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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, 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 44](#) for a complete list of ingredients in DARZALEX FASPRO[®].

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

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 has been divided into 4 main chapters to help you find information that matters to you easily, depending 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 [▶](#)



The Treatment Decision

Discover why you should talk to your doctor about whether DARZALEX FASPRO[®] is the right treatment for you [▶](#)



Getting the Most From DARZALEX FASPRO[®]

Understand the benefits of continuing on treatment as directed by your doctor [▶](#)



The Power of Teamwork

Get to know your support system and resources, and how they can help you along your treatment journey [▶](#)

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



Have a better chance of staying committed to your treatment plan



Work toward your treatment goals you discussed with your doctor



Realize you have a voice when discussing treatment with your care team

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[®].

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WHAT TO KNOW AT DIAGNOSIS

A multiple myeloma diagnosis may be overwhelming, but being knowledgeable at the start of your journey can be helpful on your road ahead.



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The key highlights from this chapter include:

- ✓ Multiple myeloma is a type of blood cancer
- ✓ Although there is no cure for multiple myeloma at this time, there are many treatment regimens that may help manage it
- ✓ It's important to work with your healthcare team to develop a treatment plan that helps toward:
 - Starting and continuing treatment to delay your disease from progressing
 - Understanding and working toward your treatment goals
 - Finding ways to help stay positive throughout your journey
- ✓ There are different treatment options available, and you can have an active role in deciding which medicines are right for you
- ✓ Some key goals are for you to respond to your treatment and to delay relapse or your disease from getting worse for as long as possible. Starting and continuing with a treatment as directed can help to achieve these results

[Learn more](#)

[Learn more](#)

[Learn more](#)

SELECT IMPORTANT SAFETY INFORMATION (cont)

- **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 IS MULTIPLE MYELOMA?



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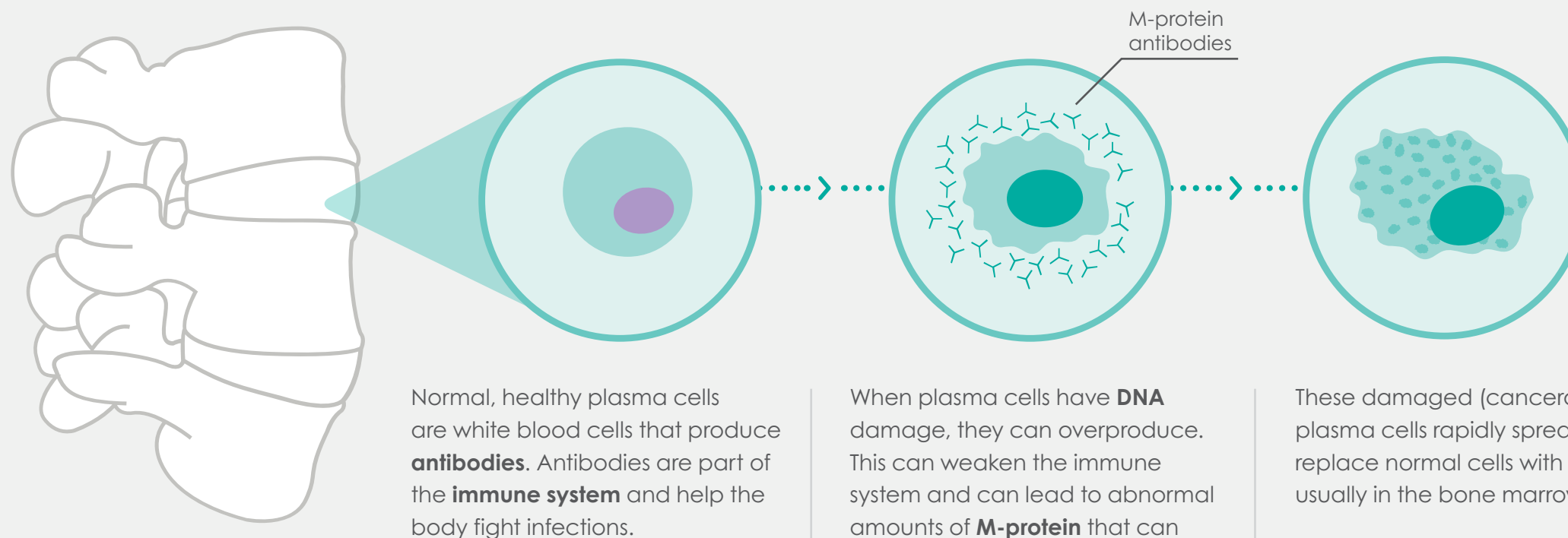
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Multiple myeloma is a blood cancer that affects a type of white blood cell called a plasma cell. These white blood cells are found mostly in bone marrow, the soft substance inside some hollow bones where blood cells are made.



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HOW IS MULTIPLE MYELOMA TREATED?



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When working with your doctor to determine the right treatment regimen for you, there are different options to consider.

It is important to discuss with your healthcare team and your care partner(s) all the potential benefits and risks associated with the treatment options you are considering.

Commonly used multiple myeloma treatments and supportive medications

-  **Monoclonal antibodies** kill cancer cells directly as well as help the immune system attack them and 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, replacing them with healthy stem cells (cells that have not yet finished developing)
-  **Steroids** help decrease inflammation and swelling
-  **Bone support medication** such as bisphosphonates 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.

