

Daratumumab and hyaluronidase-fihj (Darzalex Faspro)

About This Drug

Daratumumab and hyaluronidase-fihj is used to treat cancer. It is given subcutaneously (injection in the skin).

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 (fatigue), and raise your risk of bleeding.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- Fever
- Tiredness
- Muscle spasms
- Back pain
- Effects on the nerves are called peripheral neuropathy. You may feel numbness, tingling, or pain in your hands and feet. It may be hard for you to button your clothes, open jars, or walk as usual. The effect on the nerves may get worse with more doses of the drug. These effects get better in some people after the drug is stopped but it does not get better in all people.
- Trouble sleeping
- Cough
- Trouble breathing
- Pneumonia
- Upper respiratory infection

Note: Each of the side effects above was reported in 20% or greater of patients treated with daratumumab and hyaluronidase-fihj. Your side effects may depend on whether you are receiving this drug alone or in combination with other chemotherapy. Not all possible side effects are included above.

Warnings and Precautions

- Severe decrease in the number of white blood cells and platelets



- While you are getting this drug in your vein (IV), you may have a reaction to the drug, which may be life - threatening. Sometimes you may be given medication to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, 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 infusion or injection.
- This medication 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.

Important Information

- This drug may reactivate the hepatitis B virus. Talk to your doctor if you have ever had or might have a hepatitis B infection.
- If you are taking this drug in combination with lenalidomide, talk to your doctor and/or nurse about precautions you may need to take with blood and/or sperm donation.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

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 doctor or nurse 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 nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.



- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you are having trouble sleeping, talk to your nurse or doctor on tips to help you sleep better.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- Infusion reactions may rarely occur after your infusion. **If this happens, call 911 for emergency care.**
- While you are getting this drug, please tell your nurse right away if you get a rash, swelling or bruising or your skin gets red, warm, itchy or painful at the site of your infusion or injection

Food and Drug Interactions

- There are no known interactions of daratumumab and hyaluronidase-fihj with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist 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 doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Pain in your chest
- Coughing up yellow, green, or bloody mucus
- Wheezing or trouble breathing
- Tiredness that interferes with your daily activities
- Trouble falling or staying asleep
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- No bowel movement in 3 days or when you feel uncomfortable
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Pain that does not go away, or is not relieved by prescribed medicines
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- Numbness, tingling, or pain in your hands and feet



- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug may have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 3 months after treatment. Let your doctor know right away if you think you may be pregnant. If you are taking this drug in combination with other drugs, please refer to the prescribing information of those drugs for more specific information on pregnancy warning and precautions.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should talk to their doctor about the risks and benefits of breastfeeding during treatment with this drug because this drug may enter the breast milk and cause harm to a breastfeeding baby. If you are taking this drug in combination with other drugs, please refer to the prescribing information of those drugs for more specific information on breastfeeding.
- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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