, 29% of patients achieved stringent complete response, compared with 20% of patients treated with VTd. Overall, 93% of patients achieved a response to DARZALEX® + VTd treatment vs 90% of patients on VTd alone.

At a median follow-up of 18.8 months, 92% (498 of 543) of patients lived without their disease getting worse with DARZALEX® + VTd compared with 83% (451 of 542) in the VTd group.

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Injection site reactions.** Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX FASPRO®. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection of DARZALEX FASPRO®.

DARZALEX® may cause serious reactions, including:

- **Infusion-related reactions.** Infusion-related reactions are common with DARZALEX®. Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX®. Your healthcare provider may temporarily stop your infusion or completely stop treatment with DARZALEX® if you have infusion-related reactions. Get medical help right away if you get any of the following symptoms: shortness of breath or trouble breathing, dizziness or lightheadedness (hypotension), cough, wheezing, heart beating faster than usual, low oxygen in the blood (hypoxia), throat tightness or irritation, runny or stuffy nose, headache, itching, high blood pressure, eye pain, nausea, vomiting, chills, fever, chest discomfort, or blurred vision

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Clinical Study: DARZALEX[®] + Rd

DARZALEX[®] (daratumumab) (IV version) and DARZALEX FASPRO[®] (injection under the skin) both contain the medicine daratumumab and are given differently.

DARZALEX[®], the IV version, was studied in combination with lenalidomide and dexamethasone (DARZALEX FASPRO[®] + Rd), compared with Rd alone.

Your treatment goals may be similar to results shown in clinical studies. Here's a look at what other patients were able to achieve with ongoing DARZALEX[®] treatment.

Who participated?



737 people



Newly diagnosed with multiple myeloma



Not eligible to receive a type of stem cell transplant that uses the patients own stem cells

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO[®] may cause serious reactions, including:

• **Decreases in blood cell counts.** DARZALEX FASPRO[®] can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX FASPRO[®] but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX FASPRO[®]. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.

DARZALEX[®] may cause serious reactions, including:

• **Changes in blood tests.** DARZALEX[®] can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX[®]. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX[®]. **Tell all of your healthcare providers that you are being treated with DARZALEX[®] before receiving blood transfusions**

Please [click here](#) to see the Product Information. Please [click here](#) to see full Important Safety Information.

What were the goals of the study?



The main goal was to measure how long patients lived without their multiple myeloma getting worse



A second goal was to measure response to treatment using markers in blood, urine, and bone marrow



The study was continued to see the ongoing results of DARZALEX[®] + Rd over time.

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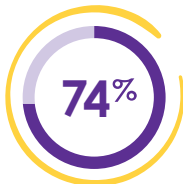
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Clinical Study: DARZALEX® + Rd (cont)

DARZALEX® (daratumumab) + Rd helped more patients live without their disease getting worse compared with Rd alone

At a median follow-up of 28 months:



More patients lived progression free*

74% of patients (271 of 368) in the DARZALEX® + Rd group lived without their disease getting worse, compared with 61% (226 of 369) in the Rd group



More patients responded to treatment

93% of patients (342 of 368) responded to DARZALEX® + Rd compared with 81% (300 of 369) treated with Rd alone

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

*Living progression free refers to the length of time a patient lived without having their disease getting worse, or passing away.

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

• **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX FASPRO® if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX FASPRO®.

- | | | | | | |
|--|------------|-------------------------------------|------------------------|------------|------------------|
| ◦ shortness of breath or trouble breathing | ◦ cough | ◦ low oxygen in the blood (hypoxia) | ◦ runny or stuffy nose | ◦ eye pain | ◦ fever |
| ◦ dizziness or lightheadedness (hypotension) | ◦ wheezing | ◦ heart beating faster than usual | ◦ headache | ◦ nausea | ◦ chest pain |
| | | ◦ throat tightness or irritation | ◦ itching | ◦ vomiting | ◦ blurred vision |
| | | | ◦ high blood pressure | ◦ chills | |

The most common side effects of DARZALEX® include cold-like symptoms (upper respiratory infection); diarrhea; constipation; decreased red blood cells; nerve damage causing tingling, numbness, or pain; tiredness; swollen hands, ankles, or feet; nausea; cough; fever; shortness of breath; feeling weak. These are not all the possible side effects of DARZALEX®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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Clinical Study: DARZALEX FASPRO® + VMP

In a clinical trial, DARZALEX FASPRO® was studied in combination with bortezomib, melphalan, and prednisone (DARZALEX FASPRO® + VMP).

Who participated?

-  67 people
-  Newly diagnosed with multiple myeloma
-  Not eligible to receive a type of stem cell transplant that uses the patient's own stem cells

What was the goal of the study?

-  The main goal to measure the overall response rate, which is the percentage of patients who responded to treatment

Study Results



At a median follow-up of 6.9 months, 88% (about 9 out of 10) patients responded to treatment with DARZALEX FASPRO® in combination with VMP

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Changes in blood tests.** DARZALEX FASPRO® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX FASPRO®. **Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO® before receiving blood transfusions.**

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Clinical Study: DARZALEX® + VMP



DARZALEX® (daratumumab) (IV version) and DARZALEX FASPRO® (injection under the skin) both contain the medicine daratumumab and are given differently.

In a clinical trial, DARZALEX®, the IV version, was studied in combination with bortezomib, melphalan, and prednisone (DARZALEX® + VMP) compared to treatment with VMP alone.

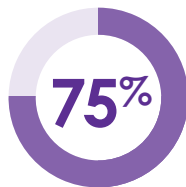
Who participated?

-  706 people
-  Newly diagnosed with multiple myeloma
-  Not eligible to receive a type of stem cell transplant that uses the patient's own stem cells

What were the goals of the study?

-  The main goal was to measure how long patients lived without their multiple myeloma getting worse or passing away from any cause
-  A second goal was to measure the overall response rate, which is the percentage of patients who responded to treatment

Study Results



DARZALEX® + VMP increased the time patients lived without their multiple myeloma getting worse.

At a median follow-up of 16.5 months, 75% of patients (262 of 350) lived without their disease getting worse with DARZALEX® + VMP vs 60% (213 of 356) with VMP alone.

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

The most common side effects of DARZALEX FASPRO® when used alone include cold-like symptoms (upper respiratory infection) and decreased red blood cell counts.

DARZALEX® may cause serious reactions, including:

- **Decreases in blood cell counts.** DARZALEX® can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX® but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding

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Clinical Study: DARZALEX FASPRO® + Rd

In a clinical trial, DARZALEX FASPRO® was studied in combination with lenalidomide and dexamethasone (DARZALEX FASPRO® + Rd).

Who participated?



65 people with relapsed or refractory multiple myeloma



Previously treated with at least 1 medicine for multiple myeloma

What was the goal of the study?