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

UNDERSTANDING THE POTENTIAL GOALS OF YOUR TREATMENT



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There are many goals of treatment. You and your healthcare team should discuss and agree to them when deciding on a treatment plan that works for you.

Some key goals of treatment may be:



Treatment response

Everyone responds to treatment differently. You may experience a partial response, a very good partial response, or a complete response.

A complete response is when your doctor finds no signs or symptoms of multiple myeloma as seen through imaging or other specific blood or bone marrow tests after treatment.



Progression-free survival

Progression-free survival is the length of time from the beginning of treatment in which a patient is living with a disease that does not get worse.

At this time, there is no cure for this disease, but there are many treatment regimens that may help manage it.
Starting and continuing with a treatment enables you to keep benefiting from the treatment your doctor has prescribed.

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

THE TREATMENT DECISION

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 in adults who have tried other medicines first. It can be used alone or in combination with other medicines.



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The key highlights from this chapter include:

 DARZALEX FASPRO[®] is a subcutaneous (under the skin) injection that is not chemotherapy. It is an immunotherapy that works with your immune system to fight disease

[Learn more](#)

 Daratumumab, the main component of 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 the intravenous (IV) formulation of DARZALEX[®] (daratumumab) in treating multiple myeloma when used as monotherapy (by itself)

[Learn more](#)

 In a clinical study, nearly 3X fewer patients experienced injection reactions (systemic) on DARZALEX FASPRO[®] vs DARZALEX[®]

- 13% of the 260 patients who received DARZALEX FASPRO[®] experienced injection reactions (systemic), compared with 34% of the 258 patients who received the IV formulations of DARZALEX[®]

[Learn more](#)

 It is a treatment given by your healthcare provider under the skin in the stomach area (abdomen) that takes about 3 to 5 minutes*

[Learn more](#)

*3 to 5 minutes refers to the time it takes to administer DARZALEX FASPRO[®] and does not account for all aspects of treatment.

SELECT IMPORTANT SAFETY INFORMATION (cont)

- **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[®].

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

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DARZALEX FASPRO® is a subcutaneous (under the skin) injection that is not chemotherapy. It is an immunotherapy that works with your immune system to fight disease.

It is made up of 2 main components:



Daratumumab (pronounced da-ra-tu-mu-mab)

Daratumumab is the ingredient that treats multiple myeloma.

Daratumumab is the same medicine that is contained in the product DARZALEX®. DARZALEX® is a medicine given as an intravenous (IV) infusion (with a needle inserted into a vein in your arm).



Hyaluronidase (pronounced hy-a-lur-on-i-dase)

Hyaluronidase helps daratumumab to be injected into the skin and absorbed into the body.



Daratumumab attaches itself to CD38 protein on the surface of multiple myeloma cells, as well as other types of cells such as red blood cells.



Daratumumab directly 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.

DARZALEX FASPRO® may cause serious reactions, including: serious allergic reactions and other severe injection-related reactions, injection site reactions, decreases in blood cell counts, and changes in blood tests.

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

- **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

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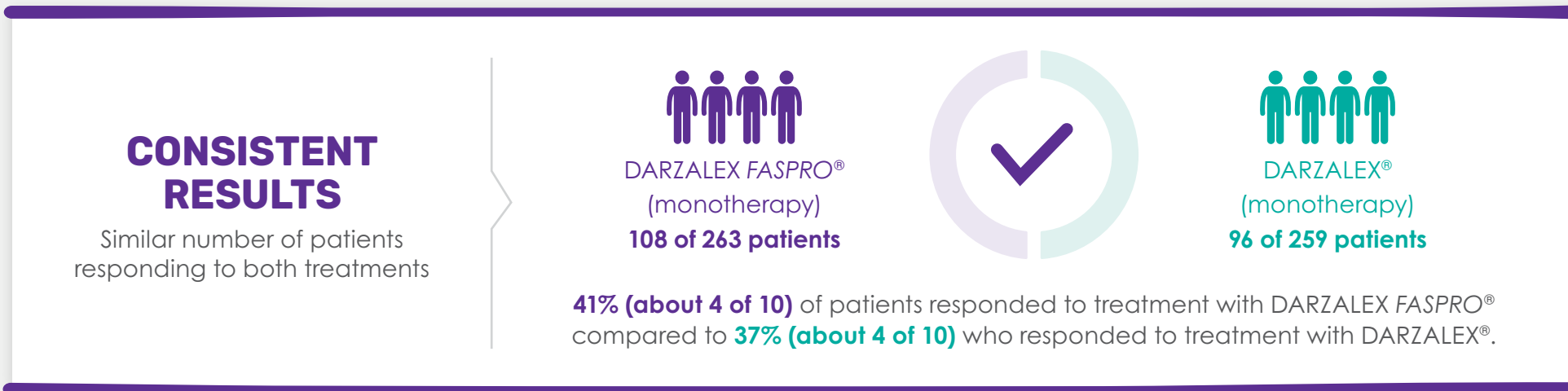
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DARZALEX[®] (daratumumab) and DARZALEX FASPRO[®] (daratumumab and hyaluronidase-fihj) both contain the medicine daratumumab, but are given differently (by intravenous injection or by injection underneath the skin). DARZALEX FASPRO[®] has been evaluated in medical studies to show that it can work as well as DARZALEX[®] when treating multiple myeloma. In a clinical study with more than 500 patients, DARZALEX FASPRO[®] (subcutaneous injection) gave patients results comparable to the IV formulation of DARZALEX[®] in treating multiple myeloma when used as monotherapy (by itself).

