



My DARZALEX FASPRO™ Dosing Calendar

INDICATIONS

What is DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj)?

DARZALEX FASPRO™ is a prescription medicine used to treat adult patients with multiple myeloma:

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

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

SELECT IMPORTANT SAFETY INFORMATION

Do not receive DARZALEX FASPRO™ if you have a history of a severe allergic reaction to daratumumab or any of the ingredients in DARZALEX FASPRO™.

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

See the Important Safety Information on the pages that follow or by clicking the link below.

Please [click here](#) to see Important Safety Information.

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





My DARZALEX FASPRO™ Dosing Calendar

Keep track of your DARZALEX FASPRO™ treatment regimen.

DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj) can be prescribed by itself or in combination with other treatment regimens. **Your healthcare provider will work with you to determine which regimen and treatment schedule is best for you. Have your healthcare team fill out this dosing calendar with you so that it accurately reflects the regimen that was prescribed.**

Your personalized dosing calendar will include when to go for your DARZALEX FASPRO™ injections and when to take the other medicines in your regimen. You can use this dosing calendar to keep track of your treatment schedule, as determined by your healthcare provider. Keep your dosing calendar handy so you'll know at a glance when it's time for your next dose of a medicine. You can print it out and carry it with you, or post it in a convenient location.

Remember that it is recommended that you continue your DARZALEX FASPRO™ treatment regimen for as long as your doctor tells you to.

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



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 the 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

*Three to five minutes refers to the time it takes to administer DARZALEX FASPRO™ and does not account for all aspects of treatment.

SELECT IMPORTANT SAFETY INFORMATION

Do not receive DARZALEX FASPRO™ if you have a history of a severe allergic reaction to daratumumab or any of the ingredients in DARZALEX FASPRO™.

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

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

Sample Dosing Calendar



This is an **example** of how your dosing calendar may be filled out.

Please have your healthcare team fill out your own personalized dosing calendar with you to ensure accuracy.

| | | |
|-------------------|----------------------|--|
| WEEKS | <u>1</u> to <u>9</u> | DOSING SCHEDULE: CYCLES 1-2 |
| START DATE | <u>5 /14/20</u> | You and your healthcare team can work together to fill this out to make sure it is accurate. |

The example regimen is:



DARZALEX FASPRO™



Revlimid® (lenolidomide)



dexamethasone

| | S | M | T | W | T | F | S |
|--------|-----------------|-----------------|-----------------|-----------------|---------------------|-----------------|-----------------|
| Week 1 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | 5 / 14 ✓ ☆ ✓ □ ✓ | 5 / 15 ☆ ✓ ✓ | 5 / 16 ☆ ✓ ○ |
| Week 2 | 5 / 17 ☆ ✓ ○ | 5 / 18 ☆ ✓ ○ | 5 / 19 ☆ ✓ ○ | 5 / 20 ☆ ✓ ○ | 5 / 21 ✓ ☆ ✓ ✓ | 5 / 22 ☆ ✓ ✓ | 5 / 23 ☆ ✓ ○ |
| Week 3 | 5 / 24 ☆ ✓ ○ | 5 / 25 ☆ ✓ ○ | 5 / 26 ☆ ✓ ○ | 5 / 27 ☆ ✓ ○ | 5 / 28 ✓ ☆ ✓ ✓ | 5 / 29 ☆ ✓ ✓ | 5 / 30 ☆ ✓ ○ |
| Week 4 | 5 / 31 ☆ ✓ ○ | 6 / 1 ☆ ✓ ○ | 6 / 2 ☆ ✓ ○ | 6 / 3 ☆ ✓ ○ | 6 / 4 ✓ ☆ □ ✓ | 6 / 5 ☆ □ ✓ | 6 / 6 ☆ □ ○ |
| Week 5 | 6 / 7 ☆ □ ○ | 6 / 8 ☆ □ ○ | 6 / 9 ☆ □ ○ | 6 / 10 ☆ □ ○ | 6 / 11 ✓ ☆ ✓ ✓ | 6 / 12 ☆ ✓ ✓ | 6 / 13 ☆ ✓ ○ |
| Week 6 | 6 / 14 ☆ ✓ ○ | 6 / 15 ☆ ✓ ○ | 6 / 16 ☆ ✓ ○ | 6 / 17 ☆ ✓ ○ | 6 / 18 ✓ ☆ ✓ ✓ | 6 / 19 ☆ ✓ ✓ | 6 / 20 ☆ ✓ ○ |
| Week 7 | 6 / 21 ☆ ✓ ○ | 6 / 22 ☆ ✓ ○ | 6 / 23 ☆ ✓ ○ | 6 / 24 ☆ ✓ ○ | 6 / 25 ✓ ☆ ✓ ✓ | 6 / 26 ☆ ✓ ✓ | 6 / 27 ☆ ✓ ○ |
| Week 8 | 6 / 28 ☆ ✓ ○ | 6 / 29 ☆ ✓ ○ | 6 / 30 ☆ ✓ ○ | 7 / 1 ☆ ✓ ○ | 7 / 2 ✓ ☆ □ ✓ | 7 / 3 ☆ □ ✓ | 7 / 4 ☆ □ ○ |
| Week 9 | 7 / 5 ☆ □ ○ | 7 / 6 ☆ □ ○ | 7 / 7 ☆ □ ○ | 7 / 8 ☆ □ ○ | 7 / 9 ✓ ☆ ✓ ✓ | 7 / 10 ☆ ✓ ✓ | 7 / 11 ☆ ✓ ○ |

Note: Your dosing schedule for CYCLE 2 may end earlier than Week 9.