The main goal was to measure the overall response rate, which is the percentage of patients who responded to treatment

Study Results



91% (about 9 out of 10) patients responded to treatment with DARZALEX FASPRO® in combination with Rd

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

Do not receive DARZALEX FASPRO® if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO®. See [page 52](#) for a complete list of ingredients in DARZALEX FASPRO®.

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Clinical Study: DARZALEX® + Rd

DARZALEX® (daratumumab) (IV version) and DARZALEX FASPRO® (injection under the skin) both contain the medicine daratumumab and are given differently.

In a clinical trial, DARZALEX®, the IV version, was studied in combination with lenalidomide and dexamethasone (DARZALEX® + Rd) compared to treatment with Rd alone.

Who participated?



569 people



Previously treated with at least 1 medicine for multiple myeloma

What were the goals of the study?

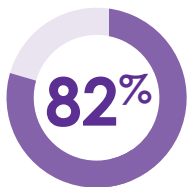


The main goal was to measure how long patients lived without their multiple myeloma getting worse or passing away from any cause



A second goal was to measure the overall response rate, which is the percentage of patients who responded to treatment

Study Results



DARZALEX® + Rd increased the time patients lived without their multiple myeloma getting worse.

At a median follow-up of 13.5 months, 82% of patients (233 of 286) in the DARZALEX® + Rd group lived without their disease getting worse vs 59% (167 of 283) in the Rd group.

About 9 of 10 patients responded to DARZALEX® + Rd compared with about 7 of 10 patients treated with Rd alone.

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

Before you receive DARZALEX FASPRO®, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of breathing problems
- have had shingles (herpes zoster)

Do not receive DARZALEX® if you have a history of a severe allergic reaction to daratumumab or any of the ingredients in DARZALEX®. See [page 55](#) for a complete list of ingredients.

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Clinical Study: DARZALEX FASPRO® + Pd

In a clinical trial, DARZALEX FASPRO® was studied in combination with pomalidomide + dexamethasone (DARZALEX FASPRO® + Pd) compared with Pd alone.

Who participated?



304 people with relapsed or refractory multiple myeloma



Previously treated with at least 1 medicine for multiple myeloma



Previously treated with lenalidomide and a proteasome inhibitor

What was the goal of the study?



The main goal was to measure how long patients lived without their multiple myeloma getting worse or passing away from any cause

Study Results



DARZALEX FASPRO® + Pd increased the time patients lived without their multiple myeloma getting worse.

At a follow-up of 18 months, 44% (67 of 151) of patients in the DARZALEX FASPRO® + Pd group lived without having their disease get worse vs 31% (47 of 153) in the Pd group.

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

Before you receive DARZALEX FASPRO®, tell your healthcare provider about all of your medical conditions, including if you:

- have ever had or might now have a hepatitis B infection as DARZALEX FASPRO® could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX FASPRO®. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.

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Clinical Study: DARZALEX® + Pd

DARZALEX® (daratumumab) (IV version) and DARZALEX FASPRO® (injection under the skin) both contain the medicine daratumumab and are given differently.
In a clinical trial, DARZALEX®, the IV version, was studied in combination with pomalidomide and dexamethasone (DARZALEX® + Pd).


Who participated?

-  103 people
-  Previously treated with a proteasome inhibitor (PI) and an immunomodulatory agent

Patients in this study had received a median of 4 prior lines of therapy for multiple myeloma

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

What was the goal of the study?

-  The main goal of this study was to measure the overall response rate, which is the percentage of patients who responded to treatment

Study Results



DARZALEX® + Pd showed an overall response rate in more than half of the patients.

At a median follow-up of 13.6 months, nearly 60% of patients responded to the DARZALEX® + Pd regimen.

SELECT IMPORTANT SAFETY INFORMATION (cont)

Before you receive DARZALEX FASPRO®, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. DARZALEX FASPRO® may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX FASPRO®.

DARZALEX® may cause serious reactions, including:

- **Infusion-related reactions.** Infusion-related reactions are common with DARZALEX®. Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX®. Your healthcare provider may temporarily stop your infusion or completely stop treatment with DARZALEX® if you have infusion-related reactions. Get medical help right away if you get any of the following symptoms: shortness of breath or trouble breathing, dizziness or lightheadedness (hypotension), cough, wheezing, heart beating faster than usual, low oxygen in the blood (hypoxia), throat tightness or irritation, runny or stuffy nose, headache, itching, high blood pressure, eye pain, nausea, vomiting, chills, fever, chest discomfort, or blurred vision

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Clinical Study: DARZALEX FASPRO® + Kd

In a clinical trial, DARZALEX FASPRO® was studied in combination with carfilzomib + dexamethasone (DARZALEX FASPRO® + Kd).

Who participated?



66 people



Previously treated with at least 1 medicine for multiple myeloma



Previously treated with lenalidomide and a proteasome inhibitor

What was the goal of the study?



The main goal was to measure how long patients lived without their multiple myeloma getting worse or passing away from any cause

Study Results



84% (about 8 out of 10) patients responded to treatment with DARZALEX FASPRO® in combination with Kd

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

Before you receive DARZALEX FASPRO®, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. DARZALEX FASPRO® may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX FASPRO®.
 - Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX FASPRO®. Talk to your healthcare provider about birth control methods that you can use during this time.
 - Before starting DARZALEX FASPRO® in combination with lenalidomide, thalidomide, or pomalidomide, females and males must agree to the instructions in the lenalidomide, thalidomide, or pomalidomide REMS program.
 - The lenalidomide, thalidomide, and pomalidomide REMS have more information about effective methods of birth control, pregnancy testing, and blood donation for females who can become pregnant.
 - For males who have female partners who can become pregnant, there is information in the lenalidomide, thalidomide, and pomalidomide REMS about sperm donation and how lenalidomide, thalidomide, and pomalidomide can pass into human semen.

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Clinical Study: DARZALEX® + Kd

DARZALEX® (daratumumab) (IV version) and DARZALEX FASPRO® (injection under the skin) both contain the medicine daratumumab and are given differently.

In a clinical trial, DARZALEX®, the IV version, was studied in combination with carfilzomib and dexamethasone (DARZALEX® + Kd) compared to treatment with Kd alone.

Who participated?



466 people



Previously treated with at least 1 medicine for multiple myeloma

What were the goals of the study?

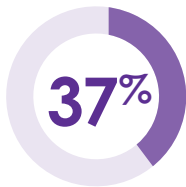


The main goal was to measure how long patients lived without their multiple myeloma getting worse or passing away from any cause



A second goal was to measure the overall response rate, which is the percentage of patients who responded to treatment

Study Results



DARZALEX® + Kd increased the time patients lived without their multiple myeloma getting worse.

Patients in the DARZALEX® + Kd group experienced a 37% reduction in the risk of their disease getting worse vs patients treated with Kd alone.

