

# DARZALEX *Faspro*<sup>®</sup>

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

## Guiding your patients through their treatment with DARZALEX FASPRO<sup>®</sup>



### You play an important role in their treatment journey

An open dialogue with your patients may help them better understand their treatment plan and feel prepared in the regimen chosen by their doctor. This tool can help you talk about DARZALEX FASPRO<sup>®</sup> and answer questions about their diagnosis and treatment plan.

# How to use this guide

**There are 2 versions of this guide.** One version is for you to share with your patients, either as a PDF via email, as a printout given in-office, or via screen sharing on a video call. **This version is for healthcare providers only; do not share this with patients.** Use this document as a reference for talking points and helpful tips when discussing DARZALEX FASPRO® with your patients.

**This conversation guide covers a range of topics about multiple myeloma and DARZALEX FASPRO®, including:**

- What is multiple myeloma and how does it develop
- Approved regimens of DARZALEX FASPRO®
- How DARZALEX FASPRO® works
- Clinical studies for DARZALEX FASPRO®
- What to expect before, during, and after treatment
- Important Safety Information for DARZALEX FASPRO®
- Cost support

You can tailor the conversation to your patient's needs by scrolling between pages or using the buttons at the bottom to jump to new sections. Additional resources and a glossary are also available at the end of the guide. You may direct patients to this section for further information about DARZALEX FASPRO® and useful tools to help them on their treatment journey.

Use these dots to keep track of how many pages are left in a section.



## Short on time?

Use the navigation below to discuss what information you think is most important for your patient to know. The 15-minute and 30-minute buttons here and **at the top of every page** will also take you to recommended sections for patients who are starting treatment soon.



We have 15 minutes ▶



We have 30 minutes ▶

If you're short on time, use these buttons to skip ahead to important sections.

START 15-MINUTE DISCUSSION

START 30-MINUTE DISCUSSION

Use this page to discuss with patients where they are in their treatment journey.

## Talking points

- Your journey is as unique as you are
- Your healthcare team shares your goal of treating your disease in the way that's best for you
  - This conversation will help you learn about DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) and why your healthcare team believes **this is the appropriate treatment for your multiple myeloma**
- If you have any questions or concerns as we discuss DARZALEX FASPRO®, feel free to ask them now or make note of them to bring to your next doctor's appointment. **Remember, you are your own best advocate**
- Any bolded terms you see throughout this guide are defined in the glossary at the end

FOR PATIENTS RECEIVING

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

**Managing your multiple myeloma with DARZALEX FASPRO®**

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.

[DARZALEX Faspro®](#) | [About multiple myeloma](#) | [About DARZALEX FASPRO®](#) | [Clinical benefits](#) | [Expectations for treatment](#) | [Important Safety Information](#) | [Patient support](#) | [Glossary](#)

**Your journey with multiple myeloma is unique.**

**For your specific needs, your healthcare team chose a treatment regimen with DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj).**

This guide will help you learn more about DARZALEX FASPRO® and how it fits into your treatment plan for multiple myeloma. Remember, you are your own best advocate. If you have any concerns about your treatment plan, feel free to ask questions to stay involved.

Any terms in **bold** are defined at the end of this guide in the glossary.

**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
- in combination with the medicines carfilzomib and dexamethasone in people 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.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.

[DARZALEX Faspro®](#) | [About multiple myeloma](#) | [About DARZALEX FASPRO®](#) | [Clinical benefits](#) | [Expectations for treatment](#) | [Important Safety Information](#) | [Patient support](#) | [Glossary](#)



Ask the patient if they have a support system in place. Having a friend or family member who can help run errands or a caregiver who can come to appointments and support their treatment journey may help ease the burden.

# What is multiple myeloma?

START 15-MINUTE DISCUSSION >

START 30-MINUTE DISCUSSION >

Direct patients to click on the About multiple myeloma button. Use this page to give a summary of how multiple myeloma develops and how it affects the body. If your patient is already familiar with this information, you may skip ahead to the About DARZALEX FASPRO® section.

## Key takeaway

Multiple myeloma affects plasma cells in bone marrow, which can lead to long-term damage and problems throughout the body.

## Talking points

- **Multiple myeloma is a blood cancer** that affects a type of white blood cell called plasma cells
  - These cells are found mostly in the bone marrow, the soft substance inside some hollow bones where blood cells are made
- Normal, healthy plasma cells are responsible for producing antibodies
  - Antibodies are part of the immune system and help the body fight infections
- **In multiple myeloma, the DNA, or genetic material, of plasma cells are damaged,** causing them to overproduce
  - This can weaken the immune system and lead to the production of abnormal amounts of antibodies
  - These antibodies are called M-proteins
  - M-proteins are abnormal antibodies that don't help the body fight infections
  - **High amounts of M-protein can damage the kidneys**
  - **These damaged or cancerous plasma cells rapidly spread and replace normal cells with tumors,** usually in the bone marrow

**What is multiple myeloma?**

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.

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

[Click here](#) for Important Product Information. Please see additional Important Safety information on pages 18-21.

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

About multiple myeloma

About DARZALEX FASPRO® | Clinical benefits | Expectations for treatment | Important Safety Information | Patient support | Glossary

Use this page to discuss the possibility of multiple myeloma getting worse and how the doctor will manage the various stages.

## Key takeaway

Multiple myeloma can get worse over time, so it's important to stay on top of treatment and communicate with your doctor.

