

■ 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 500 mcg/mL solution for injection in single-use prefilled syringes
- Disposable needles
- Ice pack

- **Sharps disposal container**

It is important to note that BESREMi prefilled syringes are fragile and need to be stored at a temperature between 36°F and 46°F (2°C and 8°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 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

What is BESREMi?

BESREMi is a prescription medicine that is used to treat adults with polycythemia vera

IMPORTANT SAFETY INFORMATION

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 serious side effects during treatment with BESREMi. If symptoms get worse, or become severe and continue, your healthcare provider may tell you to stop taking BESREMi. 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](#).

■ 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
 - 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
- Ask the TSA officer for a visual inspection of your BESREMi medicine. Do not put BESREMi through the x-ray screening
- Keep BESREMi 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 cold at all times, in a cooler pack, until you need it



Traveling back home

- Any syringes 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)

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

- 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, or thoughts of hurting yourself or others, or thoughts of suicide. If you develop any of these symptoms, you, your caregiver, or family member should call your healthcare provider immediately. Your healthcare provider should carefully monitor you during treatment with BESREMi.

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IMPORTANT SAFETY INFORMATION (continued)

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

- 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 tiredness, are 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.

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 may include itching, swelling of your face, tongue, throat, trouble breathing, feeling dizzy or faint, and chest pain
- have certain types of liver problems
- have received a transplant and take immunosuppressive medicines

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, a blood clot, or low blood cell counts
- have a condition that suppresses your immune system, such as certain cancers
- have hepatitis B or HIV infection
- have kidney or 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.

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IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of BESREMi?

BESREMi can cause serious side effects including:

- **Decreased blood cell counts:** Your healthcare provider should check your blood cell counts before you start and during treatment with BESREMi. If your blood cell counts are too low you can develop anemia, infections or have problems with bleeding or bruising.
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 and skin 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. 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, or 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, or 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

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