

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

Treatment is a shared decision—
talk with your doctor about
DARZALEX FASPRO[®]

Please [click here](#) to see Important Safety Information for DARZALEX FASPRO[®].

Please [click here](#) to see Important Product Information for DARZALEX FASPRO[®]
and discuss any questions you may have with your doctor.

Table of contents

This brochure will help you and your loved one learn more about DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj), a treatment that you and your healthcare provider may choose to use during your treatment journey. Use the table of contents as a guide to important information about DARZALEX FASPRO® that can help with deciding whether this treatment is right for you.

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INDICATIONS

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 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 bortezomib and dexamethasone in people who have received at least one prior medicine 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®.

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 see additional Important Safety Information on pages 15-18 or [click here](#).

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



If you have multiple myeloma

Here are some facts you should know

Whether you are newly diagnosed, exploring treatment options, or beginning treatment for multiple myeloma, this information can help with preparing to move forward.

What is multiple myeloma?

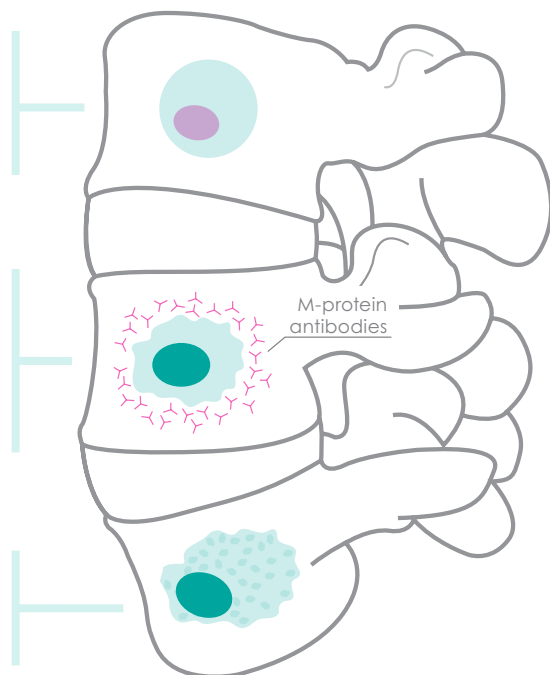
Multiple myeloma is a blood cancer that affects a type of white blood cell called a plasma cell. The diagram below shows how normal, healthy plasma cells become cancerous and start to grow out of control.

How multiple myeloma develops

Normal, healthy plasma cells are white blood cells that produce antibodies. Antibodies are part of the immune system and help the body to fight infections.

When plasma cells have **DNA** damage, they can overproduce. This can weaken the immune system and can lead to abnormal amounts of **M-protein** that can damage the kidneys.

These damaged (cancerous) plasma cells rapidly spread and replace normal cells with tumors, usually in the bone marrow.



How is multiple myeloma treated?

For people who are not experiencing signs or symptoms, treatment may not be necessary. If treatment is needed, there are several different options available.

It is important to discuss all the potential benefits and risks associated with the treatment options you are considering.

- **Monoclonal antibodies** kill cancer cells directly and help the immune system attack them
- **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
- **Steroids** help decrease inflammation and swelling
- **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)
- **Bone support medication** such as bisphosphonates help improve bone strength and prevent loss of bone mass

Glossary of terms can be found on [page 20](#).



For useful resources and more information about multiple myeloma, visit darzalex.com/faspro.

*Not everyone is eligible for stem cell transplant.

Please see additional Important Safety Information on pages 15-18 or [click here](#).
Please [click here](#) to see Important Product Information.






Deciding on treatment

Talking with your healthcare team

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

Why is treatment a shared decision?

There are many different medicines and other therapies available to treat multiple myeloma. Because the treatment chosen will affect you, and may affect your entire family, there are several factors to consider. For example:

-  **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?**

You will be asked by your healthcare provider for input into this decision, which may impact both your daily life and long-term health.