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

My DARZALEX FASPRO™ Dosing Calendar

| | | |
|-------------------|-----------------|--|
| WEEKS | ___ to ___ | DOSING SCHEDULE: CYCLES 1-2 |
| START DATE | ___ / ___ / ___ | You and your healthcare team can work together to fill this out to make sure it is accurate. |

My regimen is: DARZALEX FASPRO™ _____ _____

| | S | M | T | W | T | F | S |
|--------|------------|------------|------------|------------|------------|------------|------------|
| Week 1 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 2 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 3 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 4 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 5 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 6 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 7 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 8 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 9 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |

Note: Your dosing schedule for CYCLE 2 may end earlier than Week 9.

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



| | | |
|-------------------|-----------------|------------------------------------|
| WEEKS | ___ to ___ | DOSING SCHEDULE: CYCLES 3-6 |
| START DATE | ___ / ___ / ___ | |

You and your healthcare team can work together to fill this out to make sure it is accurate.

My regimen is:  DARZALEX Faspro™  _____  _____

| | S | M | T | W | T | F | S |
|---------|------------|------------|------------|------------|------------|------------|------------|
| Week 10 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 11 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 12 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 13 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 14 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 15 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 16 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 17 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 18 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 19 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 20 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 21 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 22 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 23 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 24 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |

Note: Your dosing schedule for CYCLE 3 may not begin at Week 10.

Please [click here](#) to see Important Safety Information.

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

| | | |
|-------------------|-----------------|---|
| WEEKS | ___ to ___ | DOSING SCHEDULE: CYCLES 7+ You and your healthcare team can work together to fill this out to make sure it is accurate. |
| START DATE | ___ / ___ / ___ | |

My regimen is:  DARZALEX Faspro™  _____  _____

| | S | M | T | W | T | F | S |
|---------|------------|------------|------------|------------|------------|------------|------------|
| Week 25 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 26 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 27 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 28 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 29 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 30 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 31 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 32 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 33 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 34 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 35 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 36 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 37 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 38 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |
| Week 39 | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ | / ☆ □ ○ |

Note: Your dosing schedule for CYCLES 7+ may exceed Week 39.

Please [click here](#) to see Important Safety Information.

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

Indications and Important Safety Information

What is DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihj)?

DARZALEX FASPRO™ is a prescription medicine used to treat adult patients with multiple myeloma:

- in combination with the medicines bortezomib, melphalan, and prednisone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant)
- in combination with the medicines lenalidomide and dexamethasone in people with newly diagnosed multiple myeloma who cannot receive a type of stem cell transplant that uses their own stem cells (autologous stem cell transplant) and in people whose multiple myeloma has come back or did not respond to treatment, who have received at least one prior medicine to treat multiple myeloma
- in combination with the medicines bortezomib and dexamethasone in people who have received at least one prior medicine 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 or any of the 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 at least 3 months after your final 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 and dexamethasone, females and males must agree to the instructions in the lenalidomide REMS program.
 - The lenalidomide REMS has 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 REMS about sperm donation and how lenalidomide can pass into human semen.
- are breastfeeding or plan to breastfeed. It is not known if DARZALEX FASPRO™ passes into your breast milk.

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

Continued on next page

Please [click here](#) to see Important Safety Information.

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

Indications and Important Safety Information (cont)

DARZALEX FASPRO™ may cause serious reactions, including:

- **Serious allergic reactions and other severe injection-related reactions.** Serious allergic reactions and reactions due to release of certain substances by your body (systemic) that can lead to death, can happen with DARZALEX FASPRO™. Tell your healthcare provider or get medical help right away if you get any of these symptoms during or after an injection of DARZALEX FASPRO™.

- shortness of breath or trouble breathing
- dizziness or lightheadedness (hypotension)
- cough
- wheezing
- heart beating faster than usual
- low oxygen in the blood (hypoxia)
- throat tightness
- runny or stuffy nose
- headache
- itching
- high blood pressure
- nausea
- vomiting
- chills
- fever
- chest pain

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

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

- **Changes in blood tests.** DARZALEX FASPRO™ can affect the results of blood tests to match your blood type. These changes can last for up to 6 months after your final dose of DARZALEX FASPRO™. Your healthcare provider will do blood tests to match your blood type before you start treatment with DARZALEX FASPRO™.

Tell all of your healthcare providers that you are being treated with DARZALEX FASPRO™ before receiving blood transfusions.

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

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

- tiredness
- nausea
- diarrhea
- shortness of breath
- trouble sleeping
- fever
- cough
- muscle spasms
- back pain
- vomiting
- cold-like symptoms (upper-respiratory infection)
- nerve damage causing tingling, numbness, or pain
- constipation
- lung infection (pneumonia)

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

General information about the safe and effective use of DARZALEX FASPRO™

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

Active ingredient: daratumumab and hyaluronidase-fihj

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

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

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