This study compared treatments in patients with multiple myeloma who received at least 3 prior medicines or who did not respond to a proteasome inhibitor or an immunomodulatory agent. Of the 522 patients in the study, 263 patients received DARZALEX FASPRO[®] (monotherapy) and 259 received DARZALEX[®] (monotherapy).



 DARZALEX[®], the IV formulation, has been used to treat multiple myeloma since 2015, with 8 registrational clinical trials, and has extensive data to support its use.

SELECT IMPORTANT SAFETY INFORMATION (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.

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

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DARZALEX FASPRO[®] works effectively with other medicines to fight multiple myeloma

DARZALEX FASPRO[®] can help strengthen the fight against multiple myeloma when combined with other medicines.

- **Combination study 1:** This study evaluated treatments in 67 patients with newly diagnosed multiple myeloma unable to have a transplant using DARZALEX FASPRO[®] + bortezomib + melphalan + prednisone (DVMP), and in 65 patients who received at least 1 prior medicine using DARZALEX FASPRO[®] + lenalidomide + dexamethasone (DRd)

In this study:

ABOUT 9 OF 10 PATIENTS

responded to DARZALEX FASPRO[®] in combination with other medicines.

In patients who received DVMP, 88% had a response to treatment.
In patients who received DRd, 91% had a response to treatment.



Look Ahead to Key Milestones!

Responding to treatment is a big accomplishment in your journey. Give yourself another reason to celebrate by working with your doctor to help you continue seeing a response for as long as you are on this treatment.

SELECT IMPORTANT SAFETY INFORMATION (cont)

- **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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- **Combination study 2:** This study compared treatment with DARZALEX FASPRO[®] + pomalidomide + dexamethasone (DPd) vs pomalidomide + dexamethasone (Pd) in 304 patients who received at least 1 prior medicine and previously treated with lenalidomide and a proteasome inhibitor

In this study, at a median follow-up of ~17 months:

MORE PATIENTS EXPERIENCED PROGRESSION-FREE SURVIVAL WITH DPd*



DPd

63 of 151 patients

VS



Pd

39 of 153 patients

*Progression-free survival (PFS): the length of time from the beginning of treatment in which a patient is living with a disease that does not get worse.



Look Ahead to Key Milestones!

Progression-free survival is a key treatment goal to work toward for patients with multiple myeloma.

[Learn more](#)

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[®].

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- **Combination study 3:** This study evaluated treatment with DARZALEX FASPRO[®] + carfilzomib + dexamethasone (DKd) in 66 patients with relapsed or refractory multiple myeloma who received at least 1 prior medicine

In this study:

MORE THAN 8 OUT OF 10 PATIENTS

responded to DARZALEX FASPRO[®] in combination with other medicines.

In patients who received DKd, 84.8% had a response to treatment.



Look Ahead to Key Milestones!

Responding to treatment is a big accomplishment in your journey. Give yourself another reason to celebrate by working with your doctor to help you continue seeing a response for as long as you are on this treatment.

SELECT IMPORTANT SAFETY INFORMATION (cont)

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

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

These are not all the possible side effects of DARZALEX FASPRO[®].

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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[®].

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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HOW TO PREPARE FOR YOUR INJECTION



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Wear comfortable clothing that is loose around the waist: DARZALEX FASPRO[®] is injected about 3 inches to the left or right of the belly button



Set aside enough time:

- To ask questions, if you have any
- To discuss your treatment goals
- For your healthcare provider to monitor for a reaction to the injection, particularly for the first few injections that you receive



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



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)

- **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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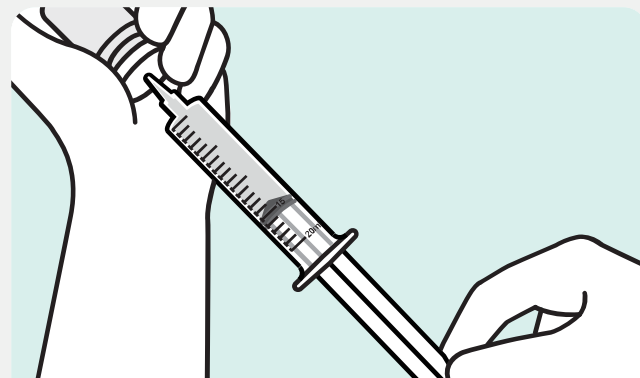
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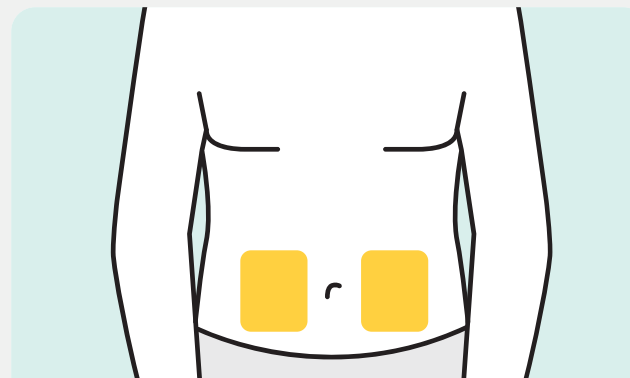
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Before you proceed with treatment with DARZALEX FASPRO[®], it's important to talk with your healthcare provider about expectations. Knowing what to expect can help prepare you and give you a sense of purpose as you make an effort to meet your treatment goals.

