



For people with newly diagnosed multiple myeloma, regardless of transplant eligibility status[†]

Talk to your doctor about starting treatment with **DARZALEX FASPRO[®] + VRd**

VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

[†]Eligibility is determined by your doctor.



What is **DARZALEX FASPRO[®]** (daratumumab and hyaluronidase-fihj)?

DARZALEX FASPRO[®] is a prescription medicine used to treat adult patients with multiple myeloma:

- in combination with the medicines bortezomib, 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, lenalidomide, and dexamethasone in newly diagnosed people who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)

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 page 15 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)

Please see Important Safety Information throughout on pages [14-17](#). Please see Important Product Information [here](#).

- 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[®].
- 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[®].

Understanding multiple myeloma and how to treat it

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

1

Normal Bone Marrow

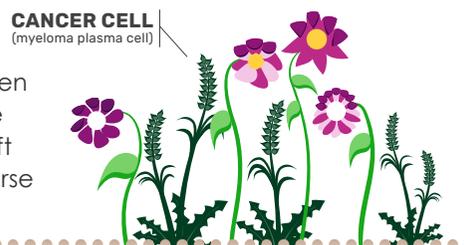
Bone marrow can be thought of as a garden. Healthy bone marrow is similar to thriving flowers without the threat of weeds.



2

Disease Diagnosis

A multiple myeloma diagnosis occurs when cancer cells begin to overtake your bone marrow. Early treatment is important. If left untreated, multiple myeloma can get worse over time.



3

Treatment Goals

Multiple myeloma treatment aims to slow the growth of cancer cells to gain control of the disease.



4

Potential Treatment Outcomes

- **Complete response and minimal residual disease (MRD) negativity:** Complete response means that you have responded to treatment; there are no signs of cancer seen in imaging, blood, or bone marrow tests. Your doctor can also check for minimal residual disease (MRD). MRD negativity was defined in the trial as follows: after treatment, not 1 cancer cell was detected out of every 100,000 normal cells.
- **Progression-free survival:** Living progression free can be thought of as the length of time that the disease does not get worse. This can be a sign that the cancer is not getting worse, similar to controlling the spread of weeds in a garden.



Time on treatment matters. For the best outcomes, it's important to start multiple myeloma treatment as soon as possible.

Levels of response for multiple myeloma

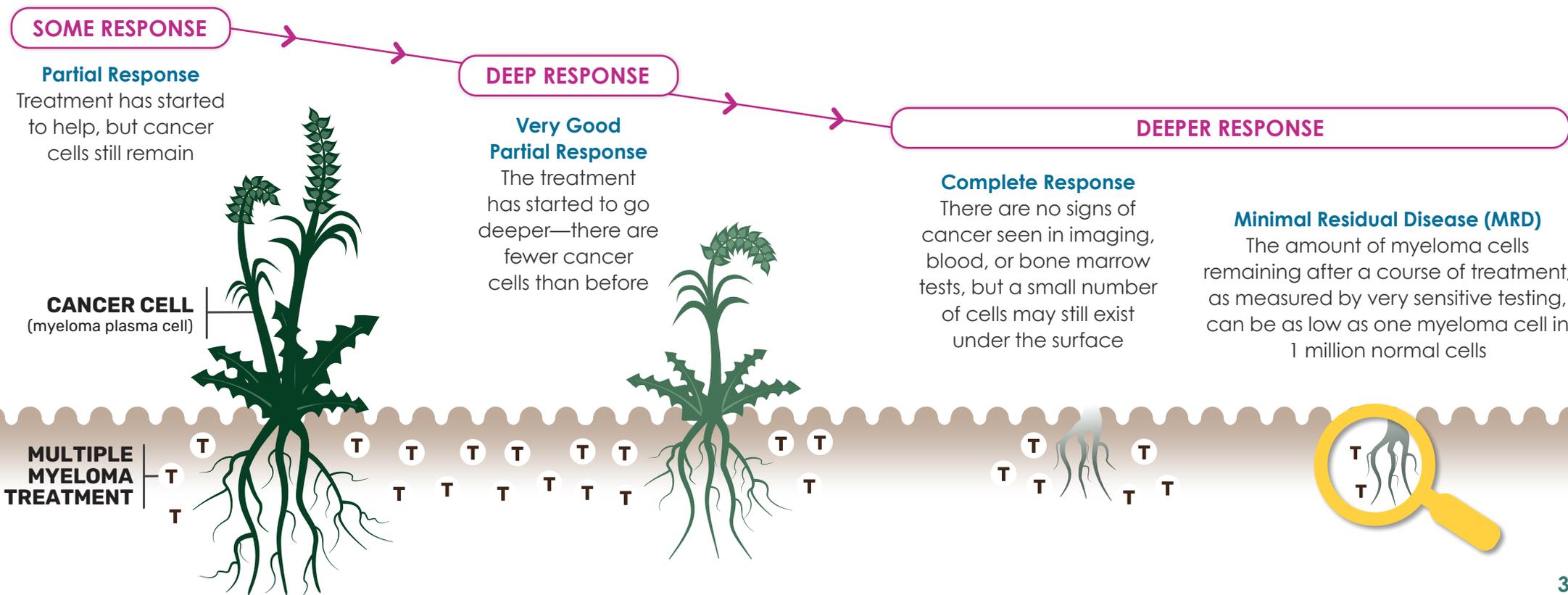
There are many goals of multiple myeloma treatment. One goal is to live progression free. This can be thought of as the length of time that the disease does not get worse. Treatment response is another key goal. This refers to how well the multiple myeloma cells in your body are being controlled by treatment. As response deepens (or gets better), fewer cancer cells remain.