## Talking points

- Over time, multiple myeloma can get worse
- **You may start to show more symptoms as the cancer spreads** to different parts of the body
  - Depending on where the cancer spreads, **you may experience different symptoms**
- To experience the full benefits of your treatment plan, **stay on treatment** as directed by your doctor
- **If you experience any negative side effects, let your doctor know immediately**
  - If you are experiencing reactions to the treatment, you and your doctor can decide next steps together

The thumbnail shows the top portion of the 'Staying on treatment' page. It features a purple header with the title 'Staying on treatment' and a yellow background for the main content. The text reads: 'Over time, multiple myeloma can get worse.' Below this are three key points, each with an icon: 1. A person icon: 'As multiple myeloma progresses, you may start to show more symptoms, or the cancer might start to spread and impact other parts of your body.' 2. A calendar icon: 'To experience the full benefits of your treatment plan, it's important to receive treatment as directed by your doctor and stay on it as long as your doctor determines is appropriate.' 3. A speech bubble icon: 'If you experience any negative side effects, let your doctor know immediately and you can decide on the next steps together.' At the bottom of the thumbnail, there is a footer with a 'Click here' link for product information and a navigation menu with links for 'About DARZALEX FASPRO', 'Clinical benefits', 'Expectations for treatment', 'Important Safety Information', 'Patient support', and 'Glossary'. A page number '4' is visible in the bottom right corner of the thumbnail.

Direct patients to click on the About DARZALEX FASPRO® button. Use this page to discuss the patient's prescribed regimen with DARZALEX FASPRO®.

## Key takeaway

DARZALEX FASPRO® is approved in several regimens for multiple myeloma. Let's talk about the one prescribed for your needs.

## Talking points

- DARZALEX FASPRO® is a prescription medicine used to treat different types of patients with multiple myeloma
- It is given as a **subcutaneous injection**
  - That means DARZALEX FASPRO® is injected by your healthcare provider under the skin near your stomach
- Use the appropriate graphic to discuss your patient's regimen:
  - If you are newly diagnosed with multiple myeloma and cannot receive a type of transplant that uses your own stem cells (autologous stem cell transplant), you may receive **DARZALEX FASPRO® in combination with Revlimid® (lenalidomide) and dexamethasone, in combination with Velcade® (bortezomib), melphalan, and prednisone**
  - If you are newly diagnosed with multiple myeloma and can receive a type of transplant that uses your own stem cells (autologous stem cell transplant), you may receive **DARZALEX FASPRO® in combination with Velcade® (bortezomib), thalidomide, and dexamethasone**
  - If you have received at least 1 prior medicine to treat your multiple myeloma,

you may receive **DARZALEX FASPRO® in combination with Revlimid® and dexamethasone, in combination with Pomalyst® (pomalidomide) and dexamethasone, or in combination with Velcade® and dexamethasone**

- If you have received at least one prior medicine including lenalidomide and a proteasome inhibitor, you may receive DARZALEX FASPRO® in combination with pomalidomide and dexamethasone
- If you have received at least 3 prior medicines to treat your multiple myeloma, including an immunomodulatory agent, such as Revlimid®, and a proteasome inhibitor (PI), such as Velcade®, or did not respond to a PI and an immunomodulatory agent, you may receive **DARZALEX FASPRO® as a monotherapy (by itself)**
- You should also inform your patient that they should not receive DARZALEX FASPRO® if they've had a severe allergic reaction to DARZALEX FASPRO® or any of its [ingredients](#)
  - You should begin to review some of the Important Safety Information and let the patient know that you will be discussing it in more detail later

**What is DARZALEX FASPRO®?**

DARZALEX FASPRO® is a prescription medicine used to treat different types of patients with multiple myeloma. It is given by your healthcare provider as an injection in the subcutaneous tissue (the tissue under the skin) of the stomach.

For newly diagnosed patients who cannot receive a transplant	For newly diagnosed patients who can receive a transplant	For patients who have received ≥1 prior medicine	For patients who have received ≥3 prior medicines
<b>DRd</b> DARZALEX FASPRO® + Revlimid® (lenalidomide) + dexamethasone	<b>DVd</b> DARZALEX FASPRO® + Velcade® (bortezomib) + thalidomide + dexamethasone	<b>DRd</b> DARZALEX FASPRO® + Revlimid® + dexamethasone	<b>Monotherapy</b> DARZALEX FASPRO® alone
<b>DVMP</b> DARZALEX FASPRO® + Velcade® (bortezomib) + melphalan + prednisone		<b>DRd</b> DARZALEX FASPRO® + Pomalyst® + dexamethasone	
		<b>DVd</b> DARZALEX FASPRO® + Velcade® + dexamethasone	

**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)

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.

Navigation: DARZALEX Faspro® (daratumumab and hyaluronidase-fihj) Injection for subcutaneous use | 1,800mg/50,000units | About multiple myeloma | About DARZALEX FASPRO® | Clinical benefits | Expectations for treatment | Important Safety Information | Patient support | Glossary

**Tip**

After you've discussed your patient's prescribed regimen, you may direct them to [www.darzalex.com/faspro](http://www.darzalex.com/faspro) to download a treatment calendar for their regimen to plan their appointments.



Use this page to explain the components of DARZALEX FASPRO® and how it treats multiple myeloma.

## Key takeaway

DARZALEX FASPRO® helps your own immune system identify and destroy multiple myeloma cells.

## Talking points

- DARZALEX FASPRO® has 2 main ingredients:
  - Daratumumab, which is responsible for **treating multiple myeloma**
  - Hyaluronidase, which helps daratumumab to be injected into the skin and absorbed into the body. **Hyaluronidase is what allows DARZALEX FASPRO® to be injected subcutaneously**
- DARZALEX FASPRO® is not chemotherapy. It is an immunotherapy that uses **your own body's immune system to fight multiple myeloma**
- Here's how daratumumab fights the disease:
  - Multiple myeloma cells, like other types of cancer, can go unrecognized by your body, which allows cells to grow
  - Daratumumab is a monoclonal antibody. That means it attaches specifically to the CD38 protein found on the **surface of multiple myeloma cells**, as well as other types of cells such as red blood cells
  - Daratumumab works in a few different ways. **It can directly kill multiple myeloma cells, or it can help the immune system identify cancerous cells 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

**How does DARZALEX FASPRO® work?**

DARZALEX FASPRO® is made up of 2 main components:

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

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

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

**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.

**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.

[Click here](#) for Important Product Information. Please see additional Important Safety information on pages 18-21.