Please see additional Important Safety Information on pages 15-18 or [click here](#).
Please [click here](#) to see Important Product Information.

How can we become more educated about what is available?

The doctor will have recommendations about which treatments may be right for you. You can research these treatments to find out more about them and make a list of any questions you may have to discuss with your healthcare provider.

How can my caregiver help?

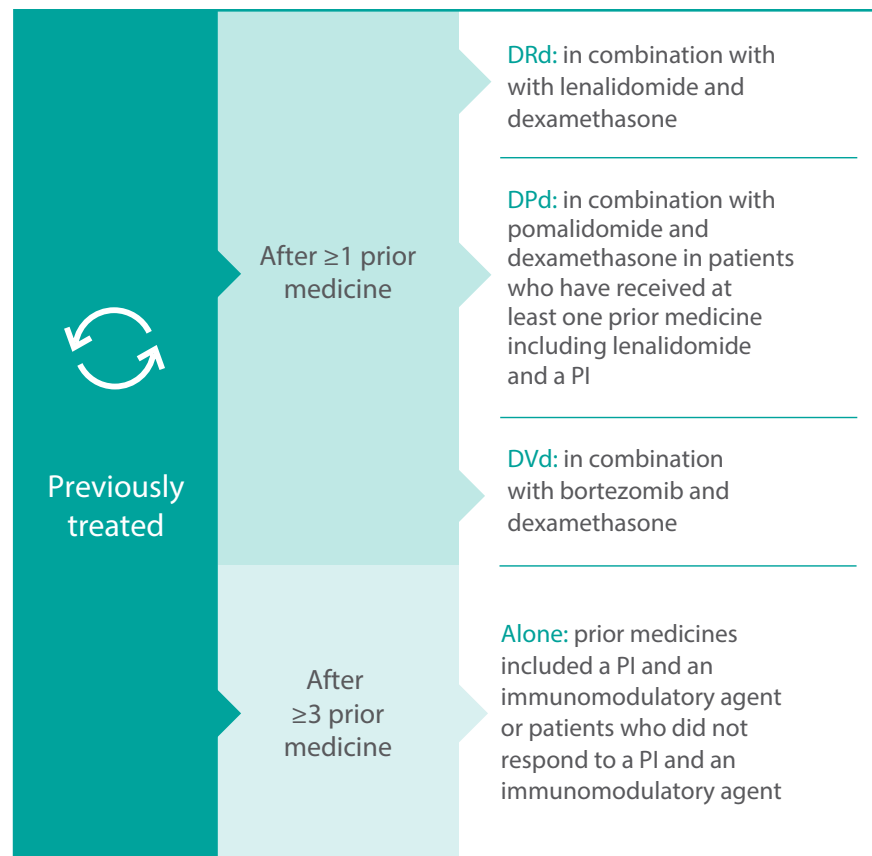
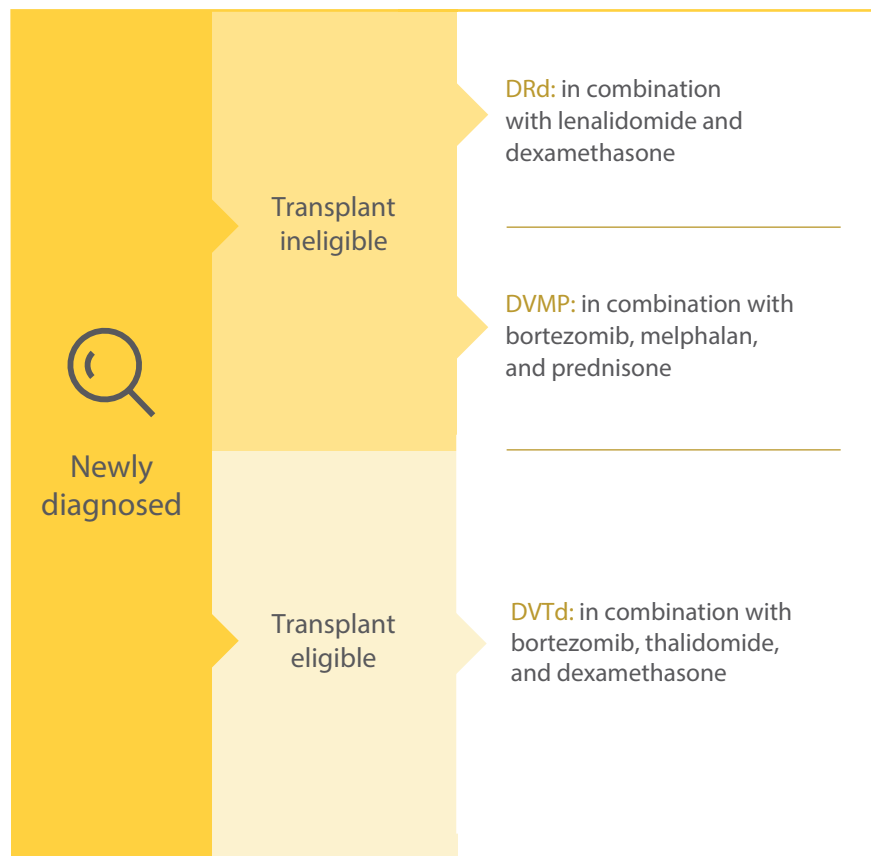
Getting a diagnosis of multiple myeloma can be overwhelming. Having someone with you during appointments can help make sure no important details get missed. Together with the doctor, you and your caregiver can assess treatment options to find the best path forward.