During the injection



Your healthcare provider will prepare the syringe



Your healthcare provider will prepare the skin and determine where to inject, rotating injection sites in the stomach area each time you receive an injection



The injection takes about 3 to 5 minutes to be given.* The medicine is injected into the subcutaneous tissue (the tissue under the skin) of the stomach.

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

SELECT IMPORTANT SAFETY INFORMATION (cont)

- **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[®].

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

WHAT TO EXPECT AFTER TREATMENT



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After the injection



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. 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
- 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

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[®].

Post-medication

Following the injection, you may also be given oral corticosteroids to reduce the risk of delayed reactions due to the administration of DARZALEX FASPRO[®].

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UNDERSTANDING THE POTENTIAL SIDE EFFECTS OF DARZALEX FASPRO[®]



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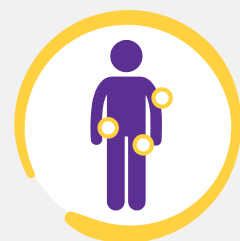
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You may experience side effects from treatment

Side effects are an unwanted or unexpected reaction to a drug that can occur anywhere in your body, due to the administration of treatment.

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

Reactions to the injections

Among all patients who participated in DARZALEX FASPRO[®] clinical studies:



9% of 898 patients taking DARZALEX FASPRO[®] by itself or in combination with other multiple myeloma and light chain (AL) amyloidosis treatments experienced a reaction related to the injection*

Most patients experienced reactions that were mild to moderate and occurred after the first injection

*898 includes 193 patients who received DARZALEX FASPRO[®] for light chain (AL) amyloidosis.

SELECT IMPORTANT SAFETY INFORMATION (cont)

- **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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Fewer patients experienced reactions with DARZALEX FASPRO[®]

3x
fewer

In a clinical study that compared DARZALEX FASPRO[®] (monotherapy) to the IV formulation of DARZALEX[®] (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 formulations 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, 8% 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)

- **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.

GETTING THE MOST FROM DARZALEX FASPRO[®]

If you and your healthcare team decide on DARZALEX FASPRO[®], you will be choosing a treatment that has been shown to help patients with multiple myeloma. In order to continue seeing any benefits of this treatment, it's important to continue on it as directed by your doctor.



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The key highlights from this chapter include:

- ✓ Continuing a treatment that works can help to keep your multiple myeloma from getting worse
 - For newly diagnosed patients who are unable to receive a transplant or for patients who have relapsed or refractory multiple myeloma

[Learn more](#)

- ✓ Progression-free survival (PFS) is often a key goal for patients with multiple myeloma. This is simply the length of time during and after treatment in which you have lived with a disease that does not get worse. For example, achieving 1 year of PFS means you have lived 1 year without your multiple myeloma spreading or getting worse

[Learn more](#)

- ✓ The IV formulation of DARZALEX[®] in combination with lenalidomide and dexamethasone has been shown to help patients live longer without their disease getting worse compared with lenalidomide (R) and dexamethasone (d) alone

[Learn more](#)

- ✓ Celebrate treatment milestones

[Learn more](#)

SELECT IMPORTANT SAFETY INFORMATION (cont)

- **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.

REASONS FOR CONTINUING ON YOUR CURRENT THERAPY



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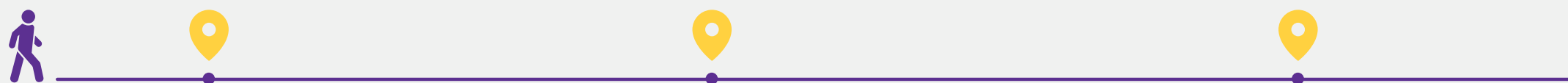
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Treatment is more like a marathon than a sprint

For newly diagnosed patients who are unable to get a transplant, or for patients who have relapsed or refractory multiple myeloma



During a marathon, a runner may clock their fastest mile ever, but if they quit the race at that point, they won't get the chance to reach additional milestones.

The goal is to keep achieving results with continuous treatment

There is currently no cure for multiple myeloma. Even if patients have a good response to treatment or appear to be in remission, there is no way to tell with certainty whether multiple myeloma cells are still in their body.

Staying the course can sustain response and keep your multiple myeloma from getting worse

Patients could think about treatment in a similar way. Everyone responds to treatment differently. Even if patients see positive results early on or experience fewer symptoms, it doesn't always mean treatment is no longer needed.

Celebrating each milestone helps promote positivity on the treatment journey

By continuing treatment as directed by your doctor, you may give yourself the best chance of reaching the treatment goals discussed with your doctor.

