

DARZALEX FASPRO® (daratumumab and hyaluronidase)

What are the possible side effects of DARZALEX FASPRO?

DARZALEX FASPRO may cause serious reactions, including:

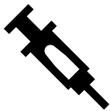
Serious allergic reactions and other severe injection-related reactions¹

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



- Shortness of breath or trouble breathing
- Dizziness or lightheadedness (hypotension)
- Cough
- Wheezing
- Heart beating faster than usual
- Low oxygen in the blood (hypoxia)
- Throat tightness or irritation
- Runny or stuffy nose
- Headache
- Itching
- High blood pressure
- Eye pain
- Nausea
- Vomiting
- Chills
- Fever
- Chest pain
- Blurred vision

Injection site reactions¹



- 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.

Heart problems in people with light chain (AL) amyloidosis¹



- Heart problems, in some cases fatal, have occurred. Your healthcare provider will monitor you closely during treatment with DARZALEX FASPRO.
- **Call your healthcare provider right away if you get any of the following symptoms: chest pain, feeling faint, swollen legs, shortness of breath, or abnormal heart rhythm.**

Infections¹



- 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 counts¹



- 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 tests¹



- 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.**

DARZALEX FASPRO® (daratumumab and hyaluronidase)

What are the possible side effects of DARZALEX FASPRO?

The most common side effects of DARZALEX FASPRO when used alone include¹:

- 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

The most common side effects of DARZALEX FASPRO when used in combination therapy include¹:

- 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; numbness, tingling, or burning sensations
- Constipation
- Lung infection (pneumonia)
- Swollen hands, ankles, or feet
- Feeling dizzy
- Bruising
- COVID-19

The most common severe abnormal blood test results with DARZALEX FASPRO include¹:

- Decreased white blood cells, platelets, and red blood cells



- These are not all of the possible side effects of DARZALEX FASPRO.¹
- Call your doctor for medical advice about side effects.¹
- You may report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088.¹

This information is provided ONLY in response to your request and is not intended as medical advice, to promote the use of our product, or suggest using it in any manner other than as described in the PRESCRIBING INFORMATION. All decisions regarding your medical treatment should be made with your healthcare professional(s). Please contact your healthcare team(s) to discuss the information in this response.

Please refer to the attached full PRESCRIBING INFORMATION and the PATIENT INFORMATION for DARZALEX FASPRO.¹

1. DARZALEX FASPRO (daratumumab and hyaluronidase-fihj) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; <https://www.injilabels.com/package-insert/product-monograph/prescribing-information/DARZALEX+Faspro-pi.pdf>.