

Ropeginterferon alfa-2b-njft (Besremi)

About This Drug

Ropeginterferon alfa-2b-njft is used to treat cancer. It is given as an injection under the skin (subcutaneously).

Possible Side Effects

- Flu-like symptoms: fever, chills, headache, muscle/joint aches, and tiredness
- Bone, muscle and/or joint pain
- Tiredness
- Itching
- Inflammation of the nasal passages and throat

Note: Each of the side effects above was reported in greater than 40% of patients treated with ropeginterferon alfa-2b-njft. 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 drugs in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Severe depression and other psychiatric disorders such as aggression, feeling irritable and/or abnormally well, confusion, thoughts of hurting yourself, and suicide.
- Changes in your thyroid function and blood sugar levels
- Heart changes such as abnormal heartbeat, changes in your heart's ability to pump blood properly which can lead to fluid build-up in your body, and/or risk of heart attack.
- 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.
- Allergic reactions, including anaphylaxis are rare but may happen in some patients. Signs of allergic reaction to this drug may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this drug. You should get urgent medical treatment.**
- Inflammation (swelling) of your pancreas

- Severe colitis, which is inflammation in the colon and can be life-threatening. Symptoms are diarrhea (loose bowel movements), stomach cramping, and sometimes blood in the bowel movements.
- Changes in your lung, including inflammation and/or scarring of the lungs, increased blood pressure in the arteries of your lungs, and infection. You may have a cough and/or trouble breathing. Some changes in your lungs can be life-threatening.
- Blurred vision or other changes in eyesight such as problems with your retina (thin membrane that covers the back of the eye) which can very rarely cause blindness (loss of vision).
- Increase in your triglyceride levels
- Changes in your liver function
- Changes in your kidney function
- Tooth and gum problems which may cause tooth loss. You may have dry mouth that can damage your teeth.
- Skin problem such as rash, itching, thickening of the skin and hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.

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

Important Information

- This drug may impair your ability to drive or use machinery. Use caution and talk your doctor and/or nurse about any precautions you may need to take.

How to Take Your Medication

- Talk to your doctor, nurse, and/or pharmacist for proper preparation, dosing, and administration if you are self-injecting this medicine.
- **Missed dose:** If you miss a dose, contact your doctor right away.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- 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.
- **Storage:** Store this medicine in the refrigerator, between 36°F to 46°F (2°C to 8°C). Store in original carton to protect from light. Do not freeze. Discuss with your nurse or your doctor how to dispose of unused medicine/needles.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.



- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- 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 have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid). 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 doctor or nurse about medicine that is available to help stop or lessen diarrhea.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your nurse and they can help you get in touch with programs in your local area.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- To help with itching, moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- Sugar-free hard candies and chewing gum can keep your mouth moist.
- Tell your dentist that you are taking this drug. Talk to your doctor about any dental problems you may have before starting this drug. You may need to see your dentist to have a dental exam and fix any dental problems before starting this drug. Take good care of your teeth and brush two times a day. Make sure you see your dentist for regular follow-up appointments.

Food and Drug Interactions

- There are no known interactions of ropeginterferon alfa-2b-njft with food.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with ropeginterferon alfa-2b-njft. 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
- Tiredness or extreme weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Blurred vision or other changes in eyesight
- Loss of vision
- Confusion
- Severe mood changes such as depression or unusual thoughts and/or behaviors
- Thoughts of hurting yourself or others, and suicide
- Feeling irritable, nervous, or restless
- Feeling abnormally well
- Easy bleeding or bruising
- 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.**
- Wheezing and/or trouble breathing
- Lips or skin turn a bluish color
- Dry cough
- Coughing up yellow, green, or bloody mucus
- Tooth and/or gum pain
- Difficulty eating/swallowing
- Sore mouth/throat
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Severe pain in your abdomen that may spread to your back
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Blood in your stool
- Weight gain of 5 pounds in one week (fluid retention)
- Unexplained weight gain or weight loss
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Pain that does not go away, or is not relieved by prescribed medicines
- Swelling of the legs, feet, or ankles
- Decreased or very dark urine
- A new rash or a rash that is not relieved by prescribed medicines
- Itching that is bothersome



- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Flu-like symptoms: fever, headache, muscle/joint aches, and tiredness
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This drug can 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 8 weeks after stopping treatment. Let your doctor know right away if you think you may be pregnant.
- In women, menstrual bleeding may become irregular or stop while you are getting this drug. Do not assume that you cannot become pregnant if you do not have a menstrual period.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 8 weeks after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** 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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