For specific questions to ask your healthcare team, please see the [Doctor Conversation Starter Guide on page 21](#) or visit darzalex.com/faspro.

What is DARZALEX FASPRO® and who is it for?

DARZALEX FASPRO® is a prescription medicine used to treat adults with multiple myeloma who are newly diagnosed and are able or unable to receive a transplant. It may also be used if you have tried other medicines. It can be used with other medicines to treat your disease or by itself. If used in combination with other medicines, your healthcare provider may mention your treatment regimen by its acronym, such as “DRd.” It’s important that you understand each component of your regimen so you can monitor your progress and be prepared for any associated side effects.



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®.

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DPd=DARZALEX FASPRO® (D) + pomalidomide (P) + dexamethasone (d);
 DRd=DARZALEX FASPRO® (D) + lenalidomide (R) + dexamethasone (d);
 DVd=DARZALEX FASPRO® (D) + bortezomib (V) + dexamethasone (d);
 DVMP=DARZALEX FASPRO® (D) + bortezomib (V) + melphalan (M) + prednisone (P);
 DVTd=DARZALEX FASPRO® (D) + bortezomib (V) + thalidomide (T) + dexamethasone (d);
 PI=proteasome inhibitor.

Here's what you should know about DARZALEX FASPRO®

DARZALEX FASPRO® is:

The subcutaneous (injected under the skin) formulation of daratumumab. 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). On the previous page, you learned who DARZALEX FASPRO® is for. **To learn about who DARZALEX® is for and to read the Important Safety Information for this medicine, [see pages 17-18](#).**



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



Approved for people who are newly diagnosed and can or cannot receive a transplant, and those who have had one or more other treatments for multiple myeloma



Prescribed alone or in combination with one or more other treatments

- 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 the release of certain substances by your body (systemic)

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
- runny or stuffy nose
- headache
- itching
- high blood pressure
- nausea
- vomiting
- chills
- fever
- chest pain

How DARZALEX FASPRO® works to fight multiple myeloma

DARZALEX FASPRO® is made up of 2 main components:

Daratumumab (pronounced da-ra-tu-mu-mab)
Daratumumab is the ingredient that treats multiple myeloma.



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



DARZALEX FASPRO®

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

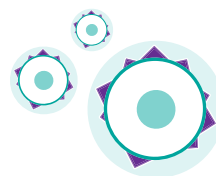
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Select Important Safety Information

- **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. 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.**

Please see additional Important Safety Information on pages 15-18 or [click here](#). Please [click here](#) to see Important Product Information.