You can think of response like weeds being treated in a garden. The weeds begin to disappear as treatment becomes more effective.



A multiple myeloma diagnosis can feel overwhelming, but you and your care team are in this together. If you have questions about your treatment goals, be sure to ask your team.

Achieving the deepest response for as long as possible is one goal of treatment



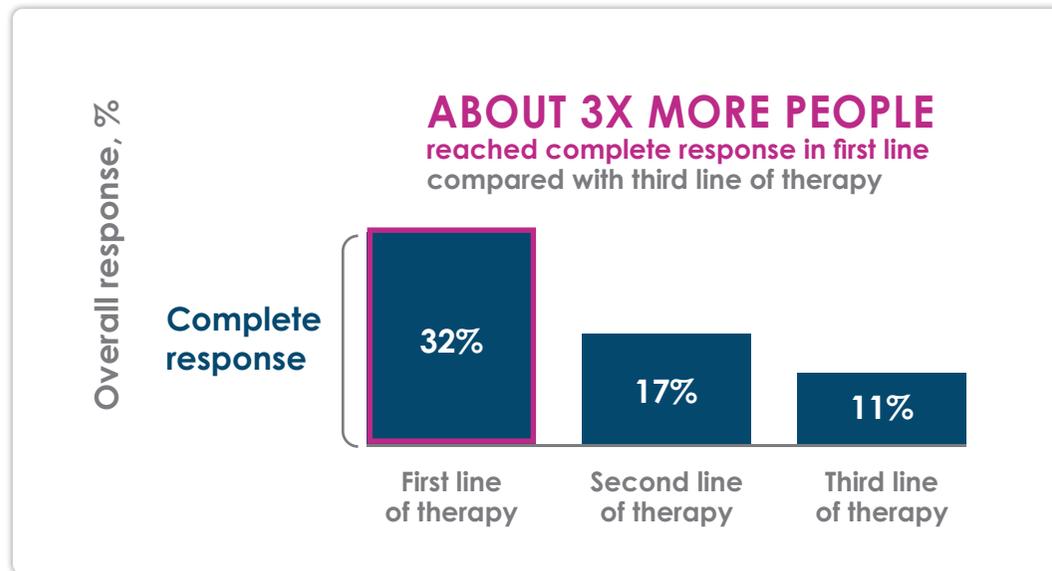
It's important to start with an effective multiple myeloma treatment first

A treatment plan that includes one or more medications is called a line of therapy. It may also include a stem cell transplant.

A change in treatment is considered a new line of therapy. This may happen if one or more treatments stop working or cause side effects that are not tolerable.

You and your care team will work together to determine the right treatment for you.

Research has shown that your best chance at deeper responses occurs more often with the first and earlier lines of therapy*



*In a retrospective study of 4997 patient charts from 7 European countries.



Resources are available to help you stay on track with treatment*

*Data rates may apply.

About DARZALEX FASPRO®

DARZALEX FASPRO® is used to treat adult people with multiple myeloma. It is not chemotherapy. It's a type of immunotherapy called a monoclonal antibody. This means it works with your immune system to fight the cancer.

