

Medication Guide
BESREMi® (bez-reh-me)
ropeginterferon alfa-2b-njft
injection, for subcutaneous use

What is the most important information I should know about BESREMi?

BESREMi can cause serious side effects that:

- may cause death, or
- may worsen certain serious diseases that you may already have

Tell your healthcare provider right away if you have any of the symptoms listed below during treatment with BESREMi. If symptoms get worse, or become severe and continue, your healthcare provider may tell you to stop taking BESREMi permanently. These symptoms may go away in some people after they stop taking BESREMi.

Mental health problems, including suicide. BESREMi may cause you to develop mood or behavior problems that may get worse during treatment with BESREMi or after your last dose, including:

- irritability (getting upset easily)
- restlessness and agitation
- confusion
- depression (feeling low, feeling bad about yourself or feeling hopeless)
- unusually grand ideas
- acting aggressive
- acting impulsively
- thoughts of hurting yourself or others, or thoughts of suicide

If you develop any of these symptoms, stop using BESREMi right away. You, your caregiver, or family member should call your healthcare provider right away. Your healthcare provider should carefully monitor you during treatment with BESREMi.

New or worsening autoimmune problems. BESREMi may cause autoimmune problems (a condition where the body's immune cells attack other cells or organs in the body), including thyroid problems, increased blood sugar (hyperglycemia), and type I diabetes. In some people who already have an autoimmune problem, it may get worse during your treatment with BESREMi. Tell your healthcare provider if you have any of the following symptoms: tiredness, urinating often, or if you are very thirsty.

Heart problems. BESREMi may cause heart problems, including problems with your heart muscle (cardiomyopathy), heart attack, abnormal heart rhythm (atrial fibrillation), and decreased blood flow to your heart. You should not use BESREMi if you: have high blood pressure that is not controlled, congestive heart failure, a serious abnormal heart rhythm, narrowing of the arteries to your heart, certain types of chest pain (angina), or a recent stroke or heart attack. If you have a heart problem before you start using BESREMi, your healthcare provider should monitor you closely during treatment with BESREMi.

Call your healthcare provider right away if you get any of the symptoms listed above during treatment with BESREMi. Before and during treatment with BESREMi you will need to see your healthcare provider regularly and have blood tests to monitor your polycythemia vera, and to check for side effects. **BESREMi can cause serious side effects.**

Some of these side effects may cause death. Tell your healthcare provider right away if you have any of the symptoms listed above during treatment with BESREMi. For more information about side effects, see "What are the possible side effects of BESREMi?"

What is BESREMi?

BESREMi is a prescription medicine that is used to treat adults with polycythemia vera. It is not known if BESREMi is safe and effective in children.

Who should not use BESREMi?

Do not use BESREMi if you:

- have or had severe mental health problems, especially severe depression, thoughts of suicide, or attempted suicide
- have or had a serious or untreated autoimmune disease
- have had a serious allergic reaction to another interferon product or to any of the ingredients in BESREMi. Symptoms of a serious allergic reaction to alpha-interferon may include itching, swelling of your face, tongue, throat,

trouble breathing, feeling dizzy or faint, and chest pain. See the end of this Medication Guide for a complete list of ingredients in BESREMi. Ask your healthcare provider if you are not sure.

- have certain types of liver problems
- have received a transplant and take immunosuppressive medicines

Talk to your healthcare provider before taking BESREMi if you have any of these conditions.

Before using BESREMi, tell your healthcare provider about all of your medical conditions, including if you:

- are being treated for a mental illness or had treatment in the past for any mental illness, including depression and have had thoughts of hurting yourself or others.
- have type 1 diabetes
- have or ever had any problems with your heart, including heart attack or high blood pressure
- have or ever had bleeding problems or a blood clot
- have or ever had low blood cell counts
- have a condition that suppresses your immune system, such as certain cancers
- have hepatitis B infection
- have HIV infection
- have kidney problems
- have liver problems
- are pregnant or plan to become pregnant. BESREMi may harm your unborn baby and may cause loss of your pregnancy (miscarriage).
 - Before you start using BESREMi your healthcare provider should do a pregnancy test.
 - You should use effective birth control during treatment and for at least 8 weeks after your final dose of BESREMi. Talk to your healthcare provider about birth control choices for you during treatment with BESREMi.
 - BESREMi can affect your menstrual cycles and may cause your menstrual periods to stop.
 - Tell your healthcare provider if you become pregnant during treatment with BESREMi.
- are breastfeeding or plan to breastfeed. It is not known if BESREMi passes into your breast milk. You should not breastfeed during treatment and for 8 weeks after your final dose of BESREMi.

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

BESREMi and certain other medicines may affect each other and cause side effects. Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use BESREMi?