Daratumumab in action



Multiple myeloma cells, like other types of cancer, can go unrecognized by your body, which allows the cells to grow.



Daratumumab attaches itself to the **CD38 protein** on the surface of multiple myeloma cells, as well as on certain 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.

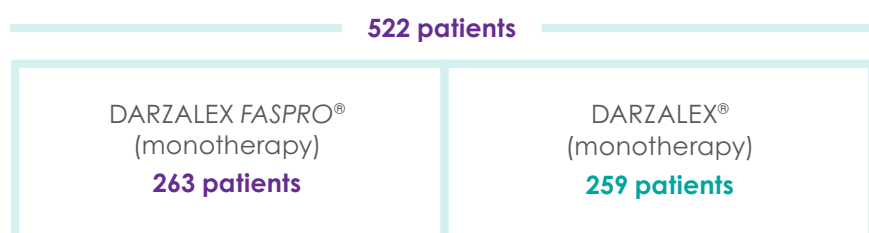
Glossary of terms can be found on [page 20](#).

Results from studies with DARZALEX FASPRO®

How well does DARZALEX FASPRO® work?

A study confirmed that DARZALEX FASPRO® gave patients results comparable to the IV formulation of DARZALEX® (daratumumab) 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 (PI) or an immunomodulatory agent.**



vs



About 4 of 10 patients responded to treatment with DARZALEX FASPRO® compared to about 4 of 10 who responded to treatment with DARZALEX®

In the clinical study, the results were consistent, with a similar number of patients responding to both treatments

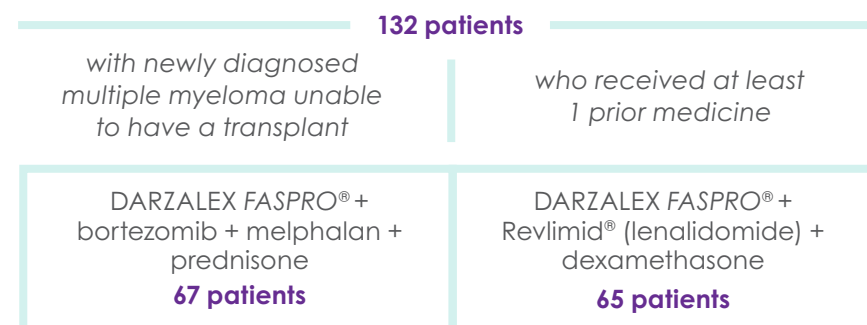
The most common side effects of DARZALEX FASPRO® when used alone include cold-like symptoms (upper respiratory infection).

The most common side effects of DARZALEX FASPRO® used in combination therapy include: tiredness; nausea; diarrhea; shortness of breath; trouble sleeping; fever; cough; muscle spasms; back pain; vomiting; cold-like symptoms (upper-respiratory infection); nerve damage causing tingling, numbness, or pain; constipation; lung infection (pneumonia); swollen hands, ankles, or feet.

Please see additional Important Safety Information on pages 15-18 or [click here](#). Please [click here](#) to see Important Product Information.

How well does DARZALEX FASPRO® work in combination with other therapies?

Additional studies confirmed that DARZALEX FASPRO® is effective when used in combination with bortezomib, melphalan, and prednisone (DVMP), and lenalidomide and dexamethasone (DRd) therapies.