DARZALEX FASPRO® is an injection given by your healthcare provider in about 3 to 5 minutes under the skin in the stomach area.*

DARZALEX FASPRO® is made up of 2 main parts:



Daratumumab (pronounced da-ra-tu-mu-mab) is the ingredient that treats multiple myeloma. It directly kills multiple myeloma cells and/or helps your immune system find and destroy them.

Because of the way daratumumab works, it may also affect normal cells.



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

Watch a video to learn more about the patient experience with DARZALEX FASPRO®. Scan the QR code* or visit darzalex.com



*Data rates may apply.

Select Important Safety Information (cont)

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®.

About DARZALEX FASPRO® + VRd

DARZALEX FASPRO® is indicated for the treatment of adult people with:



- multiple myeloma in combination with bortezomib (V), lenalidomide (R), and dexamethasone (d) for induction and consolidation in newly diagnosed people who are eligible for autologous stem cell transplant
- multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone in newly diagnosed people who are ineligible for autologous stem cell transplant

For patients eligible for transplant, first-line therapy may include different treatment phases:

1

Induction therapy: The first treatment given before stem cell transplant, aimed at reducing the number of cancer cells. It typically includes a combination of medicines

2

Stem cell transplant: A procedure that uses your own stem cells, which are collected, preserved, and infused into your bloodstream to restore blood cell production

3

Consolidation therapy: The same medications used for induction therapy, given over a shorter period of time to kill cancer cells that may be left in the body

4

Post-consolidation therapy: Following consolidation, your doctor may prescribe or continue certain medications to maintain your results

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

Please see Important Safety Information throughout on pages 14-17. Please see Important Product Information [here](#).

In the treatment of people with newly diagnosed multiple myeloma who are not eligible for a stem cell transplant

Details about the study

In a clinical trial, DARZALEX FASPRO® was studied in combination with bortezomib, lenalidomide, and dexamethasone (DARZALEX FASPRO® + VRd) and compared to treatment with VRd alone.

Who took part in the study?



Everyone who participated was newly diagnosed with multiple myeloma



People from age 31 to 80 (median age 70) who could not get a stem cell transplant were included*



395 people participated in the study

- 197 people received DARZALEX FASPRO® + VRd
- 198 people received VRd alone

Select 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®. 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®.

What were the goals of the study?



The main goal was to measure something called the minimal residual disease (MRD) negativity rate. In this study, MRD negativity means that after treatment, not one cancer cell was detected out of every 100,000 cells. In this trial, MRD negativity was studied in people who had a complete response or better.



There were other goals during the study. One goal was to see how long people lived without their disease getting worse or dying. Another goal was to measure the response people had during the study.

Response is used to measure how well multiple myeloma cells in your body are being controlled by therapy. As a response deepens (or gets better), fewer cancer cells remain. You can have a partial response, a very good partial response, or a complete response or better.

Complete response means that you have responded to treatment; there are no signs of cancer seen in imaging, blood, or bone marrow tests. Your doctor can also check for minimal residual disease (MRD). MRD negativity means that after treatment, not one cancer cell was detected out of every 100,000 cells. These measures represent thorough responses; however, they do not mean that the cancer is cured.

VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

*A doctor determined transplant eligibility for each patient.

Please see Important Safety Information throughout on pages [14-17](#). Please see Important Product Information [here](#).

In the treatment of people with newly diagnosed multiple myeloma who are not eligible for a stem cell transplant

Key results from the CEPHEUS clinical study

Initial study results at a median follow-up of 22 months

More people who were treated with DARZALEX FASPRO® + VRd achieved MRD negativity with a complete response or better vs those who were treated with VRd alone.

52%
(103 out of 197)

of people who were treated with DARZALEX FASPRO® + VRd reached **MRD negativity with a complete response or better**

vs **35%** (69 out of 198) of people who were treated with VRd alone

More people who were treated with DARZALEX FASPRO® + VRd achieved a complete response or better vs VRd alone

76%
(150 out of 197)

of people who were treated with DARZALEX FASPRO® + VRd had a **complete response or better**



vs **59%** (116 out of 198) of people who were treated with VRd alone

Results from the study were reported at a median follow-up of 39 months

More people who were treated with DARZALEX FASPRO® + VRd achieved sustained MRD negativity than those treated with VRd alone. Sustained MRD negativity means that doctors tested your bone marrow at 2 separate times, at least 1 year apart, and found no signs of multiple myeloma in the bone marrow either time—showing the disease stayed at very low levels over time.

