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.

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:

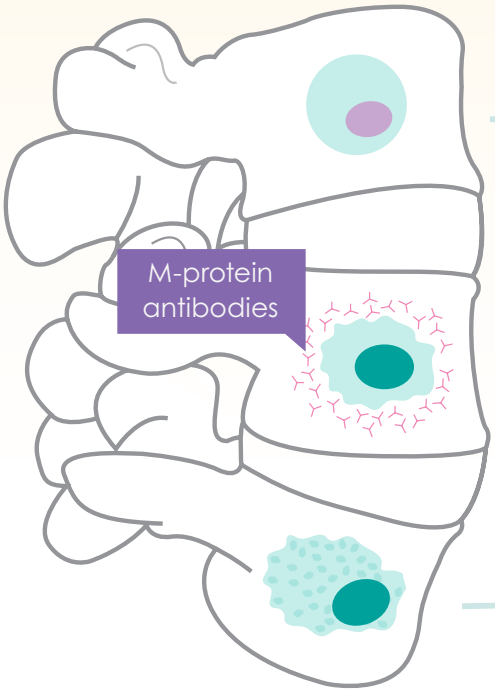
- in combination with the medicines bortezomib, melphalan, and prednisone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines lenalidomide and dexamethasone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

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

Click here for Important Product Information. Please see additional Important Safety Information on pages 18-21.

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.

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.**

Click here for Important Product Information. Please see additional Important Safety Information on pages 18-21.

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*
DRd DARZALEX *FASPRO*® + Revlimid® (lenalidomide) + dexamethasone	**DVTd** DARZALEX *FASPRO*® + Velcade® (bortezomib) + thalidomide + dexamethasone	**DRd** DARZALEX *FASPRO*® + Revlimid® + dexamethasone	**Monotherapy** DARZALEX *FASPRO*® alone
DVMP DARZALEX *FASPRO*® + Velcade® (bortezomib) + melphalan + prednisone		**DPd** DARZALEX *FASPRO*® + POMALYST® + dexamethasone	
		DVd 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.

How does DARZALEX *FASPRO*® work?

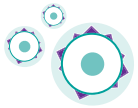
DARZALEX *FASPRO*® is made up of 2 main components:

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.

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.

Click here for Important Product Information. Please see additional Important Safety Information on pages 18-21.

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.

Click here for Important Product Information. Please see additional Important Safety Information on pages 18-21.

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.

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*® in combination with bortezomib, melphalan, and prednisone

DRd

About 9 of 10 patients responded to treatment with DARZALEX *FASPRO*® 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*®

IMPORTANT SAFETY INFORMATION (CONT)

How will I receive DARZALEX *FASPRO*®?

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

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 DARZALEX *FASPRO*®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX *FASPRO*® if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX *FASPRO*®.
  - shortness of breath or trouble breathing
  - dizziness or lightheadedness (hypotension)
  - cough
  - wheezing
  - heart beating faster than usual
  - low oxygen in the blood (hypoxia)
  - throat tightness or irritation
  - runny or stuffy nose
  - headache
  - itching
  - high blood pressure
  - eye pain
  - nausea
  - vomiting
  - chills
  - fever
  - chest pain
  - blurred vision

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**.

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.

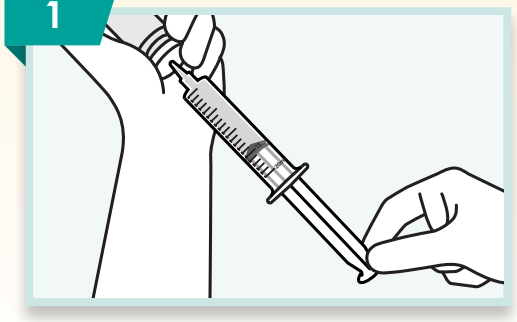
IMPORTANT SAFETY INFORMATION (CONT)

- **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. Decreases in blood cell counts are common with DARZALEX *FASPRO*® but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX *FASPRO*®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.

Click here for Important Product Information. Please see additional Important Safety Information on pages 18-21.

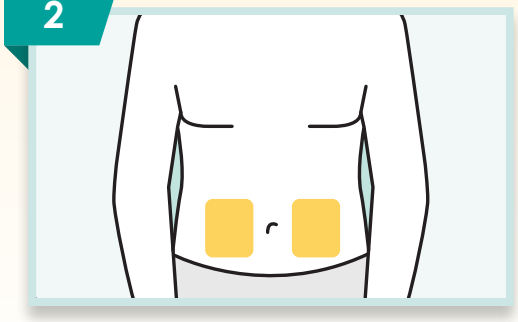
During your injection

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.

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 or irritation
- Runny or stuffy nose
- Headache
- Itching
- High blood pressure
- Eye pain
- Nausea
- Vomiting
- Chills
- Fever
- Chest pain
- Blurred vision

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

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.

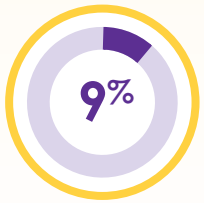
Side effects

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 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:

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

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*®

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

Active ingredient: daratumumab and hyaluronidase-fihj
Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 20, sorbitol, water for injection

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

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

IMPORTANT SAFETY INFORMATION

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

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

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

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

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*®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX *FASPRO*® if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX *FASPRO*®.
  - shortness of breath or trouble breathing
  - dizziness or lightheadedness (hypotension)
  - cough
  - wheezing
  - heart beating faster than usual
  - low oxygen in the blood (hypoxia)
  - throat tightness or irritation
  - runny or stuffy nose
  - headache
  - itching
  - high blood pressure
  - eye pain
  - nausea
  - vomiting
  - chills
  - fever
  - chest pain
  - blurred vision
- **Injection site reactions.** Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX *FASPRO*®. Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin. These reactions sometimes happen more than 24 hours after an injection of DARZALEX *FASPRO*®.
- **Decreases in blood cell counts.** DARZALEX *FASPRO*® can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX *FASPRO*® but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX *FASPRO*®. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding.
- **Changes in blood tests.** DARZALEX *FASPRO*® can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX *FASPRO*®. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX *FASPRO*®. **Tell all of your healthcare providers that you are being treated with DARZALEX *FASPRO*® before receiving blood transfusions.**

Continued on next page

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:

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

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

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

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

Active ingredient: daratumumab and hyaluronidase-fihj

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

Please click here to see the Product Information.

cp-143282v9

Support for patients and their caregivers

janssen CarePath

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.

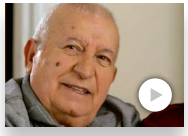
Call a Janssen CarePath Care Coordinator today at 1-844-55DARZA (1-844-553-2792), Monday-Friday 8:00 AM to 8:00 PM ET, create a Janssen CarePath Account at MyJanssenCarePath.com or visit JanssenCarePath.com/Darzalex-Faspro.

Additional resources available online

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

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.

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.

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.

Click here for Important Product Information. Please see additional Important Safety Information on pages 18-21.

Janssen Oncology