

For patients who
are not eligible
for a stem cell
transplant

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

WHEN MULTIPLE MYELOMA IS ANYTHING BUT QUIET

NEITHER AMI

For people with newly diagnosed multiple myeloma who are
ineligible for a stem cell transplant

 **Talk to your doctor about the benefits of treatment with
DARZALEX FASPRO® + Rd until disease progression**

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 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)

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 26 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®.

- 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®.

Rd= lenalidomide (R) + dexamethasone (d).

**Please see Important Safety Information on
pages 24-29. Please see full Prescribing
Information [here](#).**



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

Data rates may apply.

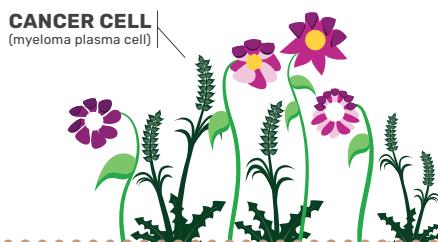
Understanding multiple myeloma and treatment

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.



CANCER CELL (myeloma plasma cell)



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.

Treatment Goals

Treatment aims to slow the growth of cancer cells to gain control of the disease. The goal of treatment is to control the growth of multiple myeloma cells.



Progression-Free Survival

Living progression-free can be thought of as the length of time that the disease does not get worse. This is a sign that the disease is under control—similar to controlling weeds in a garden.

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.

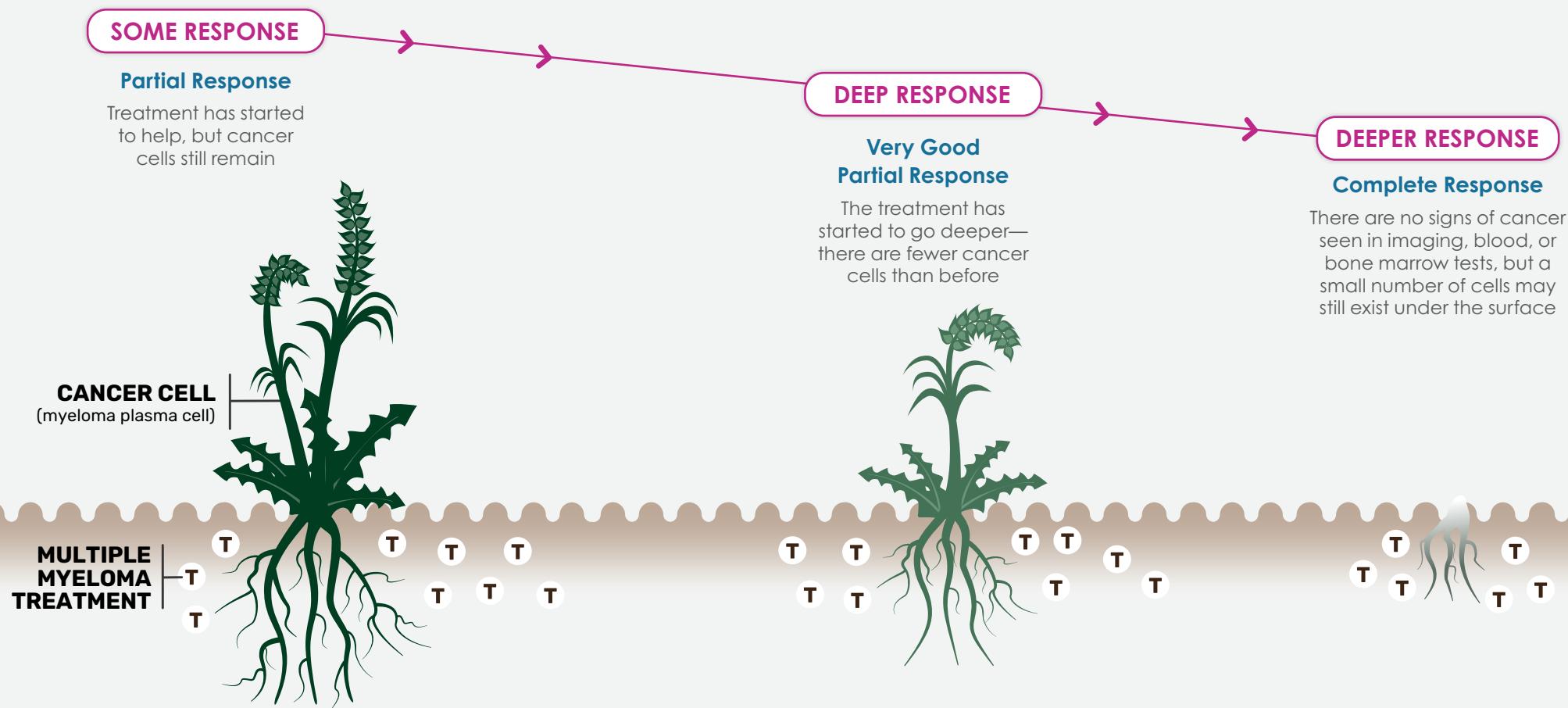
Treatment response is another key goal. This refers to how well the multiple myeloma cells in your body are being controlled by therapy. As response deepens (or gets better), fewer cancer cells remain.

