

Daratumumab and hyaluronidase-fihj (Darzalex Faspro)

About This Medicine

DARATUMUMAB; HYALURONIDASE (dar a toom ue mab; hye al ur ON i dase) treats multiple myeloma, a type of bone marrow cancer. Daratumumab works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. Hyaluronidase works by increasing the absorption of other medications in the body to help them work better. This medication may also be used to treat amyloidosis, a condition that causes the buildup of a protein (amyloid) in your body. It works by reducing the buildup of this protein, which decreases symptoms. It is a combination medication that contains a monoclonal antibody. It is given as an injection under the skin (subcutaneously).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Upper respiratory tract infection

Note: Each of the side effects above was reported in 20% or greater of people treated with daratumumab and hyaluronidase-fihj. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Severe decrease in the number of white blood cells and platelets.
- While you are getting this injection, you may have a reaction to the medicine, which may be life-threatening. Sometimes you may be given medicine to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, blurred vision or other changes in eyesight, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. These reactions may happen after your infusion. **If this happens, call 911 for emergency care.**
- Injection site reaction - you may get a rash, swelling, or bruising or your skin may get red, warm, itchy, or painful at the site of your injection.

- Severe and life-threatening heart problems in people receiving daratumumab and hyaluronidase-fihj with light chain (AL) amyloidosis.
- This medicine can affect the results of blood tests that match your blood type during your treatment and for up to 6 months after your treatment. Your blood type will be tested before treatment. Be sure to tell all healthcare providers you are taking this medicine before receiving blood transfusions, and for 6 months after your last dose.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

Important Information

- This medicine may reactivate the hepatitis B virus. Talk to your care team if you have ever had or might have a hepatitis B infection.
- If you are taking this medicine in combination with lenalidomide, thalidomide, or pomalidomide, talk to your care team about precautions you may need to take with blood and/or sperm donation.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- Injection-related reactions may rarely occur after your injection. **If this happens, call 911 for emergency care.**
- While you are getting this medicine, please tell your care team right away if you get a rash, swelling, or bruising or your skin gets red, warm, itchy, or painful at the site of your injection.

Food and Medicine Interactions

- There are no known interactions of daratumumab and hyaluronidase-fihj with food.
- This medicine may interact with other medicines. Tell your care team about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that



you are taking at this time. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Tiredness that interferes with your daily activities
- Coughing up yellow, green, or bloody mucus
- Wheezing and/or trouble breathing
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back, or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Signs of injection-related medicine reaction: fever or shaking chills, flushing, facial swelling, blurred vision or other changes in eyesight, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 3 months after the last dose. Tell your care team right away if you think you might be pregnant. When receiving daratumumab and hyaluronidase-fihj in combination with other agents, please refer to the medicine guide of those agents for more specific information.
- **Breastfeeding warning:** Talk with your care team about breastfeeding during treatment. You may need to stop breastfeeding. When receiving daratumumab and hyaluronidase-fihj in combination with other agents, please refer to the medicine guide of those agents for more specific information.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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