There are many resources that are available to help you learn more and stay on track with your therapy. Visit www.darzalex.com/faspro to download those materials.

SELECT IMPORTANT SAFETY INFORMATION (cont)

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

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

These are not all the possible side effects of DARZALEX FASPRO[®].

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UNDERSTANDING PROGRESSION-FREE SURVIVAL (PFS)



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After responding to treatment, delaying progression (when your disease spreads or gets worse) is often a key goal. Your doctor may refer to this as progression-free survival. This is a way to measure the length of time during and after treatment in which a patient is living with a disease that does not get worse.

At each check-in, it's important to talk with your doctor about PFS and how continuing with your treatment may help extend the period of time you are progression free.



Look Ahead to Key Milestones!

Every month your multiple myeloma does not progress, you've reached another milestone in your treatment.

Length of time without progression of multiple myeloma = PFS



Treatment response



Progression-free survival (PFS)



Disease progression



See how patients responded to treatment in clinical studies and lived without their disease getting worse

[Learn more](#)

SELECT IMPORTANT SAFETY INFORMATION (cont)

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 47](#) for a complete list of ingredients.

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

DARZALEX[®] CLINICAL STUDY RESULTS



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DARZALEX[®] (daratumumab) and DARZALEX FASPRO[®] (daratumumab and hyaluronidase-fihj) both contain the medicine daratumumab, but are given differently (by intravenous injection or by injection underneath the skin).

Study 1 (MAIA)

DARZALEX[®] + lenalidomide + dexamethasone (DRd) vs lenalidomide + dexamethasone (Rd) alone

DARZALEX[®] was studied in 737 patients with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant).

The main goal of the study was to measure the length of time patients lived without their multiple myeloma getting worse (progression-free survival, or PFS).

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



Results: DARZALEX[®] in combination with Rd increased the time patients lived without their multiple myeloma getting worse.

At a median follow-up of 28 months



of patients treated with DRd (n=368) lived without their disease getting worse vs **61%** of patients treated with Rd alone (n=369).

[See additional clinical studies including PFS data](#)

A third goal was to measure overall survival of patients in treatment over time. Treating with DRd, rather than Rd alone, helped patients live longer. At a ~5-year follow-up, 66% of patients treated with DRd (n=368) were still living vs 53% of patients treated with Rd alone (n=369).

SELECT IMPORTANT SAFETY INFORMATION (cont)

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[®].

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<p>Study 2 (ALCYONE) DARZALEX[®] + bortezomib, melphalan, and prednisone (DVMP) vs bortezomib, melphalan, and prednisone (VMP) alone</p>	<p>DARZALEX[®] was studied in 706 patients with newly diagnosed multiple myeloma who could not receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant).</p>	<p>To measure the length of time patients lived without their multiple myeloma getting worse (progression-free survival, or PFS) or passing away from any cause.</p>	<p>To measure overall response rate (ORR), which is the percentage of patients who responded to treatment.</p>
<p>Study 3 (CASSIOPEIA) DARZALEX[®] + bortezomib, thalidomide, and dexamethasone (DVTd) vs bortezomib, thalidomide, and dexamethasone (VTd) alone</p>	<p>DARZALEX[®] was studied in 1085 patients with newly diagnosed multiple myeloma who can receive a stem cell transplant. In this study, patients received initial (induction) therapy with either DARZALEX[®] + VTd (n=543) or VTd alone (n=542). Patients received consolidation with either DARZALEX[®] + VTd (n=543) or VTd alone (n=542).</p>	<p>The study measured stringent complete response (sCR), a sensitive measure of deep response.</p>	<p>To measure the length of time patients lived without their multiple myeloma getting worse (PFS).</p>
<p>Study 4 (POLLUX) DARZALEX[®] + lenalidomide and dexamethasone (DRd) vs lenalidomide and dexamethasone (Rd) alone</p>	<p>DARZALEX[®] was studied in 569 patients who had received at least one prior medicine to treat their multiple myeloma.</p>	<p>To measure the length of time patients lived without their multiple myeloma getting worse (PFS) or passing away from any cause.</p>	<p>To measure overall response rate, which is the percentage of patients who responded to treatment.</p>

[See additional clinical studies including PFS data](#)

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Clinical Study	Study Details	Main Goal	Another Goal
<p>Study 5 (CASTOR) DARZALEX[®] + bortezomib and dexamethasone (DVd) vs bortezomib and dexamethasone (Vd) alone</p>	<p>DARZALEX[®] was studied in 498 patients who had received at least one prior medicine to treat their multiple myeloma.</p>	<p>To measure the length of time patients lived without their multiple myeloma getting worse (progression-free survival, or PFS).</p>	<p>To measure overall response rate, which is the percentage of patients who responded to treatment.</p>
<p>Study 6 (CANDOR) DARZALEX[®] + carfilzomib and dexamethasone (DKd) vs carfilzomib and dexamethasone (Kd) alone</p>	<p>DARZALEX[®] was studied in 466 patients who had received at least one prior medicine to treat their multiple myeloma.</p>	<p>To measure the length of time patients lived without their multiple myeloma getting worse (PFS).</p>	<p>To measure overall response rate, which is the percentage of patients who responded to treatment.</p>
<p>Study 7 (EQUULEUS) DARZALEX[®] + pomalidomide and dexamethasone (DPd)</p>	<p>DARZALEX[®] was studied in 103 patients who had received at least two prior medicines to treat their multiple myeloma.</p>	<p>To measure the safety of daratumumab (D), the main ingredient in DARZALEX[®], when used in combination with pomalidomide and dexamethasone (Pd).</p>	<p>To measure overall response rate, which is the percentage of patients who responded to treatment.</p>