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

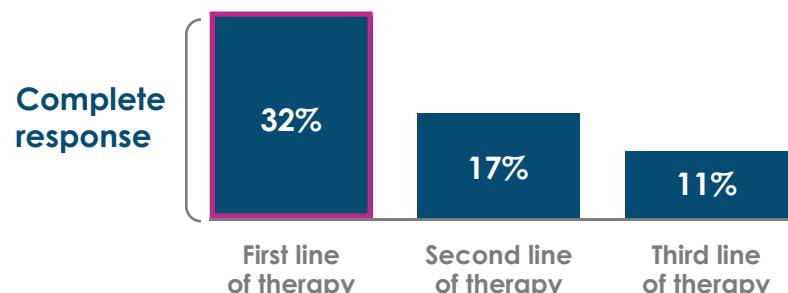
A treatment plan that includes one or more medications is called a line of therapy.

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

Research has shown that your best chance at deeper response occurs with your first line of therapy*

Overall response, %

ABOUT 3X MORE PEOPLE
reached complete response in first line
compared with third line of therapy



*In a retrospective study of 4,997 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® (daratumumab and hyaluronidase-fihj) is used to treat adult patients 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 disease for as long as you're taking it.

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.

DARZALEX FASPRO® is used with other medicines or alone, depending on your doctor's treatment plan. One combination is DARZALEX FASPRO® + lenalidomide and dexamethasone (DARZALEX FASPRO® + Rd).

This treatment combination is:



For newly diagnosed people who cannot receive a stem cell transplant with their own stem cells



Given under the skin in the stomach area by your healthcare provider in about 3 to 5 minutes*

Rd=lenalidomide (R) + dexamethasone (d).

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

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®.

Please see **Important Safety Information** on pages 24-29.

Please see full Prescribing Information [here](#).

Support and resources for your treatment journey



Once you and your doctor have decided that DARZALEX FASPRO® is right for you, sign up for DARZALEX withMe support

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.

Are you prescribed
DARZALEX FASPRO®?

Sign up for personalized support from DARZALEX withMe

[Sign up for support](#)
or call 833-565-9631,
Monday through Friday,
8:00 AM–8:00 PM ET.

Resources and patient stories at [darzalex.com](#)



Doctor Conversation Starter

Create a list of questions based on your needs and interests to bring to your next doctor's appointment



Patient Video Library

Watch to learn more about diagnosis, treatment, and what to expect with DARZALEX FASPRO®



Data rates may apply

Scan the QR code to download resources, view videos, and learn more about DARZALEX FASPRO®



MAIA clinical results with DARZALEX® + Rd

How the MAIA study was set up.

DARZALEX® (daratumumab) and DARZALEX FASPRO® both contain the medicine daratumumab but are given differently (by IV or injection under the skin, respectively).

DARZALEX®, the IV version, was studied in combination with lenalidomide and dexamethasone (DARZALEX® + Rd), compared with Rd alone.

Your treatment goals may be similar to results shown in clinical studies. Here's a look at what other patients were able to achieve with ongoing DARZALEX® + Rd treatment.



737 people participated
• 368 = DARZALEX® + Rd
• 369 = Rd alone



People had **newly diagnosed** multiple myeloma and **could not receive a stem cell transplant** that uses their own stem cells



The main goal was to measure how long patients **lived without their disease getting worse**



Another goal was to measure how well people **responded to treatment** and for how long

The study was continued to see the ongoing results of DARZALEX® + Rd over time.

IV=intravenous; Rd=lenalidomide (R) + dexamethasone (d).

SELECT IMPORTANT SAFETY INFORMATION (cont)

Do not receive DARZALEX® if you have a history of a severe allergic reaction to daratumumab or any of the ingredients in DARZALEX®. See page 29 for a complete list of ingredients.