43%
(84 out of 197)

of people who were treated with DARZALEX FASPRO® + VRd achieved **sustained MRD negativity**

vs **25%** (50 out of 198) of people who were treated with VRd alone

People who were treated with DARZALEX FASPRO® + VRd had a better chance of living without their disease getting worse. This is called progression-free survival, or PFS.

76%

of people who were treated with DARZALEX FASPRO® + VRd did **not have disease progression and were still alive**

vs **61%** of people who were treated with VRd alone

Select 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®.

Please see Important Safety Information throughout on pages [14-17](#). Please see Important Product Information [here](#).

MRD=minimal residual disease; VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

In the treatment of people with newly diagnosed multiple myeloma who are eligible for a stem cell transplant

DARZALEX FASPRO[®] + VRd is also available for people who are eligible to receive a stem cell transplant

The PERSEUS clinical study was completed with people newly diagnosed with multiple myeloma who were eligible to receive a type of stem cell transplant that uses their own stem cells.

Who participated?



709 people



People with newly diagnosed multiple myeloma who were being treated with DARZALEX FASPRO[®] + VRd vs VRd alone



Eligible to receive a type of stem cell transplant that uses the person's own stem cells*

What were the goals of the study?



The main goal was to measure how long people lived without their multiple myeloma getting worse

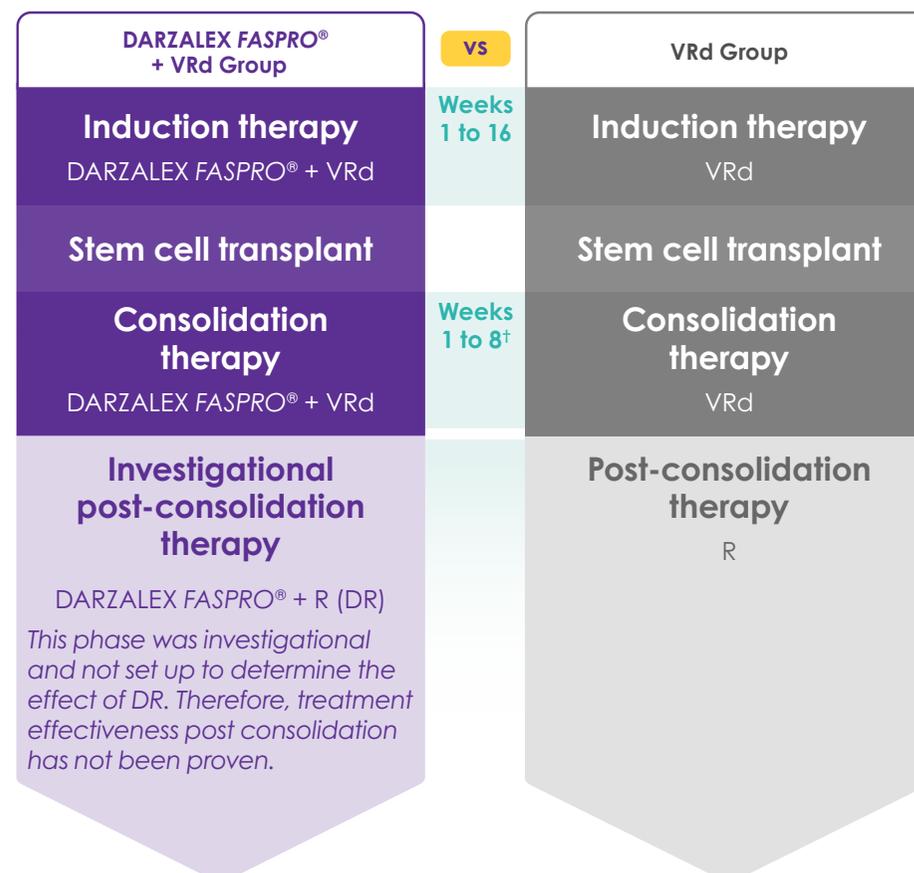


A second goal was to measure response to treatment using markers in blood, urine, and bone marrow

Select Important Safety Information (cont)

Infections. DARZALEX FASPRO[®] can cause serious life-threatening infections that can lead to death. Tell your healthcare provider right away if you develop a fever, trouble breathing, cough, burning or pain when you urinate, or any other signs and symptoms of infection during treatment.