Navigation menu: DARZALEX Faspro® (daratumumab and hyaluronidase-fihj) Injection for subcutaneous use | 1,800mg/50,000units | About multiple myeloma | About DARZALEX FASPRO® | Clinical benefits | Expectations for treatment | Important Safety Information | Patient support | Glossary

## Tip

A video explanation of the mechanism of action for DARZALEX FASPRO® is available for healthcare professionals at [www.darzalexhcp.com/faspro](http://www.darzalexhcp.com/faspro). Consider watching this video as a refresher before discussing how DARZALEX FASPRO® works with your patients.

Direct patients to click on the Clinical Benefits button in the navigation. Use this page to discuss the noninferiority study between DARZALEX FASPRO® and DARZALEX® (daratumumab). If your patient is already familiar and confident in the clinical benefits of DARZALEX FASPRO®, you may jump ahead to expectations for treatment.

## Key takeaway

DARZALEX FASPRO® was compared in a clinical study with the intravenous formulation, DARZALEX®.

## Talking points

- A clinical study evaluated how well DARZALEX FASPRO®, a subcutaneous injection, works compared to DARZALEX®, an intravenous infusion **with the same ingredient that treats multiple myeloma**
  - DARZALEX® is a **proven treatment in multiple combinations for managing multiple myeloma**
- In the study, patients with multiple myeloma had received at least 3 prior medicines or did not respond to a PI like Velcade® (bortezomib) or an immunomodulatory agent like Revlimid® (lenalidomide)
- 522 patients were enrolled in the study
  - 263 patients were given DARZALEX FASPRO® monotherapy
  - 259 patients were given DARZALEX® monotherapy
- The next page covers the results of the study

**Monotherapy study**

A clinical study confirmed that DARZALEX FASPRO® gave patients results comparable to the intravenous (IV) formulation of DARZALEX® (daratumumab) in treating multiple myeloma when used as **monotherapy** (by itself). DARZALEX® is an IV infusion with the same disease-fighting ingredient as DARZALEX FASPRO® that is proven effective in multiple combinations to fight multiple myeloma.

**Patients in this study had multiple myeloma and:**

- Received at least 3 prior medicines **OR**
- Did not respond to a **proteasome inhibitor (PI)** and an **immunomodulatory agent**

**522**  
patients in this study

DARZALEX FASPRO® (monotherapy) 263 patients	DARZALEX® (monotherapy) 259 patients
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**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.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.

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

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# Results from the monotherapy study

START 15-MINUTE DISCUSSION >

START 30-MINUTE DISCUSSION >

Use this page to discuss the results from the noninferiority study between DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) and DARZALEX® (daratumumab).

## Key takeaway

This study confirmed that DARZALEX FASPRO® monotherapy delivers responses consistent with DARZALEX® monotherapy.

## Talking points

- A similar proportion of patients responded to each treatment
  - About 4 of 10 patients responded to treatment with DARZALEX FASPRO®
  - About 4 of 10 patients responded to treatment with DARZALEX®
- DARZALEX FASPRO® delivered responses consistent with DARZALEX®, a well-studied, proven treatment for multiple myeloma

Now let's review how well DARZALEX FASPRO® works in combination with other medicines.

The infographic displays two side-by-side statistics. On the left, under 'DARZALEX FASPRO® (monotherapy)', a circular icon shows 41% with the text 'About 4 of 10 patients responded to treatment with DARZALEX FASPRO®'. On the right, under 'DARZALEX® (monotherapy)', a circular icon shows 37% with the text 'About 4 of 10 patients responded to treatment with DARZALEX®'. A 'VS' icon is placed between the two circles. Below the statistics, a line of text states: 'Responses in patients treated with DARZALEX FASPRO® were consistent with those treated with DARZALEX®, a proven treatment for multiple myeloma'. Below this is a section for 'IMPORTANT SAFETY INFORMATION (CONT)' with several bullet points regarding combination therapy and pregnancy. At the bottom, there is a navigation bar with links for 'About multiple myeloma', 'About DARZALEX FASPRO®', 'Clinical benefits', 'Expectations for treatment', 'Important Safety Information', 'Patient support', and 'Glossary'. A 'Click here for Important Product Information' link is also present.

# Combination therapy study

START 15-MINUTE DISCUSSION

START 30-MINUTE DISCUSSION

Use this page to discuss the study in which DARZALEX FASPRO® was evaluated in various combinations with other medicines for different patient types.

## Key takeaway

Studies have evaluated how well DARZALEX FASPRO® works in combination therapy. The details of one of these combination regimens is available here.

## Talking points

- A study confirmed that DARZALEX FASPRO® is **effective when used in combination with other medicines**
- This study evaluated 132 patients
  - 67 patients with newly diagnosed multiple myeloma who could not receive a transplant received DARZALEX FASPRO® in combination with Velcade®, melphalan, and prednisone
  - 65 patients who had received at least 1 prior medicine to treat their multiple myeloma received DARZALEX FASPRO® in combination with Revlimid® and dexamethasone
- The next page covers the results of this study

**Combination therapy study**

Several studies have evaluated combination therapies using DARZALEX FASPRO®. These studies confirmed that DARZALEX FASPRO® is effective when used in combination with other medicines (DVMP and DRd results are shown here).

**132**  
patients in this study

Regimen	Number of Patients
DVMP (With newly diagnosed multiple myeloma unable to have a transplant) DARZALEX FASPRO® + Velcade® (bortezomib) + melphalan + prednisone	67 patients
DRd (Who received at least 1 prior medicine) DARZALEX FASPRO® + Revlimid® (lenalidomide) + dexamethasone	65 patients

**IMPORTANT SAFETY INFORMATION (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.

**How will I receive DARZALEX FASPRO®?**

- DARZALEX FASPRO® may be given alone or together with other medicines used to treat multiple myeloma.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.

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# Results from the combination therapy study

START 15-MINUTE DISCUSSION

START 30-MINUTE DISCUSSION

Use this page to discuss the results of the combination therapy study.

## Key takeaway

DARZALEX FASPRO® was proven effective in combination with different medicines for different types of patients with multiple myeloma.