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

Before you receive DARZALEX FASPRO®, tell your healthcare provider about all of your medical conditions, including if you:

- are breastfeeding or plan to breastfeed. It is not known if DARZALEX FASPRO® passes into your breast milk. You should not breastfeed during treatment with DARZALEX FASPRO®. Talk to your healthcare provider about the best way to feed your baby during treatment with DARZALEX FASPRO®.

DARZALEX® may cause serious reactions, including:

- **Changes in blood tests.** DARZALEX® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX®. **Tell all of your healthcare providers that you are being treated with DARZALEX® before receiving blood transfusions**

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Clinical Study: DARZALEX® + Vd

DARZALEX® (daratumumab) (IV version) and DARZALEX FASPRO® (injection under the skin) both contain the medicine daratumumab and are given differently.

In a clinical trial, DARZALEX®, the IV version, was studied in combination with bortezomib and dexamethasone (DARZALEX® + Vd) compared to treatment with Vd alone.

Who participated?



498 people



Previously treated with at least 1 medicine for multiple myeloma

What were the goals of the study?

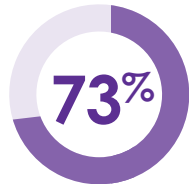


The main goal was to measure how long patients lived without their multiple myeloma getting worse or passing away from any cause



A second goal was to measure the overall response rate, which is the percentage of patients who responded to treatment

Study Results



DARZALEX® + Vd increased the time patients lived without their multiple myeloma getting worse.

At a median follow-up of 7.4 months, 73% (184 out of 251) of patients in the DARZALEX® + Vd group lived without having their disease get worse or passing away vs 51% (125 of 247) in the Vd group.

Vd= bortezomib (V) + dexamethasone (d).

SELECT IMPORTANT SAFETY INFORMATION (cont)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

DARZALEX® may cause serious reactions, including:

- **Decreases in blood cell counts.** DARZALEX® can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX® but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding

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Clinical Study: DARZALEX® monotherapy

DARZALEX® (daratumumab) (IV version) and DARZALEX FASPRO® (injection under the skin) both contain the medicine daratumumab and are given differently.



In this clinical trial, DARZALEX®, the IV version, was studied as a monotherapy (by itself).

Who participated?

-  106 people
-  Previously treated with at least 3 medicines for multiple myeloma
-  Previously treated with or did not respond to a proteasome inhibitor and an immunomodulatory agent

Patients in this study had received a median of 5 prior lines of therapy for multiple myeloma

What were the goals of the study?

-  The main goal was to measure the overall response rate, which is the percentage of patients who responded to treatment
-  A second goal was to measure the overall response rate, which is the percentage of patients who responded to treatment

Study Results



In this group, 29% of patients responded to treatment with DARZALEX®, with the average length of response lasting 7.4 months.

SELECT IMPORTANT SAFETY INFORMATION (cont)

Do not receive DARZALEX FASPRO® if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO®. See [page 52](#) for a complete list of ingredients in DARZALEX FASPRO®.

The most common side effects of DARZALEX® include cold-like symptoms (upper respiratory infection); diarrhea; constipation; decreased red blood cells; nerve damage causing tingling, numbness, or pain; tiredness; swollen hands, ankles, or feet; nausea; cough; fever; shortness of breath; feeling weak. These are not all the possible side effects of DARZALEX®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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PREPARING FOR TREATMENT

Understanding your dosing schedule and what to expect before, during, and after each injection can help you keep your DARZALEX FASPRO[®] treatment journey on track.



Key highlights in this chapter:

-  When you first start treatment, you will need to take DARZALEX FASPRO[®] every week. However, over time DARZALEX FASPRO[®] is needed less often
[Learn more](#)
-  It's important to tell your doctor if you have a history of a severe allergic reaction to any of the ingredients in DARZALEX FASPRO[®], or any existing medical conditions
[Learn more](#)
-  DARZALEX FASPRO[®] is given by your healthcare provider under the skin in the stomach area in about 3 to 5 minutes*
[Learn more](#)

-  Pay attention to how you feel and let the healthcare staff know about any discomfort during or after treatment, and especially during the first and second injections
[Learn more](#)
-  It's important to understand the side effects you may experience from treatment with DARZALEX FASPRO[®].
[Learn more](#)
-  In a clinical study, nearly 3X fewer patients experienced injection reactions (systemic) on DARZALEX FASPRO[®] vs DARZALEX[®] (daratumumab)
 - 13% of patients who received DARZALEX FASPRO[®] experienced injection reactions, compared with 34% who received DARZALEX[®][Learn more](#)

*This refers to the injection administration time and does not account for all aspects of treatment.

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HOW OFTEN TREATMENT IS GIVEN



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When you first start treatment, you will need to take DARZALEX FASPRO® every week. However, over time DARZALEX FASPRO® is needed less often. Knowing how and when DARZALEX FASPRO® is given can help you prepare for and keep track of treatment.

Treatment Combination	Weeks	Schedule
DARZALEX FASPRO® + Rd (lenalidomide and dexamethasone) DARZALEX FASPRO® + Pd (pomalidomide and dexamethasone) DARZALEX FASPRO® + Kd (carfilzomib and dexamethasone) DARZALEX FASPRO® monotherapy (by itself)	1–8	Weekly (total of 8 doses)
	9–24	Every 2 weeks (total of 8 doses)
	25 onward until disease progression	Every 4 weeks
DARZALEX FASPRO® + VMP (bortezomib, melphalan, and prednisone)	1–6	Weekly (total of 6 doses)
	7–54	Every 3 weeks (total of 16 doses)
	55 onward until disease progression	Every 4 weeks
DARZALEX FASPRO® + Vd (bortezomib and dexamethasone)	1–9	Weekly (total of 9 doses)
	10–24	Every 3 weeks (total of 5 doses)
	25 onward until disease progression	Every 4 weeks
DARZALEX FASPRO® + VTd (bortezomib, thalidomide, and dexamethasone) DARZALEX FASPRO® + VRd (bortezomib, lenalidomide, and dexamethasone)	Induction	Induction
	1–8	Weekly (total of 8 doses)
	9–16	Every 2 weeks (total of 4 doses)
	Stop for high-dose chemotherapy and ASCT	
	Consolidation	Consolidation
	1–8	Every 2 weeks (total of 4 doses)

Dosing schedule does not apply to other medicines in the combination regimen.

- DARZALEX FASPRO® is injected over 3 to 5 minutes.
- Your healthcare provider will decide the time between doses as well as how many treatments you will receive.
- Your healthcare provider will give you medicines before each dose of DARZALEX FASPRO® and after each dose of DARZALEX FASPRO® to help reduce the risk of serious allergic reactions and other reactions due to release of certain substances by your body (systemic).

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

Please [click here](#) to see the Product Information. Please [click here](#) to see full Important Safety Information.

WHAT TO DISCUSS WITH YOUR DOCTOR BEFORE TREATMENT



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Before an injection

Tell your healthcare provider if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO[®].

Do not receive DARZALEX FASPRO[®] if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO[®]. See [page 52](#) for a complete list of ingredients in DARZALEX FASPRO[®].