- See the Instructions for Use that comes with BESREMi for detailed instructions on how to prepare and inject a dose of BESREMi.
- Use BESREMi exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much BESREMi to inject and when to inject it. Do not inject more than your prescribed dose.
- BESREMi is given as an injection under your skin (subcutaneous injection). Your healthcare provider should show you how to prepare and measure your dose of BESREMi, and how to inject yourself before you use BESREMi for the first time.
- You should not inject BESREMi until your healthcare provider has shown you how to use BESREMi the right way. Your healthcare provider will prescribe the amount of BESREMi that is right for you.
- **Do not** inject more than 1 dose of BESREMi every 2 weeks without talking to your healthcare provider. Do not re-use the single-dose prefilled syringe.
- Your healthcare provider should do blood tests before you start BESREMi, and regularly during treatment to monitor your polycythemia vera, and to check you for side effects.

What should I avoid during treatment with BESREMi?

- **BESREMi may cause neurologic symptoms including dizziness, sleepiness, and hallucinations.** Avoid driving or using machinery if you develop any of these neurologic symptoms during treatment with BESREMi.

What are the possible side effects of BESREMi?

BESREMi can cause serious side effects including:

- See “What is the most important information I should know about BESREMi?”

- **Decreased blood cell counts.** Decreased blood cell counts are common with BESREMi and can sometimes also be severe, especially decreased platelets or white blood cells. Your red blood cells may also be decreased. Your healthcare provider should check your blood cell counts before you start and during treatment with BESREMi. If your blood cell counts are low you can develop anemia, infections or have problems with bleeding or bruising.

Call your healthcare provider right away if you develop any of the following symptoms:

- weakness and tiredness
- bruising easily
- you have nose bleeds often
- fever
- chills
- burning and painful urination
- urinating often
- coughing up yellow or pink mucus (phlegm)

- **Serious allergic reactions and skin reactions. BESREMi can cause serious, sudden allergic reactions.**

Get medical help right away if you get any of the following symptoms:

- skin rash or hives
- itching swelling of your face, eyes, lips tongue, or throat
- trouble breathing
- chest pain
- feeling faint

- **Eye problems.** BESREMi can cause severe eye problems with your retinas that can lead to vision loss or blindness. You should have an eye exam before and during treatment with BESREMi if you have diabetes or high blood pressure and also have retinal problems. Your healthcare provider may stop BESREMi if you develop new or worse eye problems during treatment with BESREMi.
- **Liver problems.** BESREMi can cause increases in liver enzymes and liver damage. Your healthcare provider should do blood tests to monitor your liver enzymes and liver function before you start and during treatment with BESREMi.
- **Kidney problems.** Your healthcare provider will do blood tests to check your kidney function before starting and during treatment with BESREMi. **Tell your healthcare provider right away if you develop any symptoms of a kidney problem, including:**
 - changes in the amount or color of your urine
 - blood in your urine
 - swelling in your ankles
 - loss of appetite

Your healthcare provider may stop BESREMi if you develop severe kidney problems.

- **Tooth and gum (periodontal) problems.** BESREMi can cause tooth and gum problems which can lead to tooth loss. BESREMi can also cause problems with dry mouth that can damage your teeth and the lining of the mouth during long-term treatment with BESREMi. It is important for you to brush your teeth well, two times each day and have regular dental examinations during treatment with BESREMi.
- **Skin problems.** BESREMi can cause skin problems. Signs and symptoms of a skin problem with BESREMi include:
 - itching
 - hair loss
 - rash
 - redness
 - psoriasis
 - acne
 - thickening of the skin
 - excessive sweating

Call your healthcare provider if you develop a rash that is bothersome or covers a large skin area.

The most common side effects of BESREMi include:

- flu like symptoms including: tiredness, weakness, fever, chills, muscle aches, and joint pain
- itching
- sore throat.

These are not all of the possible side effects of BESREMi.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store BESREMi?

- Store BESREMi in the refrigerator between 36° F to 46° F (2° C to 8° C).
- Keep BESREMi away from heat.
- **Do not** freeze BESREMi.
- Keep the BESREMi pre-filled syringe in the outer carton to protect it from light.

Keep BESREMi and all medicines out of the reach of children.

General information about the safe and effective use in BESREMi?

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BESREMi for a condition for which it has not been prescribed. Do not give BESREMi to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BESREMi that is written for health professionals.

What are the ingredients in BESREMi?

Active ingredient: ropeginterferon alfa-2b-njft

Inactive ingredients: benzyl alcohol, glacial acetic acid, polysorbate 80, sodium acetate, sodium chloride, Water for Injection.

Manufactured by: PharmaEssentia Corporation 2F-5 No. 3 YuanQu Street Nangang Dist. Taipei, Taiwan

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For more information, go to www.BESREMi.com or call 1-800-999-2449

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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