## Talking points

- **About 9 of 10 patients** responded to treatment with DARZALEX FASPRO® in combination with bortezomib, melphalan, and prednisone
- **About 9 of 10 patients** responded to treatment with DARZALEX FASPRO® in combination with lenalidomide and dexamethasone

If you want to know more about how well your prescribed regimen with DARZALEX FASPRO® will work, bring it up at your next doctor's appointment, or visit [www.darzalex.com/faspro](http://www.darzalex.com/faspro).

**Results from the combination therapy study**

**DVMP**  
About 9 of 10 patients responded to treatment with DARZALEX FASPRO® in combination with bortezomib, melphalan, and prednisone. **88%**

**DRd**  
About 9 of 10 patients responded to treatment with DARZALEX FASPRO® in combination with lenalidomide and dexamethasone. **91%**

Ask your doctor for more information about how they expect you will respond to your prescribed regimen of DARZALEX FASPRO®

**IMPORTANT SAFETY INFORMATION (CONT)**  
How will I receive DARZALEX FASPRO®?  
• 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.

[Click here](#) for Important Product Information. Please see additional Important Safety information on pages 18-21. **10**

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# Treatment checklist for DARZALEX FASPRO®

15-MINUTE DISCUSSION

30-MINUTE DISCUSSION

This page is a checklist that patients may refer to when preparing for their treatment plan with DARZALEX FASPRO®.

## Talking points

- This page has important steps you should take before, during, and after the day of your injection of DARZALEX FASPRO®
- As we read through these together, make note of any questions you have and we will discuss it in more detail on the following pages

**Your treatment checklist for DARZALEX FASPRO®**

**Before your injection**

**Tell your doctor about:**

- All of your medical conditions
- All of the medications you are taking

**Ask your doctor about your treatment goals with DARZALEX FASPRO®. For example:**

- How will you know this treatment is working?
- What response are you hoping to see with DARZALEX FASPRO®?
- How long should I expect to stay on this treatment regimen?

**Day of your injection**

- Wear comfortable clothing that is loose around the waist
- Set aside enough time
- Take the medications your doctor will give you prior to the injection
- Tell your healthcare providers and personnel of blood transfusion centers that you are taking DARZALEX FASPRO®

**After your injection**

- Pay attention to how you feel
- Tell your doctor immediately if you experience any side effects or reactions

**IMPORTANT SAFETY INFORMATION (CONT)**

**DARZALEX FASPRO® may cause serious reactions, including:**

- Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO®. 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
  - heart beating faster than usual
  - itching
  - dizziness or lightheadedness (hypotension)
  - low oxygen in the blood (hypoxia)
  - high blood pressure
  - fever
  - cough
  - throat tightness
  - nausea
  - chest pain
  - wheezing
  - runny or stuffy nose
  - vomiting
  - blurred vision
  - headache

[Click here](#) for important Product Information. Please see additional Important Safety Information on pages 18-21. **11**

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## Tip

Advise patients that they may want to save this checklist and add any questions they may have, and bring it to their next doctor's appointment.

12N

Direct patients to click on the **Expectations for treatment** button in the navigation. Use this page to discuss what the patient should do before starting treatment with DARZALEX FASPRO®.

## Key takeaway

Tell your doctor about all of your medical conditions and any prescription or over-the-counter medicines, vitamins, or supplements that you take.

## Talking points

- Let's now talk about what you can expect before, during, and after treatment with DARZALEX FASPRO®
- Before you receive your first injection of DARZALEX FASPRO®, **make sure you tell your healthcare provider, such as me or the 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 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

**Before your injection**

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 have a hepatitis B infection
- ✓ Are pregnant or plan to become pregnant
- ✓ Are breastfeeding or plan to breastfeed

For additional information about how these conditions are affected by or impact treatment with DARZALEX FASPRO®, download the patient brochure at [www.darzalex.com/faspro](http://www.darzalex.com/faspro).

About all of the medications you take, including:

- ✓ Prescription and over-the-counter medicines
- ✓ Vitamins
- ✓ Herbal supplements

**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®.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.

DARZALEX Faspro® (daratumumab and hyaluronidase-fihj) Injection for subcutaneous use | 1,800mg/50,000units

About multiple myeloma | About DARZALEX FASPRO® | Clinical benefits | **Expectations for treatment** | Important Safety Information | Patient support | Glossary

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, such as me or the doctor, 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.

Use this page to discuss how the patient can prepare for their first injection of DARZALEX FASPRO®. If the patient is familiar with this information, you may skip to the next page.

## Key takeaway

On the day of your injection, wear comfortable clothing and make sure you set aside enough time for your doctor's appointment.

## Talking points

- Is this the first time you are receiving treatment with DARZALEX FASPRO®? If so, let's talk about how you can prepare
- **Wear comfortable clothing that is loose around the waist.** Your healthcare provider will inject DARZALEX FASPRO® about 3 inches to the left or right of the belly button
- **Set aside enough time.** We will want you to stay afterward to monitor for any reactions to the injection
- We will give you medicines to help reduce the side effects to the injection, including:
  - Antihistamines to prevent an allergic reaction
  - Corticosteroids to prevent inflammation
  - Acetaminophen or a similar medicine to reduce any fever
- We will give you **a physical exam before the injection**, including checking your pulse and blood pressure
- Make sure you **tell your healthcare providers and personnel at blood transfusion centers 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®
  - We will do blood tests to match your blood type before you start treatment with DARZALEX FASPRO®
  - Tell all healthcare providers you are receiving DARZALEX FASPRO® before you receive a blood transfusion

The thumbnail shows the 'Preparing for your injection' page. It includes sections for 'Wear comfortable clothing that is loose around the waist', 'You will be given a physical exam before the injection', 'Set aside enough time', and 'You will be given medicines to help reduce the risk of side effects to the injection, such as:'. It also features 'IMPORTANT SAFETY INFORMATION (CONT)' and a navigation bar at the bottom with links for 'About multiple myeloma', 'About DARZALEX FASPRO®', 'Clinical benefits', 'Expectations for treatment', 'Important Safety Information', 'Patient support', and 'Glossary'. The page number '13' is visible in the bottom right corner.