Tell your doctor about all of your medical conditions, including if you:

- have a history of breathing problems
- have had shingles (herpes zoster)
- have ever had or might now have a hepatitis B infection as DARZALEX FASPRO[®] could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX FASPRO[®]. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.
- are pregnant or plan to become pregnant. DARZALEX FASPRO[®] may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX FASPRO[®].
 - Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX FASPRO[®]. Talk to your healthcare provider about birth control methods that you can use during this time.
 - Before starting DARZALEX FASPRO[®] in combination with lenalidomide, thalidomide, or pomalidomide, females and males must agree to the instructions in the lenalidomide, thalidomide, or pomalidomide REMS program.
 - The lenalidomide, thalidomide, and pomalidomide REMS have more information about effective methods of birth control, pregnancy testing, and blood donation for females who can become pregnant.
 - For males who have female partners who can become pregnant, there is information in the lenalidomide, thalidomide, and pomalidomide REMS about sperm donation and how lenalidomide, thalidomide, and pomalidomide can pass into human semen.
 - are breastfeeding or plan to breastfeed. It is not known if DARZALEX FASPRO[®] passes into your breast milk. You should not breastfeed during treatment with DARZALEX FASPRO[®]. Talk to your healthcare provider about the best way to feed your baby during treatment with DARZALEX FASPRO[®].

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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 **Dress for comfort.**
Wear clothing that is loose around the waist.
DARZALEX FASPRO® is injected about 3 inches to the left or right of the belly button

 You may be given a quick physical exam before the injection. This includes **checking your pulse and blood pressure**

 **Set aside enough time:**

- To ask questions and discuss treatment goals
- To receive pre-medications and lab work if needed
- For your healthcare provider to monitor for a reaction to the injection, particularly for the first few injections that you receive

 **You will be given medicines to help reduce the risk of side effects to the injection, such as:**

- Antihistamines to prevent an allergic reaction
- Corticosteroids to prevent inflammation
- Acetaminophen or similar medicine to reduce fever

 **You will need to inform your healthcare providers and blood transfusion centers/personnel that you are taking DARZALEX FASPRO®.**

DARZALEX FASPRO® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO®. Your healthcare provider will help you with this and do blood tests to match your blood type before you start treatment with DARZALEX FASPRO®. Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO® before receiving blood transfusions if you need one.

SELECT IMPORTANT SAFETY INFORMATION (cont)

How will I receive DARZALEX FASPRO®?

- DARZALEX FASPRO® may be given alone or together with other medicines used to treat multiple myeloma.
- DARZALEX FASPRO® will be given to you by your healthcare provider as an injection under the skin in the stomach area (abdomen).
- DARZALEX FASPRO® is injected over 3 to 5 minutes.
- Your healthcare provider will decide the time between doses as well as how many treatments you will receive.

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WHAT TO EXPECT DURING TREATMENT

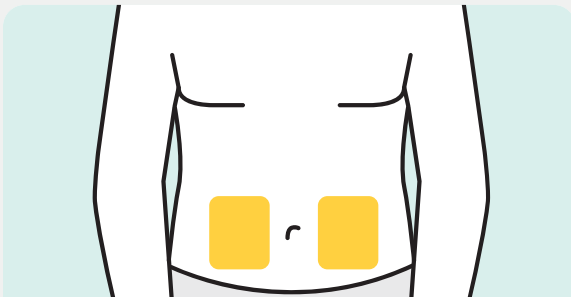


Before you start treatment with DARZALEX FASPRO®, it's important to talk with your doctor about what to expect.

During the injection



Your healthcare provider will prepare the syringe



An injection site on your stomach will be chosen and prepared

Injection sites in the stomach area will be rotated each time you receive treatment



The injection will be completed in about 3 to 5 minutes*

*This refers to the injection administration time and does not account for all aspects of treatment.

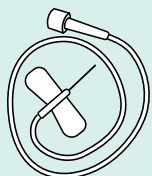
During your injection, your healthcare provider may use an injection needle or a winged infusion set.

injection
needle



OR

winged
infusion
set



SELECT IMPORTANT SAFETY INFORMATION (cont)

How will I receive DARZALEX FASPRO®?

- Your healthcare provider will give you medicines before each dose of DARZALEX FASPRO® and after each dose of DARZALEX FASPRO® to help reduce the risk of serious allergic reactions and other reactions due to release of certain substances by your body (systemic).

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After the injection



Pay attention to how you feel and tell your care team about any discomfort during or after treatment, and especially during the first and second injections. It could mean you may be having a reaction to the treatment. **Your healthcare provider may want you to remain in the office to watch for any side effects.**

Serious allergic reactions and other severe injection-related reactions

Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX FASPRO® if you have a serious reaction.

Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX FASPRO®:

- | | | |
|--|-------------------------------------|------------------|
| • shortness of breath or trouble breathing | • low oxygen in the blood (hypoxia) | • eye pain |
| • dizziness or lightheadedness (hypotension) | • throat tightness or irritation | • nausea |
| • cough | • runny or stuffy nose | • vomiting |
| • wheezing | • headache | • chills |
| • heart beating faster than usual | • itching | • fever |
| | • high blood pressure | • chest pain |
| | | • blurred vision |

Please [click here](#) to see the Product Information. Please [click here](#) to see full Important Safety Information.

In studies, injection-related reactions decreased over time



- 7% had a reaction with the first injection
- 0.2% had a reaction with the second injection
- 1% had a reaction with the following injections combined

Injection site reactions

Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX FASPRO®. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection of DARZALEX FASPRO®.

Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX FASPRO®



In clinical studies, 7% of patients had an injection-site reaction with DARZALEX FASPRO®. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin.

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UNDERSTANDING THE POSSIBLE SIDE EFFECTS OF DARZALEX FASPRO®



Decreased blood cell counts and changes in blood tests

Your doctor will do blood tests to check your blood cell count and match your blood type before treatment. DARZALEX FASPRO® can:

- Decrease white blood cell counts (help fight infections) and blood cells called platelets (help clot blood). Decreases are common with DARZALEX FASPRO® but can be severe. Tell your doctor if you get a fever or develop signs of bruising or bleeding
- Affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO®.
Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO® before receiving blood transfusions

Post medication: After your injection, you may also be given oral corticosteroids to reduce the risk of delayed reactions to DARZALEX FASPRO®.

Side effects

Do not receive DARZALEX FASPRO® if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO®.

You may experience side effects from treatment. Side effects are an unwanted or unexpected reaction to a drug that can occur anywhere in your body.

Not everyone responds to treatment the same. Talk to your care team about any side effects that are bothersome or do not go away.

