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

INSTRUCTIONS FOR USE

BESREMi Pen
(ropeginterferon alfa-2b-njft)
Injection, for subcutaneous us

Single-dose prefilled pen injector

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 on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

PharmaEssentia

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Your healthcare provider has prescribed BESREMi Pen, an injectable medicine. This guide covers all you need to know about using BESREMi Pen.

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Watch the Instructions for Use Video

Scan the QR code or visit YouTube.com/@BESREMi to find out more and watch a video that shows step-by-step instructions for using BESREMi Pen.

Still have questions about using BESREMi Pen?

- Visit BESREMi.com to get answers to frequently asked questions
- Speak with a PharmaEssentia SOURCE™ Case Manager at 800-700-5053 between 8 AM and 8 PM ET, Monday through Friday

Please see additional Important Safety Information on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

Important Information
You Need to Know Before Injecting BESREMi Pen

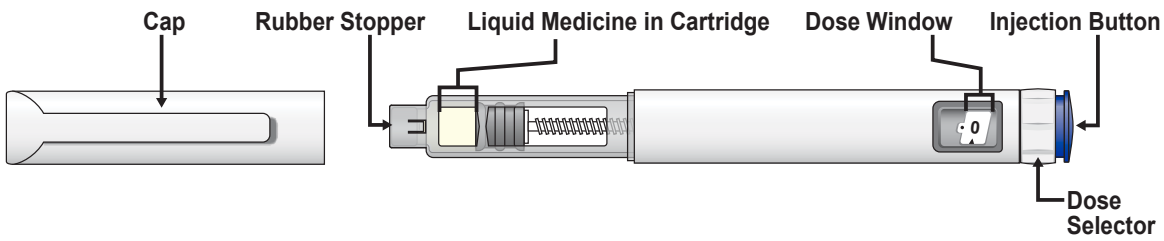
Read this Instructions for Use before using your single-dose BESREMi Pen and each time you get a new prescription. There may be new information.
This resource does not take the place of talking with your healthcare provider about your medical condition or your treatment. Ask your healthcare provider about the right way to prepare and give your BESREMi injection.

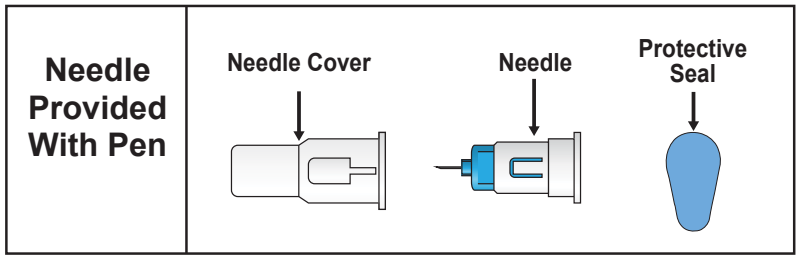
- Your healthcare provider will tell you the prescribed dose that you should take using BESREMi. Each time you inject, be sure that you know the prescribed dose of BESREMi to inject. Your dose may change over time
- **BESREMi Pens are for one-time use only. A single-use safety needle is provided with the pen and cannot be removed from the pen after attaching. Do not reuse the pen or needle**
- BESREMi is for subcutaneous (under the skin) injection only. **Do not** inject into a vein
- **Do not** use BESREMi Pen if it is **damaged or broken**, the **expiration date has passed**, or the **liquid is cloudy, discolored, or contains particles**
- Contact your pharmacist for a replacement pen or needles
- Inject BESREMi into the lower stomach (abdomen) area or top of the thighs. **Do not** inject BESREMi into any other area of the body. See Step 5 for injection site information
- Throw away (dispose of) the BESREMi Pen with the needle attached into a sharps disposal container right away after use, even if there is still medicine in the pen. See Step 14 for disposal instructions

Please see additional Important Safety Information on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