Use this page to discuss what the patient can expect during the injection and how DARZALEX FASPRO® will be administered.

## Key takeaway

DARZALEX FASPRO® is injected in about 3 to 5 minutes.

## Talking points

- During the injection, your healthcare provider will draw DARZALEX FASPRO® into a needle
- They will select where to inject and prepare the chosen area, rotating injection sites in the **stomach area** each time you receive an injection
- The injection takes about **3 to 5 minutes** to be given. It is injected into the tissue under the skin of the stomach
  - Note that 3 to 5 minutes does not include all aspects of treatment. We will ask you to stay in the office so we can **monitor for any reactions to the injection**
- **If you feel any discomfort during the injection, let us know right away**

**During your injection**

**1** Your healthcare provider will **prepare the injection**

**2** Your healthcare provider will **determine where to inject and prepare the chosen area**, 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.

**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.**

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

[Click here](#) for Important Product Information. Please see additional Important Safety information on pages 18-21.

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DARZALEX Faspro® (daratumumab and hyaluronidase-fihj) Injection for subcutaneous use | 1,800mg/50,000units

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## Tip

A video explaining how DARZALEX FASPRO® is administered is available for healthcare professionals on [www.darzalexhcp.com/faspro](http://www.darzalexhcp.com/faspro). You may find it useful to review this video prior to discussing DARZALEX FASPRO® with patients.

Use this page to discuss what patients should expect after receiving an injection of DARZALEX FASPRO®.

## Key takeaway

After the injection, you will be monitored for any reactions.

## Talking points

- After the injection, pay attention to how you feel and **let the healthcare staff know about any discomfort**, especially during the first and second injections
  - Discomfort may mean you are having a reaction to the treatment
- If you have a history of severe allergic reactions to daratumumab, hyaluronidase, or any of the ingredients in DARZALEX FASPRO®, let me know now or before you receive your first injection of DARZALEX FASPRO®
- **We may ask you to stay in the office after you receive the injection to watch for any side effects**
- 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

- 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®

The screenshot shows a patient education page with a purple header 'After your injection'. It contains several sections: 'Pay attention to how you feel...', 'Do not receive DARZALEX FASPRO® if you have a history of a severe allergic reaction...', '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.', 'Injection site reactions.', and 'It's important to stay on treatment as directed by your doctor...'. A table lists symptoms like shortness of breath, heart beating faster, high blood pressure, etc. The page number '15' is visible in the bottom right corner.

- We will also give you oral corticosteroids to reduce the risk of delayed reactions from administration of DARZALEX FASPRO®
- It's important to stay on treatment as directed by your doctor to feel the full benefits of treatment
  - Discuss next steps with your doctor if you experience any reactions to the injection



Use this page to discuss the rates of side effects of DARZALEX FASPRO® in clinical trials.

## Talking points

- You may experience side effects from treatment
  - Side effects are an unwanted or unexpected treatment reaction to a drug that can occur anywhere due to the administration of treatment
- Reactions to the injection
  - Among all patients who participated in DARZALEX FASPRO® clinical studies, 9% of the 898 patients taking DARZALEX FASPRO® by itself or in combination with other multiple myeloma treatments experienced a reaction related to the injection
    - Most reactions were mild to moderate and occurred after the first injection**
- 0.8% of the 898 patients experienced a severe injection-related reaction
  - 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, chest pain, and blurred vision

Side effects

**You may experience side effects from treatment**

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

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

**Reactions to the injection**

9%

- Among all patients who participated in DARZALEX FASPRO® clinical studies, **9% of the 832 patients taking DARZALEX FASPRO®** as monotherapy or as part of combination therapy 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.

**IMPORTANT SAFETY INFORMATION (CONT)**

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

<ul style="list-style-type: none"> <li>• tiredness</li> <li>• nausea</li> <li>• diarrhea</li> <li>• shortness of breath</li> <li>• trouble sleeping</li> <li>• headache</li> </ul>	<ul style="list-style-type: none"> <li>• fever</li> <li>• cough</li> <li>• muscle spasms</li> <li>• back pain</li> <li>• vomiting</li> <li>• high blood pressure</li> </ul>	<ul style="list-style-type: none"> <li>• cold-like symptoms (upper respiratory infection)</li> <li>• nerve damage causing tingling, numbness, or pain</li> <li>• constipation</li> <li>• lung infection (pneumonia)</li> </ul>	<ul style="list-style-type: none"> <li>• swollen hands, ankles, or feet</li> <li>• decreased red blood cell counts</li> </ul>
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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.

[Click here](#) for Important Product Information. Please see additional Important Safety information on pages 18-21.

DARZALEX Faspro®  
(daratumumab and hyaluronidase-fihj)  
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Use this page to discuss possible side effects of DARZALEX FASPRO®.

## Talking points

- In the clinical study comparing DARZALEX FASPRO® and DARZALEX®, **nearly 3 times fewer patients experienced a reaction with DARZALEX FASPRO®** compared with the IV formulation of DARZALEX®
  - 13% of the 260 patients who received DARZALEX FASPRO® **did not experience an injection reaction (systemic)** compared with 35% of the 258 patients who received DARZALEX®
- The most common side effects of DARZALEX FASPRO® are cold-like symptoms (upper respiratory tract infection) and changes in blood cell counts
  - Some patients may have skin reactions at or near the injection site (local)
  - 8% of patents had a local injection-site reaction with injection site redness (called erythema) being the most frequent
- Tell your healthcare provider if you have any side effects that are bothersome or do not go away
- Remember, these are not all the possible side effects of DARZALEX FASPRO®. Call your doctor for medical advice about side effects

**Side effects (cont)**

**Fewer patients experienced reactions with DARZALEX FASPRO®**

**nearly 3x fewer** In a clinical study that compared DARZALEX FASPRO® (monotherapy) with 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 cold-like symptoms (upper respiratory infection) and changes in blood cell counts. 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.**

**IMPORTANT SAFETY INFORMATION (CONT)**

**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

[Click here](#) for important Product Information. Please see additional Important Safety Information on pages 18-21.