The most common side effects of DARZALEX FASPRO® when used alone are:

- cold-like symptoms (upper respiratory infection)
- decreased red blood cell counts

The most common side effects of DARZALEX FASPRO® when used in combination with other therapies include:

- | | | |
|-----------------------|--|-----------------------------------|
| • tiredness | • muscle spasms | • constipation |
| • nausea | • back pain | • lung infection (pneumonia) |
| • diarrhea | • vomiting | • swollen hands, ankles, or feet |
| • shortness of breath | • high blood pressure | • decreased red blood cell counts |
| • trouble sleeping | • muscle, bone, and joint pain | |
| • headache | • cold-like symptoms (upper respiratory infection) | |
| • rash | • nerve damage causing tingling, numbness, or pain | |
| • fever | | |
| • cough | | |

These are not all the possible side effects of DARZALEX FASPRO®. Speak with your doctor about the side effects that you may experience with DARZALEX FASPRO®.

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Fewer patients experienced injection-related reactions with DARZALEX FASPRO®



In a clinical study that compared DARZALEX FASPRO® (monotherapy) to the IV formulation of DARZALEX® (daratumumab) (monotherapy), **13% of the 260 patients** who received DARZALEX FASPRO® experienced injection reactions (systemic), which is **nearly 3 times fewer** compared with **34% of the 258 patients** who received the IV formulation of DARZALEX®.

Some patients may have skin reactions at or near the injection site (local). Among all patients who participated in DARZALEX FASPRO® clinical studies, 7% had local injection-site reactions with injection site redness (erythema) being the most frequent.

You should inform your healthcare provider if you have any side effects during treatment that are bothersome or that do not go away. Open communication with your healthcare team is always encouraged.



Please note: These are not all the possible side effects of DARZALEX FASPRO®. Speak with your doctor about the side effects that you may experience with DARZALEX FASPRO®.

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Injection site reactions.** Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX FASPRO®. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection of DARZALEX FASPRO®.

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THE POWER OF TEAMWORK


It's important to remember that you are not alone on this journey.
Having the right support can help you stick to your treatment plan
and reach your goals.




Key highlights in this chapter:

 We're in this together. That includes you, your loved ones,
the multiple myeloma community, your care team, and
Johnson & Johnson

[Learn more](#)

 There are many tools and resources available to help you and
your care partner continue on your treatment journey

[Learn more](#)

 We're all working together to help you stay on treatment
and meet your goals

[Learn more](#)

WORKING TOGETHER TO MAKE THE MOST OF YOUR TREATMENT



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You have support solutions all around you throughout your treatment journey



Understanding your disease and learning more about DARZALEX FASPRO®

Finding health and wellness resources for living with cancer

Sharing lifestyle and coping skills to help you manage stress

Scheduling key milestones throughout your treatment journey

The support and resources provided by DARZALEX withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

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TREATMENT IS A SHARED DECISION



When it's time to talk about treatment, you should have an active role in choosing what's right for you. Your doctor and care team are here to work with you and give guidance.

What should you consider when choosing a treatment?

There are many treatment options available for multiple myeloma. Because the treatment will affect you and your family, there are a few things to consider.

Factors to consider:

 How well does this treatment work?

 What are the side effects?

 How is a dose given?

 How long should I expect to be on this treatment?

 What can I expect during and after treatment?

How can my care partner help?



Your care partner can be very helpful during your appointments. They can help make sure no important details get missed so you have the information you need to start and stay on treatment.



Together with your doctor, you and your care partner can choose which treatment is right for you.

Additional support resources available online at www.darzalex.com/faspro

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Considerations for transitioning your care



Transitioning care is when a patient moves from one center to another.

There are many reasons why you may need to go to another center to receive your care. Staying organized and keeping in touch with your new healthcare team can help make your transition smoother.

If you transition to a new treatment center:



Be sure to ask your current care team to write down your treatment plan prior to any transition to prevent confusion between your care teams



Ask your current treatment center how you can get a digital or physical copy of your health records to share with your new care team



Work with your current center to schedule an appointment with your new doctor right away



Talk to your care team and insurance provider about any possible change in costs

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FAQs ABOUT TREATMENT WITH DARZALEX FASPRO®



It's okay to speak up if you have questions. We can help you learn from the experiences of others who have had this treatment. Here are some common questions patients have had:

Q What is DARZALEX FASPRO®?

A DARZALEX FASPRO® is a prescription medicine that is used to treat adults with multiple myeloma. You may receive DARZALEX FASPRO® by itself or in combination with other multiple myeloma treatments, depending on the number of prior treatments you've received, or if you're newly diagnosed and eligible or ineligible for a transplant.

[Discover how DARZALEX FASPRO® treats multiple myeloma](#)

Q How has DARZALEX FASPRO® been studied?

A DARZALEX FASPRO® was studied as a combination therapy with other medicines and as a monotherapy (by itself). You can find information about each of the studies by clicking on the link below.

[See the results from clinical studies](#)

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO® may cause serious reactions, including:

- **Decreases in blood cell counts.** DARZALEX FASPRO® can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX FASPRO® but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX FASPRO®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.

Please [click here](#) to see the Product Information. Please [click here](#) to see full Important Safety Information.

Q How are DARZALEX FASPRO® treatments given?

A DARZALEX FASPRO® is given in about 3 to 5 minutes as an injection in the stomach area. Note: This does not account for all aspects of treatment. The dosing schedule of DARZALEX FASPRO® depends upon the treatment combination prescribed.

[Learn about the different aspects of treatment](#)

Q What can I expect when I get a DARZALEX FASPRO® treatment?

A You will be given a quick physical exam before the injection, including checking your pulse and blood pressure. You will also be given medicines to help reduce the risk of side effects and injection-related reactions. A healthcare professional will monitor you after your first few injections.

[Learn how to prepare for the injection](#)

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Q What are the possible side effects of DARZALEX FASPRO®?

A DARZALEX FASPRO® may cause serious reactions, including:

- Serious allergic reactions and other severe injection-related reactions. Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX FASPRO® if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX FASPRO®.
 - shortness of breath or trouble breathing
 - low oxygen in the blood (hypoxia)
 - eye pain
 - dizziness or lightheadedness (hypotension)
 - throat tightness or irritation
 - nausea
 - cough
 - runny or stuffy nose
 - vomiting
 - wheezing
 - headache
 - chills
 - heart beating faster than usual
 - itching
 - fever
 - high blood pressure
 - chest pain
 - blurred vision

- **Injection site reactions.** Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX FASPRO®. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection of DARZALEX FASPRO®.
- **Decreases in blood cell counts.** DARZALEX FASPRO® can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX FASPRO® but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX FASPRO®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.
- **Changes in blood tests.** DARZALEX FASPRO® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX FASPRO®. Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO® before receiving blood transfusions.



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FAQs ABOUT TREATMENT WITH DARZALEX FASPRO®



Q What are the possible side effects of DARZALEX FASPRO®? (cont)

A The most common side effects of DARZALEX FASPRO® when used alone include cold-like symptoms (upper respiratory infection) and decreased red blood cell counts.