About 9 of 10 patients responded to treatment with DARZALEX FASPRO® in combination with DVMP

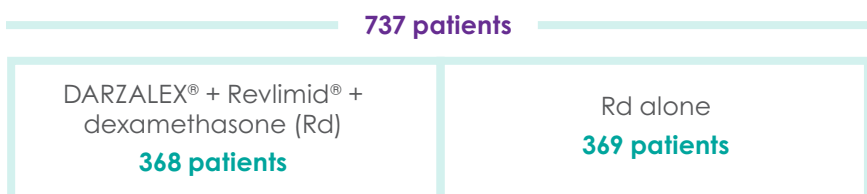


About 9 of 10 patients responded to treatment with DARZALEX FASPRO® in combination with DRd

Additional results

The IV formulation of DARZALEX® (daratumumab) was studied in 737 patients in combination with Revlimid® (lenalidomide) + dexamethasone (Rd) vs Rd alone

- Patients studied had newly diagnosed multiple myeloma and could not receive a type of stem cell transplant that uses their own stem cells



What were some of the main goals of the study?

- 1 To measure the length of time patients lived without their multiple myeloma getting worse
- 2 To measure overall response rate, which is the percentage of patients who responded to treatment

The most common side effects of DARZALEX® include:

- tiredness
- feeling weak
- nerve damage causing tingling, numbness, or pain
- nausea
- fever
- swollen hands, ankles, or feet
- diarrhea
- cough
- constipation
- shortness of breath
- cold-like symptoms (upper respiratory infection)

Please see additional Important Safety Information on pages 15-18 or [click here](#). Please [click here](#) to see Important Product Information.

What were the results of the study?*

The IV formulation of DARZALEX®, in combination with Rd, increased the time patients lived without their multiple myeloma getting worse.



74% of patients treated with the IV formulation of DARZALEX® + Revlimid® + dexamethasone (DRd)

61% of patients treated with Rd alone

More patients responded (overall response rate) to the IV formulation of DARZALEX® in combination with Rd vs Rd alone.



About 9 of 10 patients responded to the IV formulation of DARZALEX® + Rd

About 8 of 10 patients responded to Rd alone

*At a median follow-up of 28 months.

DARZALEX FASPRO® has a fast injection time

DARZALEX FASPRO® is given in about 3 to 5 minutes as an injection



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

- The dosing schedule of DARZALEX FASPRO® depends upon the treatment regimen prescribed

Over time, DARZALEX FASPRO® treatments are needed only once every 4 weeks.

Dosing schedule example

In 4-week-cycle regimens such as DRd, you would receive treatment:

Every week



Weeks 1 to 8

Every 2 weeks



Weeks 9 to 24

Every 4 weeks



after Week 24

- Approximately 20 injections during first year of treatment

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

The healthcare provider will develop a treatment plan that is right for you. If you have questions about the specific DARZALEX FASPRO® regimen, follow up with your healthcare provider.

Keep track of your treatment schedule by downloading the DARZALEX FASPRO® Dosing Calendar at darzalex.com/faspro.

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®. 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) | • nausea |
| • dizziness or lightheadedness (hypotension) | • throat tightness | • vomiting |
| • cough | • runny or stuffy nose | • chills |
| • wheezing | • headache | • fever |
| • heart beating faster than usual | • itching | • chest pain |
| | • high blood pressure | |

Please see additional Important Safety Information on pages 15-18 or [click here](#).

What to expect before, during, and after treatment with DARZALEX FASPRO®

Before the injection

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®.

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.
 - 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 medications you take, including:

- prescription and over-the-counter medicines
- vitamins
- herbal supplements

Please see additional Important Safety Information on pages 15-18 or [click here](#).
Please [click here](#) to see Important Product Information.

What to expect before, during, and after treatment with DARZALEX FASPRO® (cont)

Preparing for the injection

If this is the first time you are receiving treatment with DARZALEX FASPRO®, you may have questions about what it's like and what you need to do to prepare. Here is some information that may help.



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 a reaction to the injection.



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



Tell healthcare providers and blood transfusion centers/personnel that you are taking DARZALEX FASPRO®.

