BESREMi®
(ropeginterferon alfa-2b-njft)
INJECTION

First **FDA-approved ET treatment** in nearly 30 years

What to Expect Guide
Start Strong With BESREMi

BESREMi is the only FDA-approved treatment for essential thrombocythemia (ET) that targets the source of the disease.

Read this Important Safety Information carefully. It explains the serious risks of BESREMi and how to take it safely. Talk to your healthcare provider if you have any questions.

What is BESREMi used for?
BESREMi is for the treatment of adults with essential thrombocythemia.

What is the most important information I should know about BESREMi?
BESREMi can cause serious side effects, including conditions that may cause death or may worsen certain serious diseases you may already have. 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.

See a term you don't recognize?

Visit **BESREMi.com/ET/resources** to see a glossary of key terms to know on your journey with ET and BESREMi.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning and Medication Guide.

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Your treatment journey

BESREMi (bez-REH-me) is different from other treatments you may have tried. **BESREMi is not chemotherapy**. **It's an innovative immunotherapy** that targets the source of ET in your bone marrow. Because BESREMi works over time, it's important to stay in close contact with your healthcare team throughout treatment.

Checking your progress
Your doctor will monitor your blood counts and ET signs and symptoms to understand how you're responding to treatment.

Results may take time
It may take several months to see results with BESREMi. Keep taking BESREMi as prescribed and talk to your doctor about what to expect along the way.

Keep the conversation going
If side effects come up, it's important to talk to your doctor. They may have recommendations for ways to help manage them.

Use this guide to learn what to expect as you get started with BESREMi and throughout treatment.

IMPORTANT SAFETY INFORMATION (continued)

Mental health problems, including suicide

BESREMi may cause mood or behavior problems that can get worse during treatment or after your last dose, including:

- Irritability (getting upset easily)
- Restlessness and agitation
- Confusion
- Depression (feeling low, hopeless, or bad about yourself)
- Unusually grand ideas
- Acting aggressive or impulsively
- Thoughts of hurting yourself or others, or thoughts of suicide

If you develop any of these symptoms, call your healthcare provider immediately.

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Monitoring your ET treatment

Comprehensive disease control can track how well your ET treatment is working and includes:

Platelet counts in the normal range

White blood cell counts in the normal range

Spleen size improved or maintained

No blood clots or major bleeding events

Your doctor can monitor your progress at your appointments.

IMPORTANT SAFETY INFORMATION (continued)

New or worsening autoimmune problems

BESREMi may cause your immune system to attack healthy cells, leading to conditions such as thyroid disease, increased blood sugar (hyperglycemia), or type 1 diabetes. Call your healthcare provider if you experience:

- Extreme tiredness
- Frequent urination
- Excessive thirst

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What to expect as your body responds to treatment

BESREMi works with your immune system to fight ET, which may make you more likely to experience some side effects. In clinical trials for BESREMi, some of these side effects lessened over time.

Here are some suggestions for how to manage the most common side effects of BESREMi:

Flu-like symptoms

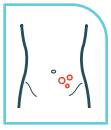
- **Talk with your doctor about taking acetaminophen to help reduce fever symptoms or ibuprofen to help reduce aches and pains**
- Stay hydrated

Tiredness

- Start injections on a day and time that is convenient for your schedule
- Alternate periods of rest and activity

Itching

- Avoid hot showers
- Use unscented body products
- Ask your doctor about taking an antihistamine



Injection site reactions

- Apply ice to the injection site
- Rotate your injection site

Talk to your doctor for more tips on managing side effects.

IMPORTANT SAFETY INFORMATION (continued)

Heart problems

BESREMi may cause heart problems, including:

- Cardiomyopathy (heart muscle disease)
- Heart attack
- Irregular heartbeat (atrial fibrillation)
- Decreased blood flow to the heart