BESREMi Pen Components and Storage

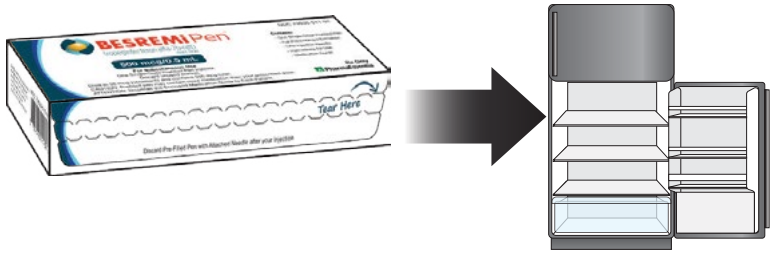
Guide to BESREMi Pen





Storing BESREMi Pen

- **Store the BESREMi Pen carton in a refrigerator** at 36 °F to 46 °F (2 °C to 8 °C)
- Keep the BESREMi Pen in the original carton to protect it from light
- **Do not** freeze the BESREMi Pen
- **Keep the BESREMi Pen, needles, and all medicines out of the reach of children**



Store BESREMi Pen Carton in Refrigerator

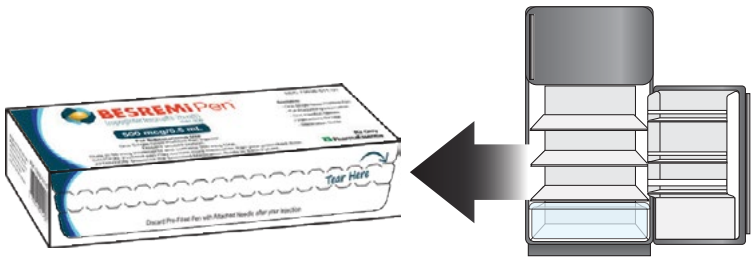
Please see additional Important Safety Information on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

PREP: Prepare to Inject BESREMi Pen

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

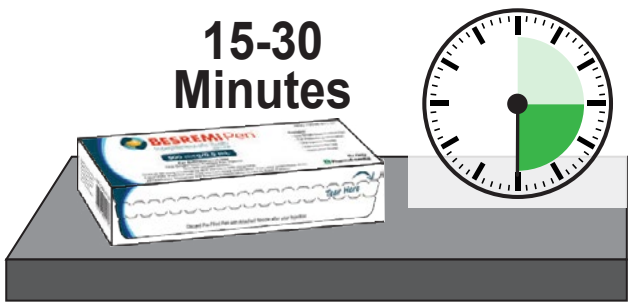
STEP 1 Prepare BESREMi Pen

1.1 Take the BESREMi Pen carton out of the refrigerator.



1.2 Let the carton containing the BESREMi Pen sit on a flat, clean work surface for **15 to 30 minutes to allow it to come to room temperature between 59 ˚F to 77 ˚F (15 ˚C to 25 ˚C)**.

Do not warm the BESREMi Pen any other way.

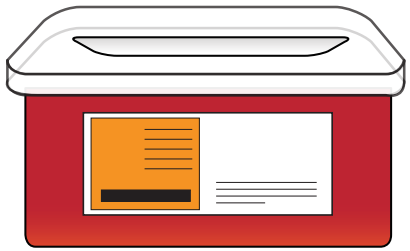


STEP 2 Gather supplies for injection

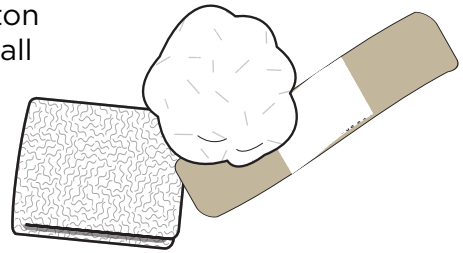
2.1 After allowing the BESREMi Pen to come to room temperature, **gather the following additional supplies** not provided in the BESREMi Pen carton.

- **Alcohol swabs**

- **Sharps disposal container**



- **Optional items:** gauze or cotton ball and a small adhesive bandage



Please see additional Important Safety Information on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

PREP: Prepare to Inject BESREMi Pen (continued)

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

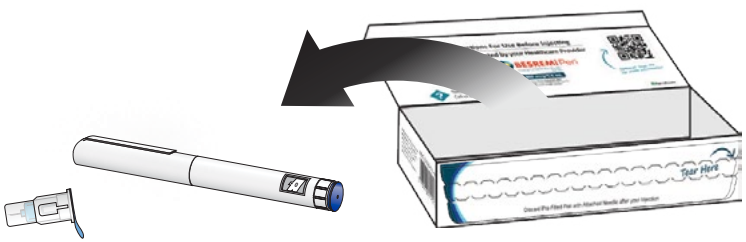
STEP 3 — Wash hands, check expiration date, and remove BESREMi Pen from carton

