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MULTIPLE MYELOMA

NEITHER AM I

HERE'S WHAT TO EXPECT WHEN YOU START DARZALEX FASPRO[®]



BEFORE

How to dress, and what to expect when you arrive at your healthcare provider's office.



DURING

A quick description of the injection process for DARZALEX FASPRO[®], and how long it takes.



AFTER

What your healthcare provider may look for after your first few injections, and the importance of continuing your treatment as directed by your doctor.

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 below for a complete list of ingredients in DARZALEX FASPRO[®].

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

BEFORE YOUR INJECTION

If this is the first time you're receiving an injection of DARZALEX FASPRO[®], you may have some questions about what it's like and what you need to do to prepare. Here is some information that may help.



PREPARING FOR THE INJECTION



Dress for comfort

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

For the first few injections, your healthcare provider may want you to stay afterward to monitor for any reactions to the injection.

BEFORE YOUR INJECTION

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



Antihistamines to prevent an allergic reaction



Acetaminophen or similar medicine to reduce fever



Corticosteroids to prevent inflammation



You will be given a quick physical exam before the injection, including checking your pulse and blood pressure.



Your healthcare provider will do blood tests to match your blood type before you start treatment with 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[®]. Tell all of your healthcare providers and blood transfusion center personnel that you are being treated with DARZALEX FASPRO[®] before receiving blood transfusions.

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)

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



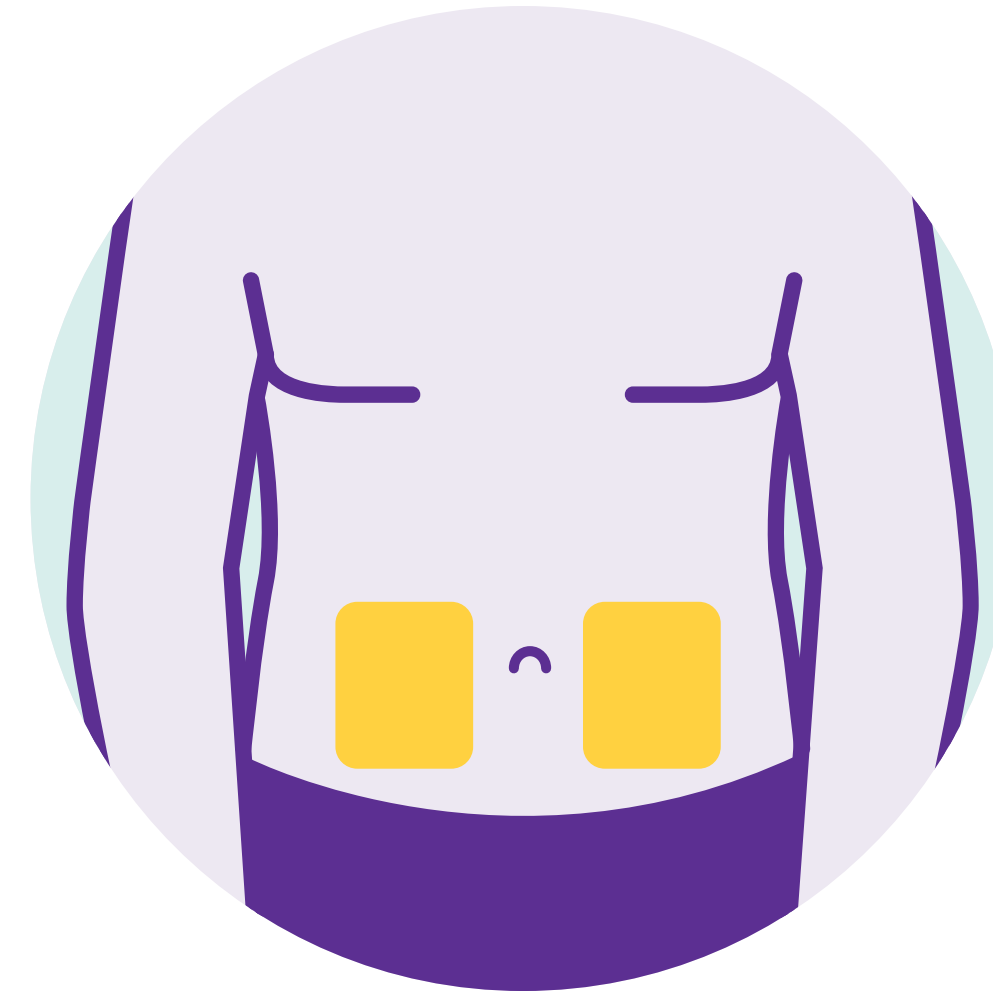
DURING YOUR INJECTION

PREPARATION



Your healthcare provider will prepare the syringe.

LOCATION



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

TIMING



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)

- 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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AFTER YOUR 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.

Do not receive DARZALEX FASPRO[®] if there is a history of a severe allergic reaction to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO[®].

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

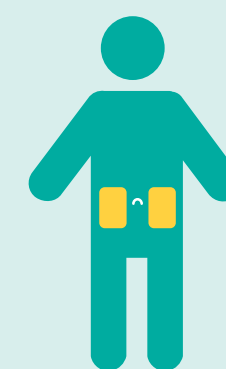
Fever

High blood pressure

Chest pain

Blurred vision

! 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 will also be given oral corticosteroids to reduce the risk of delayed reactions due to the administration of DARZALEX FASPRO[®].

SELECT IMPORTANT SAFETY INFORMATION (cont)

- 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.

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



LOOKING FORWARD: HERE'S WHAT TO REMEMBER AS YOU CONTINUE ON DARZALEX FASPRO[®]



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As you continue to receive DARZALEX FASPRO[®] injections in the long-term, your healthcare provider will develop a treatment plan that is right for you. **Over time, DARZALEX FASPRO[®] treatments are needed only once every 4 weeks for most patients.**



Make it a goal, and celebrate reaching a monthly dosing schedule. By continuing treatment as directed by your doctor, you may give yourself the best chance of reaching the treatment goals discussed with your doctor.

REMEMBER



Dress comfortably and in loose-fitting clothing.



Be prepared for a quick physical exam when you visit your healthcare provider.



You may need to take medications before your injection to help reduce the risk of side effects.



The injection time for DARZALEX FASPRO[®] is **about 3-5 minutes**.*

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

janssen compass[™]



WE'RE HERE FOR YOU

Visit Janssen Compass[™] for ongoing support. Simply visit us online at darzalex.com/faspro/janssen-compass.

SELECT IMPORTANT SAFETY INFORMATION (cont)

- ° 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.

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





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, 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)
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- 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[®].
 - 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.

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



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- 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 | ◦ throat tightness or irritation | ◦ high blood pressure | ◦ chills |
| ◦ dizziness or lightheadedness (hypotension) | ◦ wheezing | ◦ runny or stuffy nose | ◦ eye pain | ◦ fever |
| | ◦ heart beating faster than usual | ◦ headache | ◦ nausea | ◦ chest pain |
| | ◦ low oxygen in the blood (hypoxia) | ◦ itching | ◦ vomiting | ◦ 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[®] used in combination therapy include:

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

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.

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