[See additional clinical study results](#)

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Clinical Study	Results
Study 2 (ALCYONE)	DARZALEX [®] in combination with bortezomib (V), melphalan (M), and prednisone (P) increased the time patients lived without their multiple myeloma getting worse. At a median follow-up of 16.5 months, 75% of patients lived without their disease getting worse with DARZALEX[®] + VMP (n=350) vs 60% with VMP alone (n=356).
Study 3 (CASSIOPEIA)	29% of patients treated with DARZALEX [®] in combination with bortezomib (V), thalidomide (T), and dexamethasone (d) (n=543) achieved stringent complete response vs 20% of patients treated with VTd (n=542) alone. The overall response rate (which includes all levels of response) was 93% of patients treated with DARZALEX [®] + VTd vs 90% of patients treated with VTd alone. At a median follow-up of 18.8 months, 92% of patients lived without their disease getting worse with DARZALEX[®] + VTd (n=543) vs 83% with VTd alone (n=542).
Study 4 (POLLUX)	DARZALEX [®] in combination with lenalidomide (R) and dexamethasone (d) increased the time patients lived without their multiple myeloma getting worse. At a median follow-up of 13.5 months, 82% of patients lived without their disease getting worse with DARZALEX[®] + Rd (n=286) vs 59% of patients treated with Rd alone (n=283).

[See additional clinical study results](#)

SELECT IMPORTANT SAFETY INFORMATION (cont)

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[®].

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Clinical Study	Results
Study 5 (CASTOR)	DARZALEX [®] in combination with bortezomib and dexamethasone (DVd) increased the time patients lived without their multiple myeloma getting worse. At a median follow-up of 7.4 months, 73% of patients lived without their disease getting worse with DVd (n=251) vs 51% of patients treated with bortezomib and dexamethasone alone (n=247).
Study 6 (CANDOR)	DARZALEX [®] in combination with carfilzomib and dexamethasone (DKd) increased the time patients lived without their multiple myeloma getting worse. The DKd regimen (n=312) demonstrated a 37% reduction in the risk of disease progression or death vs patients treated with carfilzomib and dexamethasone (n=154) alone.
Study 7 (EQUULEUS)	DARZALEX [®] in combination with pomalidomide + dexamethasone (DPd) 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 DPd regimen.

SELECT IMPORTANT SAFETY INFORMATION (cont)

Infusion-related reactions (cont): 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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Motivate yourself. Treat every injection as a milestone on the way to your goal.

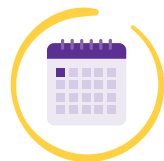
- If your doctor prescribed a 4-week cycle regimen such as **DARZALEX FASPRO[®] + lenalidomide + dexamethasone (DRd)**, then DARZALEX FASPRO[®] is needed every week
- As time goes on, you will get DARZALEX FASPRO[®] every 2 weeks
- Eventually you will only need DARZALEX FASPRO[®] once every 4 weeks



Look Ahead to Key Milestones!

With every dose you are continuing to allow DARZALEX FASPRO[®] to work for you.

If your doctor prescribed a 4-week cycle regimen such as DRd



After 6 months of therapy, you will receive DARZALEX FASPRO[®] **once every 4 weeks**



Equaling 13 times per year

Applies to Year 2 of therapy and beyond

Download the [dosing calendar](#) for more details 

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

[See dosing schedules for other DARZALEX FASPRO[®] regimens](#)

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 44](#) for a complete list of ingredients in DARZALEX FASPRO[®].

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When you first start treatment, you will need to receive DARZALEX FASPRO[®] every week. However, over time DARZALEX FASPRO[®] treatments are needed less frequently. Knowing how and when DARZALEX FASPRO[®] is administered can help you be prepared and keep track of your treatment.

Indicated Regimen	Weeks	Schedule
With lenalidomide (R) (4-week cycle) and dexamethasone (d), pomalidomide (P) and dexamethasone (d), or carfilzomib (K) and dexamethasone (d); or for monotherapy	1–8	Weekly (total of 8 doses)
	9–24	Every 2 weeks (total of 8 doses)
	25 onward until disease progression	Every 4 weeks
With bortezomib (V), melphalan (M), and prednisone (P) (6-week cycle)	1–6	Weekly (total of 6 doses)
	7–54	Every 3 weeks (total of 16 doses)
	55 onward until disease progression	Every 4 weeks
With bortezomib (V) and dexamethasone (d) (3-week cycle)	1–9	Weekly (total of 9 doses)
	10–24	Every 3 weeks (total of 5 doses)
	25 onward until disease progression	Every 4 weeks
With bortezomib (V), thalidomide (T), and dexamethasone (d) (4-week cycle)	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.