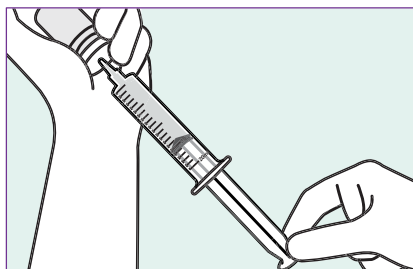
DARZALEX FASPRO® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX FASPRO®. **Tell all of your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

What to expect before, during, and after treatment with DARZALEX FASPRO® (cont)

During the injection

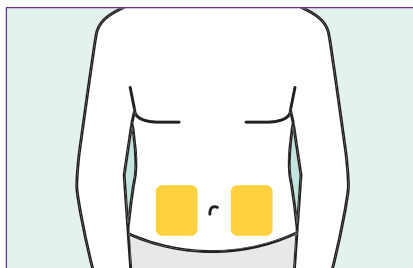
1

Your healthcare provider will prepare the syringe



2

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



3

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.

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®. 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, runny or stuffy nose, headache, itching, high blood pressure, nausea, vomiting, chills, fever, or chest pain.

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

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

Side effects of DARZALEX FASPRO®

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

Reactions to the injection



Among all patients who participated in DARZALEX FASPRO® clinical studies, **9% of the 832 patients taking DARZALEX FASPRO®** by itself or in combination with other multiple myeloma treatments experienced a reaction related to the injection, with most reactions being mild to moderate and occurring after the first injection.

- In these studies, **0.8% of the 832 patients** experienced a severe injection-related reaction with DARZALEX FASPRO®. Signs and symptoms included 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, runny or stuffy nose, headache, itching, high blood pressure, nausea, vomiting, chills, fever, and chest pain



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 **nearly 3 times fewer injection reactions** (systemic) as compared with **34% of the 258 patients** who received the IV formulation of DARZALEX®.

The most common side effects of DARZALEX FASPRO® are tiredness; nausea; diarrhea; shortness of breath; trouble sleeping; fever; cough; muscle spasms; back pain; vomiting; cold-like symptoms (upper-respiratory infection); nerve damage causing tingling, numbness, or pain; constipation; lung infection (pneumonia); and swollen hands, ankles, or feet. In addition, some patients may have skin reactions at or near the injection site (local). In a clinical trial, 8% of patients had local injection-site reactions with injection site redness (erythema) being the most frequent.

Tell your healthcare provider if you have any side effects that are bothersome or that do not go away.

These are not all the possible side effects of DARZALEX FASPRO®. Call your doctor for medical advice about side effects.

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)
- 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 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 bortezomib and dexamethasone in people who have received at least one prior medicine 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.

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- 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.
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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.

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Important Safety Information for DARZALEX FASPRO® (cont)

- 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.

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®. 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
 - runny or stuffy nose
 - headache
 - itching
 - high blood pressure
 - nausea
 - vomiting
 - chills
 - fever
 - chest pain
- **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. 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).

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

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

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 healthcare provider or pharmacist 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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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
- 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 has more information about effective methods of birth control, pregnancy testing, and blood donation for females who can become pregnant

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Important Safety Information for DARZALEX® (cont)

- 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 normal, low oxygen in the blood (hypoxia), throat tightness or irritation, runny or stuffy nose, headache, itching, high blood pressure, nausea, vomiting, chills, fever, or chest discomfort

- **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. 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: tiredness; nausea; diarrhea; shortness of breath; feeling weak; fever; cough; cold-like symptoms (upper respiratory infection); nerve damage causing tingling, numbness, or pain; swollen hands, ankles, or feet; constipation.

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 healthcare provider or pharmacist for information about DARZALEX® that is written for health professionals.

Active ingredient: daratumumab.

Inactive ingredients: glacial acetic acid, mannitol, polysorbate 20, sodium acetate trihydrate, sodium chloride, and water for injection.

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

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Support for patients and their caregivers

Once you and your doctor have decided DARZALEX FASPRO® is right for you, Janssen CarePath will help you find the resources you may need to get started and stay on track. We will give you information on your insurance coverage, potential out-of-pocket costs, and treatment support, as well as identify options that may help make your treatment more affordable.