DARZALEX® may cause serious reactions, including Infusion-related reactions, changes in blood tests, and decreases in blood cell counts.

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.

A commitment to ongoing treatment with DARZALEX® + Rd until disease progression is supported through MAIA trial results

Based on the overall response rate seen in the primary analysis, 48% of people achieved a complete response or better by staying with DARZALEX® + Rd vs 25% (Rd alone). Those who achieved a complete response or better had a deeper response over time.

Original MAIA Study (median 28-month follow-up):



More people lived progression-free*

- 74% of patients (271 of 368) in the DARZALEX® + Rd group lived without their disease getting worse, compared with 61% (226 of 369) in the Rd group
- The percentage of patients who had adverse events that led to discontinuation of the trial treatment was 7.1% in the DARZALEX® +Rd group vs 15.9% in the Rd group



More people responded to treatment

9 out of 10 patients responded to DARZALEX® + Rd compared with 8 out of 10 patients treated with Rd alone

Long-term data (5-year follow-up)



More patients were still alive

The estimated number of patients still alive after 5 years was 67% for patients in the DARZALEX® + Rd group and 54% in the Rd alone group

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

Please see Important Safety Information on pages 24-29.
Please see full Prescribing Information [here](#).



Side effects

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 26 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 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

In studies, injection-related reactions decreased over time



- 7% had a reaction with the first injection
- 0.2% 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.

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



In clinical studies, 7% 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.

These reactions sometimes happen more than 24 hours after an injection of DARZALEX FASPRO®.

Decreased 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 alone are:

- cold-like symptoms (upper respiratory infection)
- decreased red blood cell counts

The most common side effects of DARZALEX FASPRO® when used in combination with other therapies include:

• tiredness	• cough
• nausea	• muscle spasms
• diarrhea	• back pain
• shortness of breath	• vomiting
• trouble sleeping	• high blood pressure
• headache	• muscle, bone, and joint pain
• rash	• cold-like symptoms (upper respiratory infection)
• fever	

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®.

Additional results of the MAIA trial showing complete responses over time with DARZALEX® + Rd vs Rd alone

Additional evaluations of the MAIA study were conducted after the completion of the main or “primary” analyses of the study. These are referred to as “post hoc” analyses.



- After the planned evaluation of the MAIA clinical trial outcomes was completed, researchers explored additional ways of looking at these results
- Additional evaluations that are not planned are called post hoc analyses. These post hoc analyses offer a chance to better understand the study results
- It is important to note that post hoc analyses may represent outcomes that can be due to chance and cannot be considered conclusive
- Because post hoc analyses were not planned, they are not as rigorous as the main study evaluations that the clinical trial was designed for
- Post hoc analysis of the MAIA study can provide insight, but because the clinical trial was not designed to evaluate these additional results, the true effects may vary in unknown ways

Rd= lenalidomide (R) + dexamethasone (d).

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®.

How the post hoc analysis of the MAIA study results was done

In this post hoc analysis, researchers looked at how people responded to DARZALEX® + Rd over time at 6, 18, and 36 months. This was done to explore long-term treatment responses with DARZALEX® + Rd vs Rd alone.

Out of the original MAIA study group



342 OF THE 368 PEOPLE
 who received DARZALEX® + Rd achieved overall response rates (ORR) by 36 months and were included



301 OF THE 369 PEOPLE
 who received Rd alone achieved overall response rates (ORR) by 36 months and were included

Patients who dropped out of the study for any specific reasons (eg, due to disease progression or achieving response at earlier times) were still included in this analysis.



The results you see may be numerically accurate but differences between treatments or the levels of the treatments' effects may not be an accurate estimate of the expected effects in the study population.

Please see Important Safety Information on pages 24-29.
 Please see full Prescribing Information [here](#).

Looking closer at responses over time

Each bar shows the treatment responses by specific time points (6, 18, and 36 months).