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DARZALEX Faspro® (daratumumab and hyaluronidase-fihj) Injection for subcutaneous use | 1,800mg/50,000units

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## Tip

Ask your patient if they have any more questions about DARZALEX FASPRO®. Tell them to make note of any questions that you cannot answer using this guide and to bring them to their next doctor's appointment.

Stress the importance of open communication during visits. Ask patients to keep track of what they notice during and between injections.

This page contains Important Safety Information for patients taking DARZALEX FASPRO®. It is important that you review the Important Safety Information with each patient. Emphasize the need for patients to make their doctor aware of any side effect that bothers them or does not go away.

## Talking points

- This is important information for patients who are treated with DARZALEX FASPRO®; as I read through it with you, make a note of any questions you might have
- Remember to be mindful of how you're feeling
- Letting your treatment team know of any side effects that bother you or don't go away is incredibly important

## Tip

Provide patients with a copy of the Important Safety Information and/or the patient brochure. Encourage patients to read through them thoroughly and write down any questions they may have.

### Indications and Important Safety Information

**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
- in combination with the medicines carfilzomib and dexamethasone in people 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 [labeling](#) 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)

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[Click here](#) for Important Product Information.

### 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.
- 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.

**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.

Continued on next page **19**

[Click here](#) for Important Product Information.

### Important Safety Information (cont)

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

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[Click here](#) for Important Product Information.

### Important Safety Information (cont)

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

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

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

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.**  
 cp-1432827

Continued on next page **21**

[Click here](#) for Important Product Information.



Direct patients to click on the Patient support button in the navigation. Use this page to discuss the patient support program for DARZALEX FASPRO® with Janssen CarePath as well as additional resources available to help them on their treatment journey.

## Talking points

- Support for patients and their caregivers
  - Once you and your doctor have decided that DARZALEX FASPRO® is right for you, Janssen CarePath will help you find the resources you may need to get started and stay on track
  - Janssen CarePath will give you information on your insurance coverage, potential out-of-pocket costs, and treatment support, and identify options that may help make your treatment more affordable
  - **Call a Janssen CarePath Care Coordinator today at 1-844-55DARZA (1-844-553-2792), Monday-Friday 8:00 AM to 8:00 PM ET, create a Janssen CarePath Account at [MyJanssenCarePath.com](http://MyJanssenCarePath.com) or visit [JanssenCarePath.com/Darzalex-Faspro](http://JanssenCarePath.com/Darzalex-Faspro)**
- Here are some additional resources available on the website for DARZALEX FASPRO®, [www.darzalex.com/faspro](http://www.darzalex.com/faspro)
- Consider using these materials to help you on your treatment journey
- To download the information discussed in this piece and find these resources, visit [www.darzalex.com/faspro](http://www.darzalex.com/faspro)

The screenshot shows the 'Support for patients and their caregivers' page. At the top, there's a header with a person icon and the text 'Support for patients and their caregivers'. Below this is a section for 'Janssen CarePath' with a message: 'Once you and your doctor have decided that 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, and identify options that may help make your treatment more affordable. Call a Janssen CarePath Care Coordinator today at 1-844-55DARZA (1-844-553-2792), Monday-Friday 8:00 AM to 8:00 PM ET, create a Janssen CarePath Account at [MyJanssenCarePath.com](http://MyJanssenCarePath.com) or visit [JanssenCarePath.com/Darzalex-Faspro](http://JanssenCarePath.com/Darzalex-Faspro).' Below this is a section titled 'Additional resources available online' with a sub-header: 'If you're looking for more information about DARZALEX FASPRO®, visit [www.darzalex.com/faspro](http://www.darzalex.com/faspro) for useful tools and materials to help you on your treatment journey:'. There are four resource cards: 'Patient Brochure' (Use this comprehensive resource to learn more about the treatment experience with DARZALEX FASPRO®), 'Watch a patient's experience' (See another patient's treatment journey with DARZALEX FASPRO®), 'Doctor Conversation Starter' (Create a list of questions based on your needs and interests to bring to your next doctor's appointment), and 'Treatment Calendar' (Keep track of your dosing schedule and plan with your doctor for your next visit). At the bottom, there's a footer with a navigation menu: 'DARZALEX Faspro® (daratumumab and hyaluronidase-fihj) Injection for subcutaneous use | 1,800mg/30,000units', 'About multiple myeloma', 'About DARZALEX FASPRO®', 'Clinical benefits', 'Expectations for treatment', 'Important Safety Information', 'Patient support' (highlighted with a person icon), and 'Glossary'. A page number '22' is visible in the bottom right corner.

## Tip

Patients may consider enrolling in Janssen CarePath patient support for DARZALEX FASPRO® for continual support throughout their treatment journey.

# Glossary

This glossary defines terms that patients may be unfamiliar with. Encourage them to ask you for definitions as you come across the bolded terms in your discussion.

## Talking points

- This glossary contains the definitions for the bolded terms that appear throughout this piece
- This is the last page we have to review
- Let your healthcare team know if you have any questions



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**Glossary**

**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 treatment to treat a certain disease or condition.

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

**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.

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

[Click here](#) for important Product Information. Please see additional Important Safety Information on pages 18-21.

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**Glossary (cont)**

**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.

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FOR PATIENTS RECEIVING

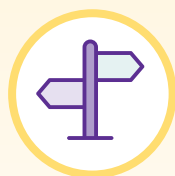


**DARZALEX Faspro**<sup>®</sup>  
(daratumumab and hyaluronidase-fihj)  
Injection for subcutaneous use | 1,800mg/30,000units

## Managing your multiple myeloma with DARZALEX FASPRO<sup>®</sup>

[Click here](#) for Important Product Information.

Please see additional Important Safety Information on pages 18-21.



# Your journey with multiple myeloma is unique.

## For your specific needs, your healthcare team chose a treatment regimen with **DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)**.

This guide will help you learn more about DARZALEX FASPRO® and how it fits into your treatment plan for multiple myeloma. Remember, you are your own best advocate. If you have any concerns about your treatment plan, feel free to ask questions to stay involved.