The most common side effects of DARZALEX FASPRO® used in combination therapy include:

- | | | | |
|-----------------------|-----------------|--|-----------------------------------|
| • tiredness | • rash | • high blood pressure | • constipation |
| • nausea | • fever | • muscle, bone, and joint pain | • lung infection (pneumonia) |
| • diarrhea | • cough | • cold-like symptoms (upper respiratory infection) | • swollen hands, ankles, or feet |
| • shortness of breath | • muscle spasms | • nerve damage causing tingling, numbness, or pain | • decreased red blood cell counts |
| • trouble sleeping | • back pain | | |
| • headache | • vomiting | | |

[Learn about the side effects of DARZALEX FASPRO®](#)

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FAQs ABOUT TREATMENT WITH DARZALEX FASPRO[®]



Q What's the difference in administration between DARZALEX FASPRO[®] and DARZALEX[®] (daratumumab)?

A DARZALEX FASPRO[®] is a subcutaneous injection that takes about 3 to 5 minutes. DARZALEX[®] is an infusion, given through a needle placed in a vein by a healthcare professional. On average, the first infusion can take 7 hours, 4 hours for the second infusion, and 3 hours for subsequent infusions (median).

[Learn how DARZALEX[®] is given](#)

Q What's the difference between how well DARZALEX FASPRO[®] and DARZALEX[®] work?

A A study confirmed that DARZALEX FASPRO[®] gave patients results comparable to the IV formulation of DARZALEX[®] in treating multiple myeloma when used as monotherapy (by itself). You can see details of this study by clicking on the link below.

[See the results from clinical studies](#)

IV=intravenous.

SELECT IMPORTANT SAFETY INFORMATION (cont)

DARZALEX FASPRO[®] may cause serious reactions, including:

- **Changes in blood tests.** DARZALEX FASPRO[®] can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO[®]. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX FASPRO[®]. **Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO[®] before receiving blood transfusions.**

Please [click here](#) to see the Product Information. Please [click here](#) to see full Important Safety Information.

Q Are there support programs that can help me with my DARZALEX FASPRO[®] treatment?

A Once you and your doctor have decided that DARZALEX FASPRO[®] is right for you, a DARZALEX withMe Care Navigator will help you find the resources you may need to get started and stay on track. Care Navigators can give you information on insurance coverage and treatment support, and identify options that may help make your treatment more affordable.

[Request your first call and learn more about how DARZALEX withMe can be there for you](#)

Q What resources are available to help make my treatment with DARZALEX FASPRO[®] more affordable?

A A DARZALEX withMe Care Navigator can identify cost support options that may help with managing your out-of-pocket medication costs—whether you have commercial or private health insurance, government coverage such as Medicare or Medicaid, or have no insurance coverage.

[Find a program for your needs at MyJanssenCarePath.com](#)

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SUPPORT RESOURCES

Once you and your doctor have decided that DARZALEX FASPRO® is right for you, sign up for DARZALEX withMe support

DARZALEX withMe

Personalized 1-on-1 Support

You have access to free, dedicated support. Your Care Navigator is here to help guide you to support solutions throughout your treatment journey.

The support and resources provided by DARZALEX withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

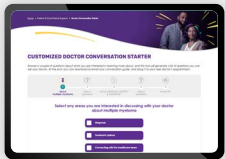
Are you prescribed
DARZALEX FASPRO®?

Sign up for personalized support throughout your treatment journey now

Sign up for support
or call 833-565-9631,
Monday through Friday,
8:00 AM–8:00 PM ET.

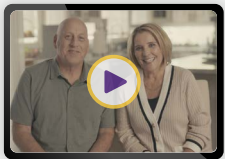
Additional resources available online

If you're looking for more information about DARZALEX FASPRO®, visit www.darzalex.com/faspro for useful tools and materials to help you on your treatment journey:



Doctor Conversation Starter

Create a list of questions based on your needs and interests to bring to your next doctor's appointment



Real Stories From Real Patients

Watch other patients share their treatment experience with DARZALEX FASPRO®



Treatment Calendar

Keep track of your dosing schedule and plan with your doctor for your next visit



What to Expect Guide

Understand what will happen before, during, and after treatment with DARZALEX FASPRO®

Please [click here](#) to see the Product Information. Please [click here](#) to see full Important Safety Information.

SUPPORT RESOURCES

Multiple myeloma education and support groups

Living with multiple myeloma, and caring for someone who has it, requires physical and emotional support. Here is a short list of independent organizations that provide education and support groups that may be able to help. For additional organizations not listed here, use the [Johnson & Johnson Advocacy Connector](#).

Johnson & Johnson is not responsible for the content of these resources.

American Cancer Society

The American Cancer Society offers information, day-to-day help, and emotional support to cancer patients as well as their family and friends. From free lodging and transportation to help making decisions about your care, they offer programs, services, and resources that can help you on your journey.

CancerCare[®]

CancerCare.org offers patients and care partners counseling, support groups, educational workshops, publications, financial assistance, and community programs.

Cancer Support Community

Cancer Support Community offers social and emotional support for people impacted by cancer, as well as a community of support available online and over the phone.

International Myeloma Foundation

The International Myeloma Foundation provides information online and by phone. They offer patient and care partner education materials, and conduct patient and family seminars, and regional community workshops. They can also help you find support groups.

Leukemia and Lymphoma Society

The Leukemia and Lymphoma Society offers information specialists, peer-to-peer support, and online chats for both patients and care partners. They also produce the “Bloodline with LLS” podcast for cancer survivors, and offer financial guidance and support.

Multiple Myeloma Research Foundation (MMRF)

The Multiple Myeloma Research Foundation offers patient education programs and a nurse support line. They can also help you find a treatment center, clinical trials, support groups, and financial assistance programs.

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SUPPORT RESOURCES

Multiple myeloma education and support groups (cont)

Myeloma Beacon

The Myeloma Beacon provides news, resources, and online forums for patients, medical professionals, and others interested in multiple myeloma.

Myeloma Crowd

The Myeloma Crowd aggregates and shares the latest research and provides social media groups where patients can exchange information. They also host live patient meetings and seminars, especially for relapsed and high-risk patients.

Patient Empowerment Network

Patient Empowerment Network (PEN) equips patients and care partners with the tools and resources needed to understand their cancer diagnosis and take an active role in their treatment journey.

Patient Power

Patient Power maintains a rich library of cancer information videos for patients and professionals alike. They can also help you locate financial, insurance, and family resources.

Additional resource from Johnson & Johnson

Advocacy Connector

Advocacy Connector is a Johnson & Johnson-sponsored resource that connects patients and care partners to national and state-specific advocacy groups that offer resources that may be relevant to your needs. [Access Advocacy Connector](#)

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It's important to understand the words you may read about or hear from your doctor or nurse. [Here are definitions of some terms you may come across.](#)

Allergic reaction

The body's overreaction to a typically harmless substance called an allergen. Anything can be an allergen.