What treatments were compared?



R=lenalidomide; VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

*A doctor determined transplant eligibility for each patient.

[†]Treatment restarted at Week 1 after recovery from stem cell transplant.

Please see Important Safety Information throughout on pages 14-17. Please see Important Product Information [here](#).

In the treatment of people with newly diagnosed multiple myeloma who are eligible for a stem cell transplant

In the DARZALEX FASPRO® + VRd group, more people lived progression free

Disease progression* was 60% less likely with DARZALEX FASPRO® + VRd compared with VRd alone†

85% in the DARZALEX FASPRO® + VRd group lived without their disease getting worse after 48 months†



compared with 67% in the VRd treatment group†

In people who received DARZALEX FASPRO® + VRd for induction and consolidation:

45%

(158 out of 355)

achieved complete response or better

vs 35% (123 out of 354) in the VRd group

58%

(204 out of 355)

achieved MRD negativity

vs 33% (115 out of 354) in the VRd group

In people who achieved complete response or better during induction and consolidation, 77% (121 out of 158) on DARZALEX FASPRO® + VRd also achieved MRD negativity, compared with 59% (72 out of 123) treated with VRd alone

MRD=minimal residual disease; VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

*Disease progression refers to the length of time a patient lived without having their disease getting worse, or passing away.

†48-month estimate based on a median follow-up of 47.5 months for the DARZALEX FASPRO® + VRd and VRd groups.

Select 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® and 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.

Please see Important Safety Information throughout on pages [14-17](#).

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

Side effects for DARZALEX FASPRO®

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 page 15 for a complete list of ingredients in DARZALEX FASPRO®.

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

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 doctor or care team may temporarily stop or completely stop treatment 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

In studies, injection-related reactions decreased over time



- 7% had a reaction with the first injection
- 0.5% had a reaction with the second injection
- 1% had a reaction with the following injections combined

Not everyone responds to treatment the same. Talk to your care team about any side effects that are bothersome or do not go away.

The most common side effects of DARZALEX FASPRO® when used alone include:

- cold-like symptoms (upper respiratory tract infection)
- muscle, bone, and joint pain
- tiredness
- diarrhea
- rash
- trouble sleeping, including sleep apnea and restless legs
- nerve problems, including increased or decreased sensitivity to touch, temperature, or pain; loss of smell; and numbness, tingling, or burning sensations
- injection site reactions

Skin reactions at or near the injection site (local), including injection site reactions, can happen with DARZALEX FASPRO®.



In clinical studies, 8% of patients had an injection site reaction with DARZALEX FASPRO®.

Symptoms at the site of injection may include itching, swelling, bruising, pain, rash, bleeding, or redness of the skin.

Infections

DARZALEX FASPRO® can cause serious life-threatening infections that can lead to death. Tell your healthcare provider right away if you develop a fever, trouble breathing, cough, burning or pain when you urinate, or any other signs and symptoms of infection during treatment.

Decreases in blood cell counts and changes in blood tests

Your doctor will do blood tests to check your blood cell count and match your blood type before treatment. DARZALEX FASPRO® can:

- Decrease white blood cell counts (help fight infections) and blood cells called platelets (help clot blood). Decreases are common with DARZALEX FASPRO® but can be severe. Tell your doctor if you get a fever or develop signs of bruising or bleeding
- Affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO®. **Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO® before receiving blood transfusions**

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

- tiredness
- nausea
- diarrhea
- shortness of breath
- trouble sleeping
- headache
- rash
- kidney problems
- movement and balance problems, muscle spasms, weakness, and tremors
- fever
- cough
- muscle spasms
- back pain
- vomiting
- high blood pressure
- muscle, bone, and joint pain
- decreased appetite
- urinary tract infection
- stomach pain
- cold-like symptoms (upper respiratory tract infection)
- nerve problems, including increased or
- decreased sensitivity to touch, temperature, or pain; loss of smell; and numbness, tingling, or burning sensations
- constipation (pneumonia)
- swollen hands, ankles, or feet
- feeling dizzy
- bruising
- COVID-19

These are not all of the possible side effects of DARZALEX FASPRO®. Speak with your doctor about the side effects that you may experience with DARZALEX FASPRO®.

Please see Important Safety Information throughout on pages 14-17. Please see Important Product Information [here](#).

