Doctor Conversation Starter Guide

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

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

SELECT IMPORTANT SAFETY INFORMATION

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

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

Please click here to see Important Safety Information.

Please click here to see Important Prescribing Information.

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

Doctor Conversation Starter Guide

Starting DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) is a decision you or your loved one makes with the doctor. Check the questions you may want to ask the doctor or nurse about multiple myeloma and treatment with DARZALEX *FASPRO*®. Print or download this guide to help get the conversation started.

When first diagnosed

About multiple myeloma

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

About treatment

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

Communicating with the doctor

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

When discussing treatment options

Available treatments

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

Managing treatment

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

When considering treatment with DARZALEX *FASPRO*®

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

When being treated with DARZALEX *FASPRO*®

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

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Please click here to see Important Prescribing Information.

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Indications and Important Safety Information for DARZALEX *FASPRO*®

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

IMPORTANT SAFETY INFORMATION

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

- have a history of breathing problems
- have had shingles (herpes zoster)
- have ever had or might now have a hepatitis B infection as DARZALEX *FASPRO*® could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX *FASPRO*®. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.
- are pregnant or plan to become pregnant. DARZALEX *FASPRO*® may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX *FASPRO*®.
  - Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX *FASPRO*®. Talk to your healthcare provider about birth control methods that you can use during this time.
  - Before starting DARZALEX *FASPRO*® in combination with lenalidomide, thalidomide, or pomalidomide, females and males must agree to the instructions in the lenalidomide, thalidomide, or pomalidomide REMS program.
    - The lenalidomide, thalidomide, and pomalidomide REMS have more information about effective methods of birth control, pregnancy testing, and blood donation for females who can become pregnant.
    - For males who have female partners who can become pregnant, there is information in the lenalidomide, thalidomide, and pomalidomide REMS about sperm donation and how lenalidomide, thalidomide, and pomalidomide can pass into human semen.
- are breastfeeding or plan to breastfeed. It is not known if DARZALEX *FASPRO*® passes into your breast milk. You should not breastfeed during treatment with DARZALEX *FASPRO*®. Talk to your healthcare provider about the best way to feed your baby during treatment with DARZALEX *FASPRO*®.

Tell your healthcare provider about all the 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).

Continued on next page

Please click here to see Important Safety Information.

Please click here to see Important Prescribing Information.

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Important Safety Information for DARZALEX *FASPRO*® (cont)

- DARZALEX *FASPRO*® is injected over 3 to 5 minutes.
- Your healthcare provider will decide the time between doses as well as how many treatments you will receive.
- Your healthcare provider will give you medicines before each dose of DARZALEX *FASPRO*® and after each dose of DARZALEX *FASPRO*® to help reduce the risk of serious allergic reactions and other reactions due to release of certain substances by your body (systemic).

If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

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

- **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX *FASPRO*®. Your healthcare provider may temporarily stop or completely stop treatment with DARZALEX *FASPRO*® if you have a serious reaction. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX *FASPRO*®.
  - shortness of breath or trouble breathing
  - 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.**

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*® when used in combination therapy include:

- tiredness
- nausea
- diarrhea
- shortness of breath
- trouble sleeping
- headache
- rash
- fever
- cough
- muscle spasms
- back pain
- vomiting
- high blood pressure
- muscle, bone, and joint pain
- 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 of 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 read full Prescribing Information for DARZALEX *FASPRO*®.

cp-143282v10

Johnson&Johnson

DARZALEX *Faspro*®
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Injection for subcutaneous use | 1,800mg/30,000units