THE POWER OF TEAMWORK

It's important to remember that you are part of a team embarking on this journey. With the right support by your side, you may find it easier to stick to your treatment plan and reach your goals.



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The key highlights from this chapter include:

-  You are not alone. We are in this together—a unified front that includes you, your loved ones, the multiple myeloma community, your healthcare team, and Janssen

[Learn more](#)

-  You and your support system are all working together toward a common goal: to help you stay the course with your treatment plan so that you may achieve the treatment goals you and your doctor discussed

[Learn more](#)

-  There are a number of tools and resources available to help you and your care partner along your treatment journey

[Learn more](#)

WORKING TOGETHER TO MAKE THE MOST OF YOUR TREATMENT



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Working together to make the most of your treatment

Treatment is a shared decision

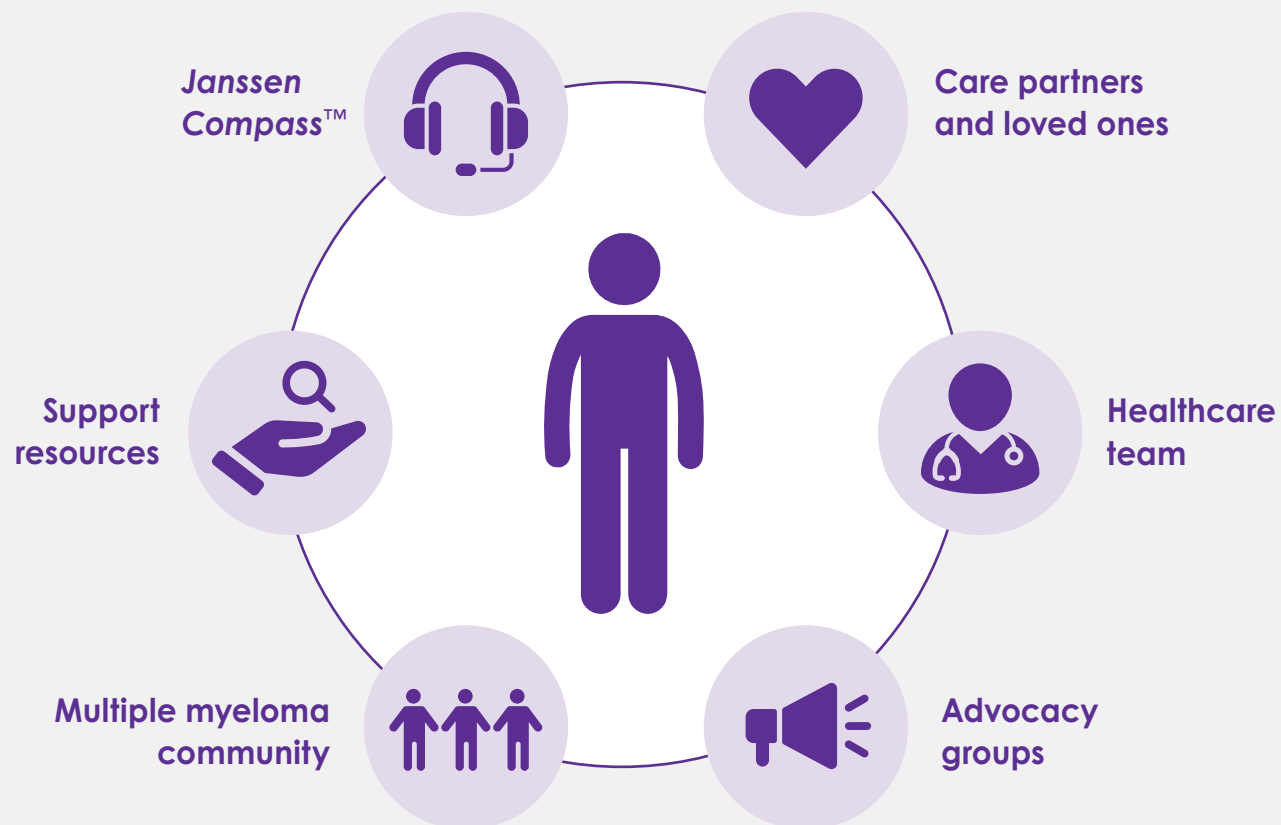
During treatment, you may need to transition to a new treatment center

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You are not alone on your journey. There's a world of support all around you. It's important for you to positively collaborate with your support system to help you work toward your treatment goals—and make your treatment count in **your fight against multiple myeloma**.



Here are some of the ways having a support system can help you:

- Providing resources to help along your journey
- Helping you understand treatment expectations and goals
- Educating you about side effects
- Explaining lab/test results to you
- Celebrating milestones with you

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

TREATMENT IS A SHARED DECISION



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When it's time to choose and discuss treatment for multiple myeloma, you can play an active role in the treatment decision. Your doctor and healthcare team are here to work with you, and provide guidance when choosing a treatment plan.

What should you consider when deciding on a treatment?

There are many different medicines and other therapies available to treat multiple myeloma. Because the treatment chosen will affect you, and may affect your family members helping you, there are several factors 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 continue on treatment.



Together with your doctor, you and your care partner can assess treatment options to find the right path forward.