Dosing for DARZALEX FASPRO® + VRd



DARZALEX FASPRO® was approved in 2020 as an ~3- to 5-minute injection under the skin (subcutaneous).

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

DARZALEX FASPRO® + VRd for people with newly diagnosed multiple myeloma who are not eligible for a stem cell transplant

With this treatment plan, people who were treated with DARZALEX FASPRO® + VRd were able to move to a **once-monthly treatment** schedule in under 6 months.



DARZALEX FASPRO® + bortezomib (V) + lenalidomide (R) + dexamethasone (d)



DARZALEX FASPRO® is given every week
Weeks 1 to 6 • 6 doses total



DARZALEX FASPRO® is given every 3 weeks
Weeks 7 to 24 • 6 doses total



DARZALEX FASPRO® is given every 4 weeks
Week 25 until disease gets worse

Your care team will determine the dosing for bortezomib (V), lenalidomide (R), and dexamethasone (d) using each drug's product information

VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

*Treatment restarted at Week 1 after recovery from stem cell transplant.

DARZALEX FASPRO® + VRd for people with newly diagnosed multiple myeloma who are eligible for a stem cell transplant

Induction: DARZALEX FASPRO® + VRd (Given before stem cell transplant)



DARZALEX FASPRO® is given every week
Weeks 1 to 8 • 8 doses total



DARZALEX FASPRO® is given every 2 weeks
Weeks 9 to 16 • 4 doses total

Stop for high-dose chemotherapy and a stem cell transplant that uses your own stem cells

CONSOLIDATION: DARZALEX FASPRO® + VRd (Given after stem cell transplant)



DARZALEX FASPRO® is given every 2 weeks
Weeks 1 to 8* • 4 doses total

Select 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.**

Please see Important Safety Information throughout on pages 14-17. Please see Important Product Information [here](#).

What to expect with treatment

1 Preparation



Dress for comfort

Wear clothing that is loose around the waist. DARZALEX FASPRO® is injected about 3 inches to the left or right of the belly button



Set aside enough time

Additional time may be needed for pre-medication, lab work, and monitoring for side effects

2 Before your injection



You may be given medicines before and after each dose of DARZALEX FASPRO® to help prevent allergic reactions, inflammation, and/or fever. A quick physical exam or blood test may be performed

Before you receive DARZALEX FASPRO®, tell your care team about all of your medical conditions, including if you:

- have a history of breathing problems
- have had shingles
- have ever had or might now have a hepatitis B infection
- are pregnant or planning to become pregnant
- are breastfeeding or plan to breastfeed



Learn more about what to expect from treatment. Scan the QR code* or visit darzalex.com

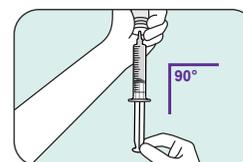
*Data rates may apply.

Select Important Safety Information (cont)

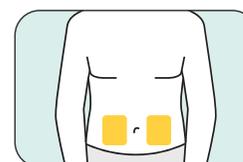
The most common side effects of DARZALEX FASPRO® when used alone include:

- cold-like symptoms (upper respiratory tract infection)
- muscle, bone, and joint pain
- tiredness
- diarrhea
- rash
- trouble sleeping, including sleep apnea and restless legs
- nerve problems, including increased or decreased sensitivity to touch, temperature, or pain; loss of smell; and numbness, tingling, or burning sensations
- injection site reactions

3 During your injection



Your healthcare provider will prepare the syringe



An injection site on your stomach will be chosen and prepared



The injection will be completed in about 3 to 5 minutes*

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



4 After treatment



Pay attention to how you feel and tell your care team about any discomfort during or after treatment, and especially during the first and second injections. It could mean you may be having a reaction to the treatment. **Your healthcare provider may want you to remain**

in the office to watch for any side effects

Injection site reactions: Skin reactions at or near the injection site (local), including injection site reactions listed on page 15, can happen with DARZALEX FASPRO®. These reactions sometimes happen more than 24 hours after an injection of DARZALEX FASPRO®.

Post medication: After your injection, you may also be given oral corticosteroids to reduce the risk of delayed reactions to DARZALEX FASPRO®.

Please see Important Safety Information throughout on pages [14-17](#). Please see Important Product Information [here](#).

DARZALEX withMe: Personalized 1-on-1 support

You have access to free, dedicated support. Your Care Navigator is here to help guide you to support solutions throughout your treatment journey, so you feel informed and empowered.