Any terms in **bold** are defined at the end of this guide in the glossary.

## 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
- in combination with the medicines carfilzomib and dexamethasone in people 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

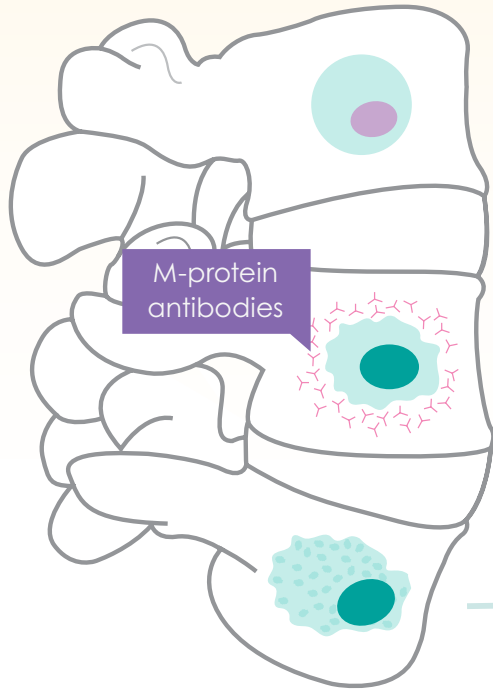
It is not known if DARZALEX FASPRO® is safe and effective in children.

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# What is multiple myeloma?

**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.



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

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# Staying on treatment

Over time, multiple myeloma can get worse.



As multiple myeloma progresses, **you may start to show more symptoms**, or the cancer might start to spread and impact other parts of your body.



To experience the full benefits of your treatment plan, **it's important to receive treatment as directed by your doctor and stay on it as long as your doctor determines is appropriate.**



If you experience any negative side effects, **let your doctor know immediately and you can decide on the next steps together.**

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# What is DARZALEX FASPRO®?

**DARZALEX FASPRO®** is a prescription medicine used to treat different types of patients with multiple myeloma. It is given by your healthcare provider as an injection in the subcutaneous tissue (the tissue under the skin) of the stomach.

*For newly diagnosed patients who cannot receive a transplant*

### DRd

DARZALEX FASPRO® + Revlimid® (lenalidomide) + dexamethasone

### DVMP

DARZALEX FASPRO® + Velcade® (bortezomib) + melphalan + prednisone

*For newly diagnosed patients who can receive a transplant*

### DVTd

DARZALEX FASPRO® + Velcade® (bortezomib) + thalidomide + dexamethasone

*For patients who have received ≥1 prior medicine*

### DRd

DARZALEX FASPRO® + Revlimid® + dexamethasone

### DPd

DARZALEX FASPRO® + Pomalyst® + dexamethasone

### DVd

DARZALEX FASPRO® + Velcade® + dexamethasone

*For patients who have received ≥3 prior medicines*

### Monotherapy

DARZALEX FASPRO® alone

## 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)

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# How does DARZALEX FASPRO® work?

DARZALEX FASPRO® is made up of 2 main components:

## Daratumumab

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

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



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

**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.

## 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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# Monotherapy study

A clinical study confirmed that DARZALEX FASPRO® gave patients results comparable to the intravenous (IV) formulation of DARZALEX® (daratumumab) in treating multiple myeloma when used as **monotherapy** (by itself). DARZALEX® is an IV infusion with the same disease-fighting ingredient as DARZALEX FASPRO® that is proven effective in multiple combinations to fight multiple myeloma.

## Patients in this study had multiple myeloma and:

- Received at least 3 prior medicines **OR**
- Did not respond to a **proteasome inhibitor** (PI) and an **immunomodulatory agent**

**522**  
patients in this study



DARZALEX FASPRO® (monotherapy)  
**263 patients**



DARZALEX® (monotherapy)  
**259 patients**

## 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.

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# Results from the monotherapy study

## DARZALEX FASPRO® (monotherapy)



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

VS

## DARZALEX® (monotherapy)



About 4 of 10 patients responded to treatment with DARZALEX®

Responses in patients treated with DARZALEX FASPRO® were consistent with those treated with DARZALEX®, a proven treatment for multiple myeloma

## 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.

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# Combination therapy study

Several studies have evaluated combination therapies using DARZALEX FASPRO®. These studies confirmed that DARZALEX FASPRO® is effective when used in combination with other medicines (DVMP and DRd results are shown here).

## 132

patients in this study

### DVMP



With newly diagnosed multiple myeloma unable to have a transplant

DARZALEX FASPRO® + Velcade® (bortezomib) + melphalan + prednisone

**67 patients**

### DRd



Who received at least 1 prior medicine

DARZALEX FASPRO® + Revlimid® (lenalidomide) + dexamethasone

**65 patients**

## IMPORTANT SAFETY INFORMATION (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.

### How will I receive DARZALEX FASPRO®?

- DARZALEX FASPRO® may be given alone or together with other medicines used to treat multiple myeloma.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.





# Results from the combination therapy study

## DVMP



**About 9 of 10 patients** responded to treatment with DARZALEX FASPRO<sup>®</sup> in combination with bortezomib, melphalan, and prednisone

## DRd



**About 9 of 10 patients** responded to treatment with DARZALEX FASPRO<sup>®</sup> in combination with lenalidomide and dexamethasone

**Ask your doctor for more information about how they expect you will respond to your prescribed regimen of DARZALEX FASPRO<sup>®</sup>**

## IMPORTANT SAFETY INFORMATION (CONT)

- DARZALEX FASPRO<sup>®</sup> will be given to you by your healthcare provider as an injection under the skin, in the stomach area (abdomen).
- DARZALEX FASPRO<sup>®</sup> 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<sup>®</sup> and after each dose of DARZALEX FASPRO<sup>®</sup> 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.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.





# Your treatment checklist for DARZALEX FASPRO®

## Before your injection

### Tell your doctor about:

- All of your medical conditions
- All of the medications you are taking

### Ask your doctor about your treatment goals with DARZALEX FASPRO®. For example:

- How will you know this treatment is working?
- What **response** are you hoping to see with DARZALEX FASPRO®?
- How long should I expect to stay on this treatment regimen?