The bars in the charts show a “cumulative response,” meaning each bar shows the total number of best responses people achieved up to that time point



Treatment responses can change over time



The group of people with the best response (complete response or better) can only become larger. The total response rates combined for everyone does not get smaller over time

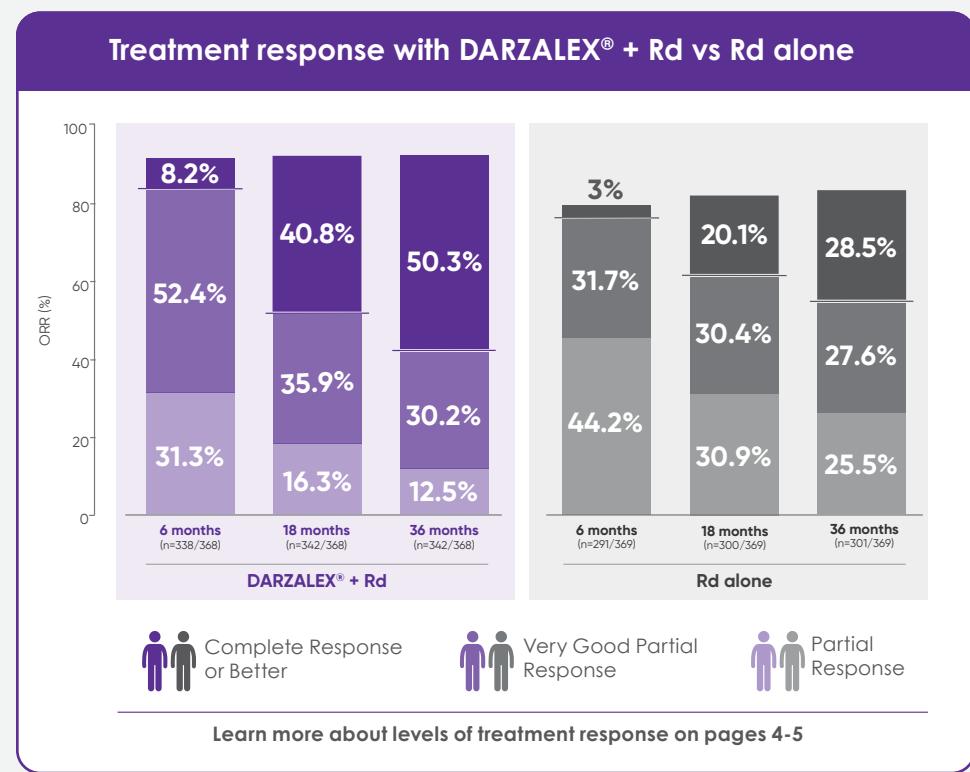


These results are not meant to display the total number of patients who were in response at that specific time point. Each time point highlights the deepest treatment response (complete response or better) that patients attained up until that point



Patients may attain a response better than a complete response, known as a stringent complete response, which is when there are no signs of cancer seen in imaging, blood, bone marrow tests, nor in very sensitive serum and urine tests

More patients on DARZALEX® + Rd reached deeper responses, including a complete response or better, at each time point, than patients who received Rd alone.



of people achieved \geq CR with 36 months of DARZALEX® + Rd treatment compared with ~8% by 6 months of DARZALEX® + Rd treatment

These results are factual, but since they were not based on the primary analysis plan, they have limitations. Also, they cannot reliably predict how patients who were not in the study may respond. Results may vary and you should discuss your specific circumstances with your doctor.

SELECT 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.

CR=complete response; ORR=overall response rate.

Please see Important Safety Information on pages 24-29.
Please see full Prescribing Information [here](#).

Post hoc analysis of DARZALEX® + Rd up to 36 months



Deeper responses were reached over time by staying with DARZALEX® + Rd vs Rd alone.

- From Month 6 through Month 36, the number of people who achieved complete response or better as their best response was **50.3% (DARZALEX® + Rd) vs 28.5% (Rd alone)**



Remember, since these analyses were not planned in the original study, no conclusions should be drawn from them.

SELECT IMPORTANT SAFETY INFORMATION (cont)

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; and decreased red blood cell counts.

Want to learn more about medical studies?

How clinical trials are designed



Clinical studies for the FDA approval of prescription drugs are designed carefully to evaluate how well a drug works (referred to as efficacy or effectiveness) and to evaluate the safety of the drug. These studies are designed to evaluate measures of effectiveness (referred to as "endpoints") that are identified before the study is conducted and are based on specific measures that are known to be meaningful and reliable to measure the intended drug effects. This, among other things, allows for statistical analyses of the study results to substantially reduce the possibility that the results happened by chance and helps to make the results interpretable. In a way, by identifying the analyses ahead of time, it reduces the possibility of subconscious "wishful thinking" where the analyses can be changed inappropriately until the more desirable result is seen.

How comparison groups are created



Studies typically also include a comparison group, that may be a placebo (eg, a sugar pill or a replica of a test medicine that does not contain medicine), or the comparison group may be another treatment known to be used for the same disease or purpose.