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

DURING TREATMENT, YOU MAY NEED TO TRANSITION TO A NEW TREATMENT CENTER



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Here's what you should know when transitioning your care



Transitioning care is the process in which a patient moves from one center to receive care from another. There are many reasons why you may need to switch to another center to receive your care.

Whatever the reason, it's important for you to **continue with the treatment plan** your doctor has prescribed.

Continuing your treatment as prescribed can help you make the most of your treatment.



More information to help with your transition is available [here](#)

If you transition to a new treatment center:



Be sure to ask your current healthcare team to write down the details of your regimen and dosing schedule



Ask your current treatment center how you can obtain a digital (ie, email, online portal) or physical copy of your electronic health records to share with your new healthcare team



Work with your current center to schedule an appointment with your new doctor right away to avoid any gaps in your care



Talk to your healthcare team and insurance provider about any change in costs associated with your transition of care

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®.

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

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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](#)

Q How are DARZALEX FASPRO[®] treatments given?

A DARZALEX FASPRO[®] is given in about 3 to 5 minutes as a subcutaneous injection in the stomach area (abdomen). The dosing schedule of DARZALEX FASPRO[®] depends upon the treatment regimen prescribed.

[Plan your appointments with a treatment calendar](#)

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](#)

SELECT IMPORTANT SAFETY INFORMATION (cont)

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[®].

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

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

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

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

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

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

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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 intravenous (IV) 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](#)

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 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 *Janssen Compass*[™] Care Navigator will help you find the resources you may need to get started and stay on track. A *Janssen Compass*[™] Care Navigator will 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 *Janssen Compass*[™] can be here for you at \[www.janssencompass.com\]\(http://www.janssencompass.com\)](#)

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

A A *Janssen Compass*[™] 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 \[www.janssencompass.com\]\(http://www.janssencompass.com\)](#)

SUPPORT RESOURCES TO HELP YOU BE HEARD

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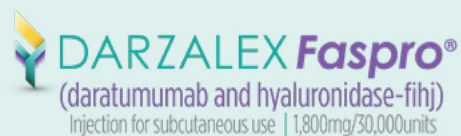
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Patient Support From Janssen Compass[™]

Personalized Support. From People Who Care.

Janssen Compass[™] is a free, personalized patient support program that can help you get started with your treatment and stay on track. Look to Janssen Compass[™] to help you understand your insurance coverage and cost support options, as well as guide you in navigating educational resources you want and need to feel confident on your Janssen therapy.

Connect with us!

Your dedicated Janssen Compass[™] Care Navigator is a phone call away! Visit www.janssencompass.com to request your first call and learn more about how Janssen Compass[™] can be here for you.

You can also call us at 844-NAV-1234 (844-628-1234), Monday through Friday, 8:30 AM – 8:30 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:



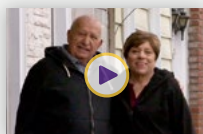
Doctor Conversation Starter

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



Treatment Calendar

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



Watch a patient's experience

See another patient's treatment journey with DARZALEX FASPRO[®]

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

MULTIPLE MYELOMA TREATMENT SUPPORT IS ALWAYS WITHIN REACH

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MyMilestones[™]

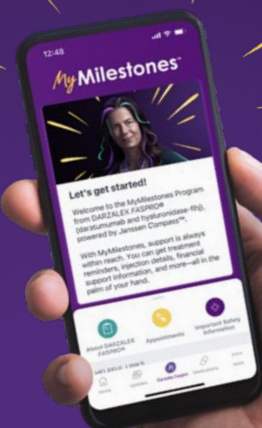
Powered by *Janssen Compass*[™]

Download Medisafe[®] on your phone, and then sign up directly through the app to get started. Or, if viewing on a computer, scan the QR code with your phone to begin the download.

Medisafe is a registered trademark of Medisafe Project, Ltd.

 Download on the
App Store

 GET IT ON
Google Play

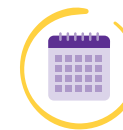


The MyMilestones[™] Program is here!

Connect to this free digital companion through Medisafe[®], the top-rated medication management app, to access valuable resources for the DARZALEX FASPRO[®] treatment journey, including:



Helpful tools and trackers



Treatment reminders



Educational videos

How to scan the QR code using your phone to access the MyMilestones[™] program:

1. Open your phone's camera app.
2. Point the camera at the QR code until a pop-up banner appears on your screen.
3. Tap on the pop-up to open the Apple App Store or Google Play Store.
4. Follow the prompts on your phone to download and install the Medisafe app.
5. Once downloaded, open the Medisafe App on your phone.
6. Tap "Get Started."
7. Tap "Continue" on the MyMilestones[™] screen and follow the prompts for adding DARZALEX FASPRO[®] reminders to the Medisafe app.



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

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 [Janssen Advocacy Connector](#).

Janssen 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.

[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.

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

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[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 Janssen

[Advocacy Connector](#)

Advocacy Connector is a Janssen-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](#)

GLOSSARY: WORDS TO KNOW



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.](#)

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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.

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.

Intravenous (IV) infusion


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

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

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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

The length of time during and after treatment in which a patient is living with a disease that does not get worse.

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.

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

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- **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.**

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

These are not all 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 see the Product Information.

cp-143282v9

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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- **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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