## Day of your injection

- Wear comfortable clothing that is loose around the waist
- Set aside enough time
- Take the medications your doctor will give you prior to the injection
- Tell your healthcare providers and personnel at blood transfusion centers that you are taking DARZALEX FASPRO®

## After your injection

- Pay attention to how you feel
- Tell your doctor immediately if you experience any side effects or reactions

## IMPORTANT SAFETY INFORMATION (CONT)

### DARZALEX FASPRO® may cause serious reactions, including:

- **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX FASPRO®. 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
  - heart beating faster than usual
  - itching
  - chills
  - dizziness or lightheadedness (hypotension)
  - low oxygen in the blood (hypoxia)
  - high blood pressure
  - fever
  - cough
  - throat tightness
  - nausea
  - chest pain
  - wheezing
  - runny or stuffy nose
  - vomiting
  - blurred vision
  - headache

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.





# Before your injection

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 have a hepatitis B infection
- ✓ Are pregnant or plan to become pregnant
- ✓ Are breastfeeding or plan to breastfeed

For additional information about how these conditions are affected by or impact treatment with **DARZALEX FASPRO®**, download the patient brochure at [www.darzalex.com/faspro](http://www.darzalex.com/faspro).

## About all of the medications you take, including:

- ✓ Prescription and over-the-counter medicines
- ✓ Vitamins
- ✓ Herbal supplements

## 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®**.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.



# Preparing for your 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.



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



**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.



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



**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

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

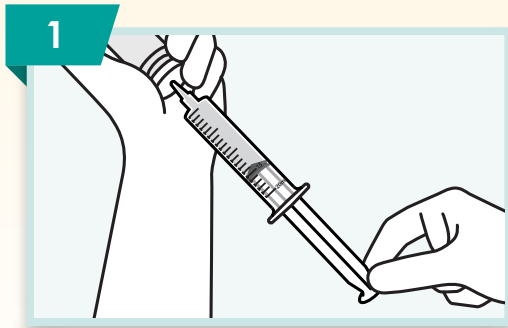
## IMPORTANT SAFETY INFORMATION (CONT)

- **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. Your healthcare provider will check your blood cell counts during treatment with DARZALEX FASPRO®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.

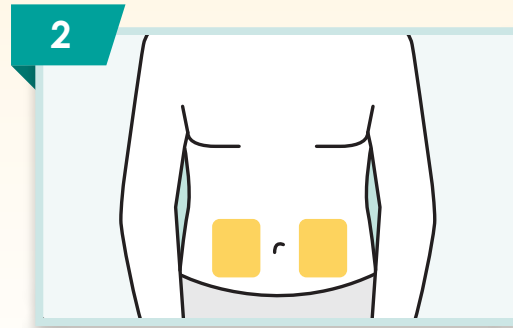
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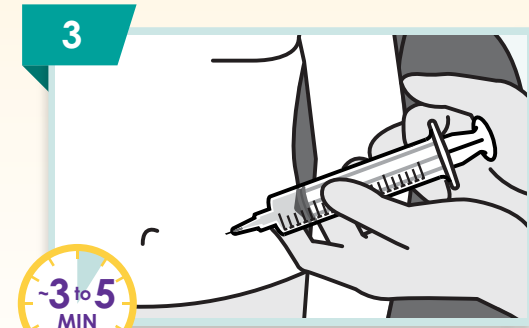
# During your injection



Your healthcare provider will **prepare the injection**



Your healthcare provider will **determine where to inject and prepare the chosen area**, 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.

## 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.**

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

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.



# 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 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®.

**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
- 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®.

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



**It's important to stay on treatment as directed by your doctor to feel the full benefits of treatment. Discuss next steps with your doctor if you experience any reactions to the injection.**

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.



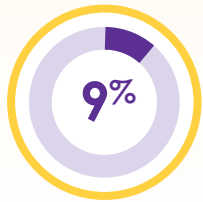
# Side effects

## You may experience side effects from treatment

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

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

## Reactions to the injection



- Among all patients who participated in DARZALEX FASPRO® clinical studies, **9% of the 898 patients taking DARZALEX FASPRO®** as monotherapy or as part of combination therapy 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 898 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.

## IMPORTANT SAFETY INFORMATION (CONT)

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.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.



# Side effects (cont)

## Fewer patients experienced reactions with DARZALEX FASPRO®



In a clinical study that compared DARZALEX FASPRO® (monotherapy) with 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 cold-like symptoms (upper respiratory infection) and changes in blood cell counts. 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.**

## IMPORTANT SAFETY INFORMATION (CONT)

### 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

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.



# Indications and Important Safety Information

## 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
- in combination with the medicines carfilzomib and dexamethasone in people 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)

Continued on next page

[Click here](#) for Important Product Information.



# 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.
- 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.

## 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.

Continued on next page

[Click here](#) for Important Product Information.





# Important Safety Information (cont)

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

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# Important Safety Information (cont)

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

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

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

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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[Click here](#) for Important Product Information.



# Support for patients and their caregivers



Once you and your doctor have decided that 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, and identify options that may help make your treatment more affordable.

**Call a Janssen CarePath Care Coordinator today at 1-844-55DARZA (1-844-553-2792), Monday-Friday 8:00 AM to 8:00 PM ET, create a Janssen CarePath Account at [MyJanssenCarePath.com](http://MyJanssenCarePath.com) or visit [JanssenCarePath.com/Darzalex-Faspro](http://JanssenCarePath.com/Darzalex-Faspro).**

## Additional resources available online

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



### Patient Brochure

Use this comprehensive resource to learn more about the treatment experience with DARZALEX FASPRO®.



### Watch a patient's experience

See another patient's treatment journey with DARZALEX FASPRO®



### 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.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.



## 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 treatment to treat a certain disease or condition.

## DNA

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

## 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.

## Monotherapy

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

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.



## **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.

[Click here](#) for Important Product Information. Please see additional Important Safety Information on pages 18-21.