Antibody

A protein produced by plasma cells that helps protect the body from infection and disease.

Autologous stem cell transplant

Procedure in which stem cells collected from a patient are transplanted back into that patient.

CD38

A protein found on the surface of certain cells and in high numbers on myeloma cells.

Chemotherapy

A chemical drug that stops the growth of cancer cells, either by killing them or by stopping them from dividing. Chemotherapy may be given by mouth, injection or infusion, or on the skin, depending on the type and stage of the cancer being treated. It may be given alone or with other treatments, such as surgery, radiation therapy, or biologic therapy.

Combination therapy

Use of more than one medicine to treat a certain disease or condition.

Complete response

When the doctor observed no signs or symptoms of the disease as seen through imaging or other specific blood and bone marrow tests after treatment.

Disease progression

Cancer continuing to grow or spread.

DNA

Deoxyribonucleic acid, the main component of chromosomes, and the carrier of genetic information.

Erythema

Reddening of the skin.

Formulation

The way in which different ingredients are combined to make a medicine.

Hyaluronidase

An ingredient that helps to disperse fluid and/or medicine throughout the body.

Immune system

Several types of cells and organs that work together to help the body fight infections and other diseases.

Immunomodulatory agents

Drugs that change a patient's immune response by enhancing or suppressing the immune system.

Immunotherapy

Drugs that stimulate the immune system to help treat or prevent disease.

Injection reaction

A response of the skin and subcutaneous tissues to any substance introduced with a needle.

Please [click here](#) to see the Product Information. Please [click here](#) to see full Important Safety Information.

GLOSSARY: WORDS TO KNOW

Intravenous (IV) infusion

Medicines or other fluids given via a needle inserted into a vein in a person’s arm.

Minimal residual disease (MRD)

The amount of myeloma cells remaining after a course of treatment, as measured by very sensitive testing.

Monoclonal antibody

Therapeutic monoclonal antibodies that are man-made and are designed to work with a person’s immune system to treat disease.

Monotherapy

Use of one type of medicine to treat a certain disease or condition.

M-protein

An antibody made in abnormal quantities by myeloma cells.

Multiple myeloma

A type of cancer formed by cancerous (also called “malignant”) plasma cells. Plasma cells are mainly found in the bone marrow.

Progression-free survival

Living progression free refers to the length of time a patient lived without having their disease getting worse, or passing away.

Proteasome inhibitors

Drugs that slow down cancer cell growth by interfering with processes that play a role in cell function.

Protein

A molecule made up of amino acids that is needed for the body to function properly. Proteins are the basis of skin, hair, and other substances in the body.

Regimen

A plan for treating a condition, such as multiple myeloma. A treatment regimen may use only one medication or it may use several medications together.

Response in multiple myeloma

A measurement made during or after treatment that measures the decrease in the extent of myeloma disease in response to treatment.

Side effect

An unwanted or unexpected reaction to a drug. Side effects can vary from minor problems like a headache or runny nose to life-threatening events, such as an increased risk of a heart attack. Sometimes referred to as an adverse event.

Stem cell

A cell that grows and divides to produce red blood cells, white blood cells, and platelets. Stem cells are found in bone marrow and blood.

Subcutaneous injection

An injection into the fatty tissue usually below the skin of the stomach that uses a needle.

Transitioning care

The process in which a patient moves from one center to receive care from another.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR DARZALEX FASPRO[®]

What is DARZALEX FASPRO[®] (daratumumab and hyaluronidase-fihj)?

DARZALEX FASPRO[®] is a prescription medicine used to treat adult patients with multiple myeloma:

- in combination with the medicines bortezomib, lenalidomide, and dexamethasone in newly diagnosed people who are eligible to receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines bortezomib, melphalan, and prednisone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines lenalidomide and dexamethasone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant) and in people whose multiple myeloma has come back or did not respond to treatment who have received at least one prior medicine to treat multiple myeloma
- in combination with the medicines bortezomib, thalidomide, and dexamethasone in newly diagnosed people who are eligible to receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines bortezomib and dexamethasone in people who have received at least one prior medicine to treat multiple myeloma
- in combination with the medicines pomalidomide and dexamethasone in people who have received at least one prior medicine, including lenalidomide and a proteasome inhibitor, to treat multiple myeloma
- in combination with the medicines carfilzomib and dexamethasone in people whose multiple myeloma has come back or did not respond to treatment who have received one to three prior medicines to treat multiple myeloma
- alone in people who have received at least three prior medicines, including a proteasome inhibitor and an immunomodulatory agent, **or** did not respond to a proteasome inhibitor and an immunomodulatory agent





It is not known if DARZALEX FASPRO[®] is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not receive DARZALEX FASPRO[®] if you have a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO[®]. See below for a complete list of ingredients in DARZALEX FASPRO[®].

Before you receive DARZALEX FASPRO[®], tell your healthcare provider about all of your medical conditions, including if you:

- have a history of breathing problems
- have had shingles (herpes zoster)
- have ever had or might now have a hepatitis B infection as DARZALEX FASPRO[®] could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX FASPRO[®]. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.
- are pregnant or plan to become pregnant. DARZALEX FASPRO[®] may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX FASPRO[®].

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- Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX FASPRO[®]. Talk to your healthcare provider about birth control methods that you can use during this time.
- Before starting DARZALEX FASPRO[®] in combination with lenalidomide, thalidomide, or pomalidomide, females and males must agree to the instructions in the lenalidomide, thalidomide, or pomalidomide REMS program.
 - The lenalidomide, thalidomide, and pomalidomide REMS have more information about effective methods of birth control, pregnancy testing, and blood donation for females who can become pregnant.
 - For males who have female partners who can become pregnant, there is information in the lenalidomide, thalidomide, and pomalidomide REMS about sperm donation and how lenalidomide, thalidomide, and pomalidomide can pass into human semen.
- are breastfeeding or plan to breastfeed. It is not known if DARZALEX FASPRO[®] passes into your breast milk. You should not breastfeed during treatment with DARZALEX FASPRO[®]. Talk to your healthcare provider about the best way to feed your baby during treatment with DARZALEX FASPRO[®].

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive DARZALEX FASPRO[®]?





- DARZALEX FASPRO[®] may be given alone or together with other medicines used to treat multiple myeloma.
- DARZALEX FASPRO[®] will be given to you by your healthcare provider as an injection under the skin in the stomach area (abdomen).
- DARZALEX FASPRO[®] is injected over 3 to 5 minutes.
- Your healthcare provider will decide the time between doses as well as how many treatments you will receive.
- Your healthcare provider will give you medicines before each dose of DARZALEX FASPRO[®] and after each dose of DARZALEX FASPRO[®] to help reduce the risk of serious allergic reactions and other reactions due to release of certain substances by your body (systemic).

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

DARZALEX FASPRO[®] may cause serious reactions, including:

- **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO[®]. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX FASPRO[®] if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX FASPRO[®].