Starting a new treatment can be overwhelming and you may still have questions. We are here to help:



Free, 1-on-1 Dedicated Care Navigator Support



Cost Support Options Regardless of Your Insurance Type



Additional Resources and Community Connections



Once a patient and their doctor have decided that **DARZALEX FASPRO®** is right for the patient, J&J withMe provides a simple, comprehensive patient support program offering cost support, a dedicated Care Navigator, and educational resources at no cost to the patient. Through one easy enrollment, patients can sign up for support to help them throughout their treatment journey.

Please see Important Safety Information throughout and on pages [14-17](#). Please see Important Product Information [here](#).

Resources and support for your treatment journey

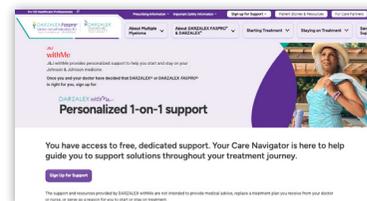
Watch Todd and Diane's story



Hear from Todd, a newly diagnosed, transplant-eligible patient, along with his wife and care partner, Diane, about their experience with DARZALEX FASPRO® + VRd.

[See all patient stories](#) >

Get personalized 1-on-1 support from a Care Navigator



You have access to free, dedicated support. Your Care Navigator is here to help throughout your treatment journey. Call 1-844-628-1234 or visit darzalex.com to learn more.

[Sign up for support](#) >

Access more helpful resources for DARZALEX FASPRO®



Download support materials, view treatment videos, and learn more about DARZALEX FASPRO® at darzalex.com.

[Explore resources](#) >

If you've been newly diagnosed with multiple myeloma and are eligible for a stem cell transplant,*

Ask your doctor if DARZALEX FASPRO® + VRd may be right for you

VRd=bortezomib (V) + lenalidomide (R) + dexamethasone (d).

*Your doctor will determine transplant eligibility.

Indications and Important Safety Information for DARZALEX FASPRO[®]

What is DARZALEX FASPRO[®] (daratumumab and hyaluronidase-fihj)?

DARZALEX FASPRO[®] is a prescription medicine used to treat adult patients with multiple myeloma:

- in combination with the medicines bortezomib, 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, lenalidomide, and dexamethasone in newly diagnosed people who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines bortezomib, 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 page 15 for a complete list of ingredients in DARZALEX FASPRO[®].

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

- have a history of breathing problems
- have had shingles (herpes zoster)
- have ever had or might now have a hepatitis B infection as DARZALEX FASPRO[®] could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX FASPRO[®]. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes.
- are pregnant or plan to become pregnant. DARZALEX FASPRO[®] may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX FASPRO[®].
 - Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX FASPRO[®]. Talk to your healthcare provider about birth control methods that you can use during this time.
 - 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 to treat multiple myeloma 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.

Indications and Important Safety Information for DARZALEX FASPRO[®] (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 | ◦ low oxygen in the blood (hypoxia) | ◦ eye pain |
| ◦ dizziness or lightheadedness (hypotension) | ◦ throat tightness or irritation | ◦ nausea |
| ◦ cough | ◦ runny or stuffy nose | ◦ vomiting |
| ◦ wheezing | ◦ headache | ◦ chills |
| ◦ heart beating faster than usual | ◦ itching | ◦ fever |
| | ◦ high blood pressure | ◦ chest pain |
| | | ◦ blurred vision |

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

- Infections.** DARZALEX FASPRO[®] can cause serious life-threatening infections that can lead to death. Tell your healthcare provider right away if you develop a fever, trouble breathing, cough, burning or pain when you urinate, or any other signs and symptoms of infection during treatment.

- 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[®] and 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 tract infection) | • trouble sleeping, including sleep apnea and restless legs |
| • muscle, bone, and joint pain | • nerve problems, including increased or decreased sensitivity to touch, temperature, or pain; loss of smell; and numbness, tingling, or burning sensations |
| • tiredness | • injection site reactions |
| • diarrhea | |
| • rash | |

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

- | | | |
|---|---|---|
| • tiredness | • back pain | touch, temperature, or pain; loss of smell; and numbness, tingling, or burning sensations |
| • nausea | • vomiting | • constipation |
| • diarrhea | • high blood pressure | • lung infection (pneumonia) |
| • shortness of breath | • muscle, bone, and joint pain | • swollen hands, ankles, or feet |
| • trouble sleeping | • decreased appetite | • feeling dizzy |
| • headache | • urinary tract infection | • bruising |
| • rash | • stomach pain | • COVID-19 |
| • kidney problems | • cold-like symptoms (upper respiratory tract infection) | |
| • movement and balance problems, muscle spasms, weakness, and tremors | • nerve problems, including increased or decreased sensitivity to | |
| • fever | | |
| • cough | | |
| • muscle spasms | | |

The most common severe abnormal blood test results with DARZALEX FASPRO[®] include decreased white blood cells, platelets, and red blood cells.