Patients in the study are also assigned to the study treatment through something called "randomization," meaning that they use a system that randomly assigns the treatment to patients to ensure that each study group contains a relatively similar group in terms of their medical background, age, ethnicity, gender, etc. Studies often also include something called "blinding" where the patient or healthcare professional (or both) do not know which treatment the patient is getting (the test treatment or the comparator).

Understanding biases

These features of a study reduce the possibility that the study results are affected by biases or that one study group is more affected by the human perceptions of the patient or the researchers. Biases can also occur as a result of study groups having an imbalance of different types of patients in one group versus another. For example, having more elderly patients in one study group than the other may affect the levels of efficacy shown in one group vs another. This can lead to difficulty in understanding the true treatment effect of the drug.

The reasons for these requirements are so that patients and healthcare professionals can make more reliable decisions that are guided by studies with high reliability.

FDA=US Food and Drug Administration; Rd=lenalidomide (R) + dexamethasone (d).

Please see Important Safety Information on pages 24-29.

Please see full Prescribing Information [here](#).

Learning more about medical studies

Understanding endpoints





Sometimes, however, researchers that have conducted the studies may evaluate other drug effects that are less rigorous to explore as much as they can about the drug. These effects may be defined ahead of time, but, because the study is not optimized by design or by statistical power, the results evaluating these effects are not as reliable as the primary and main endpoints of the study.

Understanding post hoc analyses



Sometimes, researchers create different analyses after the primary or main results are known, because they may be seeking to learn more about what happened in the study. Because these analyses are conducted after the fact, they are referred to as "post hoc" analyses, named after the Latin term meaning "after the event."

Less rigorous secondary analyses and post hoc analyses are typically considered to be exploratory, because they are exploring more about the drug, but they are not considered to be conclusive. They may be "nice to know" and can be informative, but they can also be difficult to interpret and should always be viewed with caution. They can also be simply misleading if they are inaccurate or untrue with respect to the actual effects of the drug.

When you, as a patient, are evaluating study results, you should understand the primary and main results of the study. If you are viewing other exploratory results, you should understand how they were designed and consider them with caution in light of their limitations. If you are having trouble understanding any type of medical information, including study results, talk to your healthcare provider.

Notes

Please see Important Safety Information on pages 24-29.
Please see full Prescribing 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.

Talk to your care team about the approximate length of time required for your DARZALEX FASPRO® treatments—including any lab work, pre-medications, and post-treatment 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

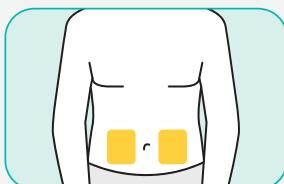
SELECT IMPORTANT SAFETY INFORMATION (cont)

- **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.**

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 26, 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®.

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, 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)
- 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®.

Indications and Important Safety Information for DARZALEX FASPRO® (cont)

- 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.
- 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

Indications and Important Safety Information for DARZALEX FASPRO® (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®.
- 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	• cough	• nerve damage causing tingling, numbness, or pain
• nausea	• muscle spasms	• constipation
• diarrhea	• back pain	• lung infection (pneumonia)
• shortness of breath	• vomiting	• swollen hands, ankles, or feet
• trouble sleeping	• high blood pressure	• decreased red blood cell counts
• headache	• muscle, bone, and joint pain	
• rash	• cold-like symptoms (upper respiratory infection)	

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 accompanying full Prescribing Information for DARZALEX FASPRO®.

cp-143282v10

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®

Indications and Important Safety Information for DARZALEX® (cont)

- 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.

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

Indications and Important Safety Information for DARZALEX® (cont)

- **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 the accompanying full Prescribing Information for DARZALEX®.

cp-109238v8

Time matters.

Stay on treatment with DARZALEX® + Rd until disease progression for the best chance of achieving the results seen in the MAIA trial.

Time on DARZALEX® + Rd matters



More time living with
DARZALEX® + Rd vs
Rd alone



More time without
the disease
getting worse



Starting and staying on DARZALEX® + Rd
can mean more time.

SELECT IMPORTANT SAFETY INFORMATION (cont)

Do not receive DARZALEX® if you have a history of a severe allergic reaction to daratumumab or any of the ingredients in DARZALEX®. See page 29 for a complete list of ingredients.

DARZALEX® may cause serious reactions, including Infusion-related reactions, changes in blood tests, and decreases in blood cell counts.

Please see Important Safety Information on pages 24-29.

Please see full Prescribing Information [here](#).