◦ shortness of breath or trouble breathing	◦ wheezing	◦ headache	◦ vomiting
◦ dizziness or lightheadedness (hypotension)	◦ heart beating faster than usual	◦ itching	◦ chills
◦ cough	◦ low oxygen in the blood (hypoxia)	◦ high blood pressure	◦ fever
	◦ throat tightness or irritation	◦ eye pain	◦ chest pain
	◦ runny or stuffy nose	◦ nausea	◦ blurred vision
- **Injection site reactions.** Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX FASPRO[®]. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection of DARZALEX FASPRO[®].

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IMPORTANT SAFETY INFORMATION FOR DARZALEX FASPRO[®] (cont)

- **Decreases in blood cell counts.** DARZALEX FASPRO[®] can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX FASPRO[®] but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX FASPRO[®]. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.
- **Changes in blood tests.** DARZALEX FASPRO[®] can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO[®]. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX FASPRO[®]. **Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO[®] before receiving blood transfusions.**

The most common side effects of DARZALEX FASPRO[®] when used alone include cold-like symptoms (upper respiratory infection) and decreased red blood cell counts.

The most common side effects of DARZALEX FASPRO[®] when used in combination therapy include:

- | | | | |
|-----------------------|-----------------|--|--|
| • tiredness | • headache | • back pain | • nerve damage causing tingling, numbness, or pain |
| • nausea | • rash | • vomiting | • constipation |
| • diarrhea | • fever | • high blood pressure | • lung infection (pneumonia) |
| • shortness of breath | • cough | • muscle, bone, and joint pain | • swollen hands, ankles, or feet |
| • trouble sleeping | • muscle spasms | • cold-like symptoms (upper respiratory infection) | • decreased red blood cell counts |

These are not all of the possible side effects of DARZALEX FASPRO[®]. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of DARZALEX FASPRO[®]

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about DARZALEX FASPRO[®] that is written for health professionals.

Active ingredient: daratumumab and hyaluronidase-fihj

Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 20, sorbitol, water for injection

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

cp-143282v10

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR DARZALEX[®]

What is DARZALEX[®] (daratumumab)?

DARZALEX[®] is a prescription medicine used to treat adults with multiple myeloma:

- In combination with the medicines lenalidomide and dexamethasone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant) and in people whose multiple myeloma has come back or did not respond to treatment who have received at least one prior medicine to treat multiple myeloma
- In combination with the medicines bortezomib, melphalan, and prednisone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- In combination with the medicines bortezomib, thalidomide, and dexamethasone in newly diagnosed people who are eligible to receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- In combination with the medicines bortezomib and dexamethasone in people who have received at least one prior medicine to treat multiple myeloma
- In combination with the medicines carfilzomib and dexamethasone in people whose multiple myeloma has come back or did not respond to treatment who have received one to three prior medicines to treat multiple myeloma
- In combination with the medicines pomalidomide and dexamethasone in people who have received at least two prior medicines to treat multiple myeloma, including lenalidomide and a proteasome inhibitor
- Alone in people who have received at least three prior medicines, including a proteasome inhibitor and an immunomodulatory agent, **or** did not respond to a proteasome inhibitor and an immunomodulatory agent

It is not known if DARZALEX[®] is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not receive DARZALEX[®] if you have a history of a severe allergic reaction to daratumumab or any of the ingredients in DARZALEX[®]. See below for a complete list of ingredients.

Before you receive DARZALEX[®], tell your healthcare provider about all of your medical conditions, including if you:

- have a history of breathing problems
- have had shingles (herpes zoster)
- have ever had or might now have a hepatitis B infection as DARZALEX[®] could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX[®]. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes

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- have hereditary fructose intolerance (HFI). DARZALEX[®] contains sorbitol. Sorbitol is a source of fructose. People with HFI cannot break down fructose, which may cause serious side effects
- are pregnant or plan to become pregnant. DARZALEX[®] may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX[®]
 - Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX[®]. Talk to your healthcare provider about birth control methods that you can use during this time
 - Before starting DARZALEX[®] in combination with lenalidomide, pomalidomide, or thalidomide, females and males must agree to the instructions in the lenalidomide, pomalidomide, or thalidomide REMS program
 - The lenalidomide, pomalidomide, and thalidomide REMS have more information about effective methods of birth control, pregnancy testing, and blood donation for females who can become pregnant
 - For males who have female partners who can become pregnant, there is information in the lenalidomide, pomalidomide, and thalidomide REMS about sperm donation and how lenalidomide, pomalidomide, and thalidomide can pass into human semen
- are breastfeeding or plan to breastfeed. It is not known if DARZALEX[®] passes into your breast milk. You should not breastfeed during treatment with DARZALEX[®]. Talk to your healthcare provider about the best way to feed your baby during treatment with DARZALEX[®]

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive DARZALEX[®]?

- DARZALEX[®] may be given alone or together with other medicines used to treat multiple myeloma
- DARZALEX[®] will be given to you by your healthcare provider by intravenous (IV) infusion into your vein
- Your healthcare provider will decide the time between doses as well as how many treatments you will receive
- Your healthcare provider will give you medicines before each dose of DARZALEX[®] and after each dose of DARZALEX[®] to help reduce the risk of infusion-related reactions
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment

DARZALEX[®] may cause serious reactions, including:

- **Infusion-related reactions.** Infusion-related reactions are common with DARZALEX[®]. Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX[®]. Your healthcare provider may temporarily stop your infusion or completely stop treatment with DARZALEX[®] if you have infusion-related reactions. Get medical help right away if you get any of the following symptoms: shortness of breath or trouble breathing, dizziness or lightheadedness (hypotension), cough, wheezing, heart beating faster than usual, low oxygen in the blood (hypoxia), throat tightness or irritation, runny or stuffy nose, headache, itching, high blood pressure, eye pain, nausea, vomiting, chills, fever, chest discomfort, or blurred vision

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IMPORTANT SAFETY INFORMATION FOR DARZALEX[®] (cont)

• **Changes in blood tests.** DARZALEX[®] can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX[®]. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX[®].
Tell all of your healthcare providers that you are being treated with DARZALEX[®] before receiving blood transfusions

• **Decreases in blood cell counts.** DARZALEX[®] can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX[®] but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX[®]. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding

The most common side effects of DARZALEX[®] include cold-like symptoms (upper respiratory infection); diarrhea; constipation; decreased red blood cells; nerve damage causing tingling, numbness, or pain; tiredness; swollen hands, ankles, or feet; nausea; cough; fever; shortness of breath; feeling weak. These are not all the possible side effects of DARZALEX[®]. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of DARZALEX[®]
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about DARZALEX[®] that is written for health professionals.

Active ingredient: daratumumab.

Inactive ingredients: may include glacial acetic acid, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, mannitol, polysorbate 20, sodium acetate trihydrate, sodium chloride, sorbitol, and water for injection.

Please [click here](#) to see the Important Product Information.
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