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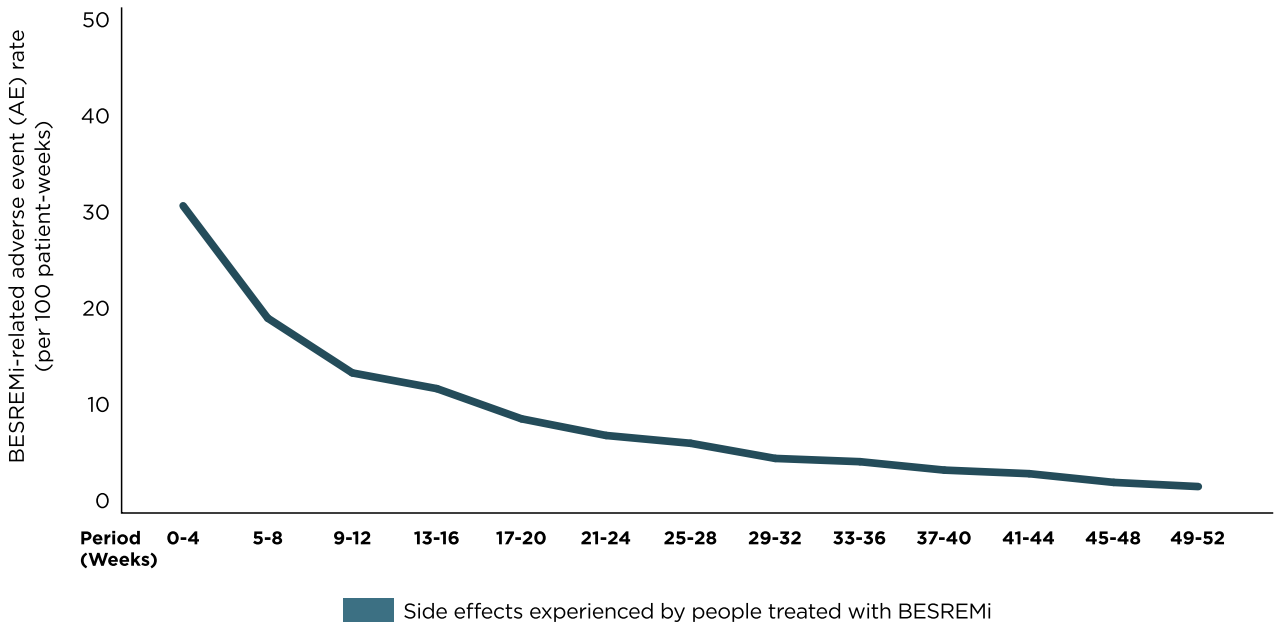
Side effects improve over time

In a clinical study of 174 adults with ET, the overall rate of side effects reported among people receiving BESREMi (91 patients) decreased over time as their bodies got used to treatment. Everyone's experience is different, and your doctor will monitor you throughout treatment.

Overall side effect rate over time



IMPORTANT SAFETY INFORMATION (continued)

Heart problems (continued)

You should not take BESREMi if you have:

- Uncontrolled high blood pressure
- Congestive heart failure
- A serious abnormal heart rhythm
- Narrowing of the arteries to your heart
- Certain types of chest pain (angina)
- A recent stroke or heart attack

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IMPORTANT SAFETY INFORMATION (continued)

Who should not take BESREMi?

Do not take BESREMi if you:

- Have or had severe mental health problems, especially depression, suicidal thoughts, or attempted suicide
- Have or had a serious or untreated autoimmune disease
- Are allergic to interferon or any ingredient in BESREMi (symptoms may include itching, swelling, trouble breathing, dizziness, or chest pain)
- Have certain types of liver disease
- Have had a transplant and take immune-suppressing medication

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

- A mental illness
- Type 1 diabetes
- Heart or bleeding problems
- Problems with your immune system
- Hepatitis B or HIV infection
- Kidney or liver problems
- Are pregnant or planning to become pregnant
  - BESREMi may harm your unborn baby. Use effective birth control during treatment and for at least 8 weeks after your last dose
  - BESREMi may affect your menstrual cycle and could stop your periods
  - Do not breastfeed while taking BESREMi

What are the possible side effects of BESREMi?
Serious side effects include:

- Low blood cell counts: Taking BESREMi can lead to infections, anemia, or bleeding problems. Call your healthcare provider right away if you develop weakness and tiredness, bruising easily, nose bleeds often, fever, chills, burning and painful urination, urinating often, or coughing up yellow or pink mucus (phlegm)
- Serious allergic reactions: Get medical help right away if you get any of the following symptoms: skin rash or hives; itching; swelling of the face, eyes, lips, tongue, or throat; trouble breathing; chest pain; or 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

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IMPORTANT SAFETY INFORMATION (continued)

Serious side effects include: (continued)

- 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, swelling in your ankles, blood in your urine, or loss of appetite
- Tooth and gum problems: BESREMi can cause tooth loss and/or dry mouth. It is important for you to brush your teeth well, two times each day and have regular dental examinations during treatment with BESREMi
- Skin reactions: BESREMi may cause reaction such as rash, itching, and hair loss
- Increased triglycerides: You may require blood tests to monitor levels

The most common side effects of BESREMi include increased liver function tests, low red blood cell counts (anemia), fever, increased protein in the urine, bacterial infection, itching, and weight loss.

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 PharmaEssentia at **1-800-999-2449** or FDA at **1-800-FDA-1088**.

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Achieve ET control beyond counts with BESREMi

Visit **BESREMi.com/ET/sign-up** to receive tips to help you start and stay on BESREMi.

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PharmaEssentia

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