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 the full Prescribing Information for DARZALEX FASPRO[®].

cp-143282v13

Indications and Important Safety Information for DARZALEX®

What is DARZALEX® (daratumumab)?

DARZALEX® is a prescription medicine used to treat adults with multiple myeloma:

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

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

IMPORTANT SAFETY INFORMATION

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

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

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

- have ever had or might now have a hepatitis B infection as DARZALEX® could cause hepatitis B virus to become active again. Your healthcare provider will check you for signs of this infection before, during, and for some time after treatment with DARZALEX®. Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes
- have hereditary fructose intolerance (HFI). DARZALEX® contains sorbitol. Sorbitol is a source of fructose. People with HFI cannot break down fructose, which may cause serious side effects
- are pregnant or plan to become pregnant. DARZALEX® may harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant during treatment with DARZALEX®
 - Females who are able to become pregnant should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of DARZALEX®. Talk to your healthcare provider about birth control methods that you can use during this time
 - Before starting DARZALEX® in combination with lenalidomide, pomalidomide, or thalidomide, females and males must agree to the instructions in the lenalidomide, pomalidomide, or thalidomide REMS program
 - The lenalidomide, pomalidomide, and thalidomide REMS 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, pomalidomide, and thalidomide REMS about sperm donation and how lenalidomide, pomalidomide, and thalidomide can pass into human semen
- are breastfeeding or plan to breastfeed. It is not known if DARZALEX® passes into your breast milk. You should not breastfeed during treatment with DARZALEX®. Talk to your healthcare provider about the best way to feed your baby during treatment with DARZALEX®

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Indications and Important Safety Information for DARZALEX[®] (cont)

How will I receive DARZALEX[®]?

- DARZALEX[®] may be given alone or together with other medicines used to treat multiple myeloma
- DARZALEX[®] will be given to you by your healthcare provider by intravenous (IV) infusion into your vein
- Your healthcare provider will decide the time between doses as well as how many treatments you will receive
- Your healthcare provider will give you medicines before each dose of DARZALEX[®] and after each dose of DARZALEX[®] to help reduce the risk of infusion-related reactions
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment

DARZALEX[®] may cause serious reactions, including:

- **Infusion-related reactions.** Infusion-related reactions are common with DARZALEX[®]. Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death can happen with DARZALEX[®]. Your healthcare provider may temporarily stop your infusion or completely stop treatment with DARZALEX[®] if you have infusion-related reactions. Get medical help right away if you get any of the following symptoms: shortness of breath or trouble breathing, dizziness or lightheadedness (hypotension), cough, wheezing, heart beating faster than 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 discomfort, or blurred vision
- **Changes in blood tests.** DARZALEX[®] can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX[®]. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX[®]. **Tell all of your healthcare providers that you are being treated with DARZALEX[®] before receiving blood transfusions**

- **Decreases in blood cell counts.** DARZALEX[®] can decrease white blood cell counts, which help fight infections, and blood cells called platelets, which help to clot blood. Decreases in blood cell counts are common with DARZALEX[®] but can be severe. Your healthcare provider will check your blood cell counts during treatment with DARZALEX[®]. Tell your healthcare provider if you develop fever or have signs of bruising or bleeding

The most common side effects of DARZALEX[®] include cold-like symptoms (upper respiratory infection); diarrhea; constipation; decreased red blood cells; nerve damage causing tingling, numbness, or pain; tiredness; swollen hands, ankles, or feet; nausea; cough; fever; shortness of breath; feeling weak.

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

General information about the safe and effective use of DARZALEX[®]

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

Active ingredient: daratumumab.

Inactive ingredients: may include glacial acetic acid, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, mannitol, polysorbate 20, sodium acetate trihydrate, sodium chloride, sorbitol, and water for injection.

Please [click here](#) to read full Prescribing Information for DARZALEX[®].

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