Janssen CarePath



Paying for DARZALEX FASPRO®

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



Getting started

Janssen CarePath can review your health plan benefits and insurance coverage for DARZALEX FASPRO®, and offer treatment education resources.



Staying on track

We understand how important it is for you to take DARZALEX FASPRO® as your doctor prescribed. Janssen CarePath provides ongoing support to help you stay on track with your DARZALEX FASPRO® treatment.

Please see additional Important Safety Information on pages 15-18 or [click here](#).
Please [click here](#) to see Important Product Information.

Call a Janssen CarePath Care Coordinator at 1-844-55DARZA (1-844-553-2792), Monday–Friday, 8:00 AM to 8:00 PM ET. Multilingual phone support is available.

Set up a personal Janssen CarePath Account at MyJanssenCarePath.com where you can: check your insurance coverage for DARZALEX FASPRO®; if eligible, enroll in the Janssen CarePath Savings Program and manage program benefits; and sign up for treatment support.

Visit JanssenCarePath.com/darzalex/faspro

Glossary

Following are definitions of some words you may read about or hear from your doctor or nurse.

Allergic reaction

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

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 treatment to treat a certain disease or condition.

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 the disease-fighting medicine in DARZALEX FASPRO® 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 your arm.

Please see additional Important Safety Information on pages 15-18 or [click here](#).

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

Median

The middle value in a list of numbers when numbers are placed in numerical order.

Monoclonal antibody

A man-made molecule that binds to certain substances in the body, including cancer cells. Monoclonal antibodies work with your immune system.

Monotherapy

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

M-protein

An abnormal antibody made by myeloma cells that does not fight germs. Also called monoclonal protein.

Multiple myeloma

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

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.

Side effect

An unwanted or unexpected reaction to a drug. Side effects can vary from minor problems like a 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

A short needle and syringe used to inject a drug into the fatty tissue usually below the skin of the stomach.

Doctor Conversation Starter Guide

Starting DARZALEX FASPRO® is a decision you or your loved one makes with the doctor. Here are some questions you may want to ask the doctor or nurse about multiple myeloma and treatment with DARZALEX FASPRO®.



When first diagnosed

About multiple myeloma

- Where is the multiple myeloma located?
- How advanced, or at what stage, is the multiple myeloma, and what does that mean?

About treatment

- Will I need other tests before making a treatment decision?
- How many patients with multiple myeloma are you treating today?

Communicating with the doctor

- Do you have an online portal for test results, appointments, and communications?
- What is the best way to communicate with you in case of an emergency?
- How do we communicate for nonemergency interactions (via email, via phone, through a nurse, through an app)?



When discussing treatment options

Available treatments

- What different treatment options are available?
- Will I need to be on multiple treatments at one time?
- What do you recommend and why?
- How quickly do we need to make a decision?

Managing treatment

- Are there transportation assistance options if I am unable to get to and from treatment?

Please see additional Important Safety Information on pages 15-18 or [click here](#). Please [click here](#) to see Important Product Information.



When considering treatment with DARZALEX FASPRO®

- How does DARZALEX FASPRO® work differently than other treatments?
- How is DARZALEX FASPRO® given?
- What are the goals of treatment with DARZALEX FASPRO®?
- What do I need to know about the treatment schedule?
- What can or should one bring to the treatment appointment?
- Will someone need to accompany me to and from treatments?
- Are there programs that can help make DARZALEX FASPRO® medication more affordable?
- How can I tell if DARZALEX FASPRO® is working?
- How will you monitor results?
- What side effects could I expect from treatment with DARZALEX FASPRO®?
- How can other medications and supplements affect treatment?



When being treated with DARZALEX FASPRO®

- What side effects should I watch for?
- Is it necessary to make any changes to one's diet during or after treatment?
- Can I exercise normally while being treated?
- What type of follow-up will I need after treatment and when?
- How will we know if the cancer has come back? What should I watch for?


Learn more about DARZALEX FASPRO®
at darzalex.com/faspro

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

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Janssen  Oncology

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