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

Letter of Medical Necessity for Travel

To Whom It May Concern:

_____ (patient's name) is currently under my medical care and is being treated with BESREMi®, which is vital to my patient's health.

This patient will be carrying the following items:

- **Cooler or travel pack containing:**
  - — BESREMi Pen, 500 mcg/0.5 mL solution for injection (in single-use pens)
  - — Single-use disposable needles
  - — Ice pack
- **Sharps disposal container**

It is important to note that the single-use pens are fragile and need to be stored at a temperature between 36 ^{0}F and 46 ^{0}F (2 ^{0}C and 8 ^{0}C). Therefore, they should not be kept in checked luggage.

Please allow _____ (patient's name) to pass through security and board their flight with BESREMi Pen and the necessary supplies.

If you have any questions or need additional information, please do not hesitate to contact me at (_____) _____ – _____

Thank you,

_____ _____

Doctor's signature Date

_____

Doctor's name

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.
- With polycythemia vera.

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.

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

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Helpful Tips for Travel

Before you travel

- Tell your doctor about your travel plans
- Call ahead to your hotel to make sure a refrigerator will be available in your room
- Remember to bring the following documents with you:
  - This Letter of Medical Necessity for Travel to show the airport and security staff that you have permission from your doctor to travel with BESREMi Pen
  - Health insurance card(s)

While at the airport

- Be sure to tell the Transportation Security Administration (TSA) officer that you're carrying a liquid medicine within a pen
- Ask the TSA officer for a visual inspection of your BESREMi Pen. Do not put BESREMi Pen through the X-ray screening
- Keep BESREMi Pen in your carry-on bag. It doesn't need to be placed in a separate clear plastic bag
  - Please visit **www.tsa.gov** for full rules and regulations about traveling with your medicine
- It is important to keep BESREMi Pen cold at all times, in a cooler pack, until you need it

Traveling back home

- Any pens and needles that you used during your trip must be transported in a sharps disposal container
  - You may put the container in your checked bag or carry-on bag

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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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

Heart problems

BESREMi may cause heart problems, including:

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

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

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

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IMPORTANT SAFETY INFORMATION (continued)

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
- 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 in essential thrombocythemia include increased liver function tests, low red blood cell counts (anemia), fever, increased protein in the urine, bacterial infection, itching, and weight loss.

The most common side effects of BESREMi in polycythemia vera include flu-like symptoms, such as 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 PharmaEssentia at **1-800-999-2449** or FDA at **1-800-FDA-1088**.

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PharmaEssentia

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