3.1 Wash your hands with soap and water, then dry your hands.

3.2 Check the expiration date (EXP) on the carton to make sure it has not passed.

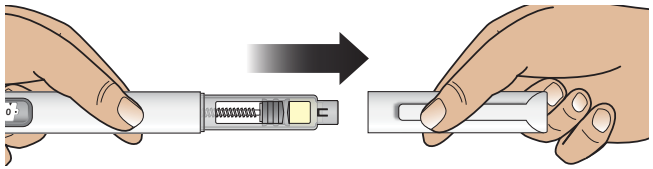
Do not use the BESREMi Pen if the expiration date has passed.

3.3 Open the carton and **remove the BESREMi Pen and needle**.



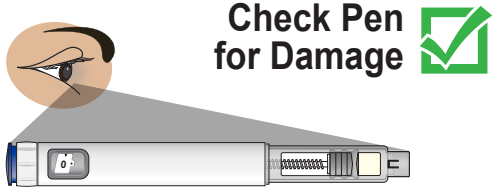
STEP 4 — Remove the pen cap, check BESREMi Pen, and check liquid medicine

4.1 Remove the pen cap by pulling it straight off the BESREMi Pen and throw away.



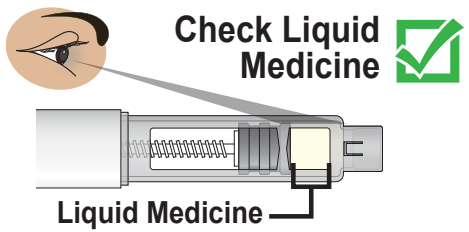
4.2 Check the BESREMi Pen to see if it is damaged or broken.

Do not use the BESREMi Pen if it shows any signs of damage or breakage.



4.3 Check the liquid medicine in the BESREMi Pen. The liquid should appear clear and colorless to slightly yellow in color.

Do not use the BESREMi Pen if the liquid is cloudy, discolored, or contains particles.



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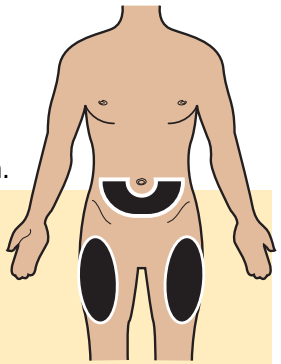
PREP: Prepare to Inject BESREMi Pen (continued)

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

STEP 5 Choose and clean injection site

5.1 Choose one of the following injection sites:

- **Lower stomach (abdomen)** area, at least 2 inches away from the belly button, or
- **Top of thighs**



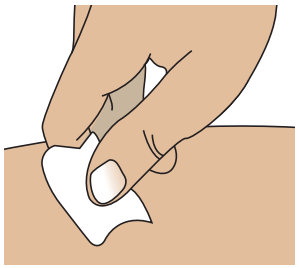
Rotate (change) the injection site for each injection.

Do not inject into skin that is irritated, red, bruised, infected, or scarred.

Do not inject into a vein. BESREMi Pen is for subcutaneous (under the skin) injection only.

5.2 Clean the chosen injection site with an alcohol swab and let it air dry. Throw away the alcohol swab after use.

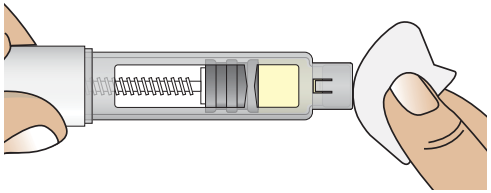
Do not blow on or touch the cleaned injection site.



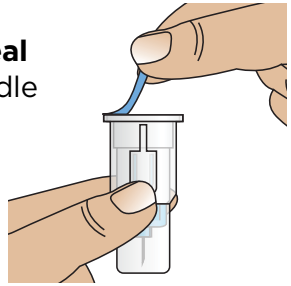
STEP 6 Clean the rubber stopper and peel off needle seal

6.1 Clean the rubber stopper on the tip of the pen with a new alcohol swab.

Throw away the alcohol swab after use.

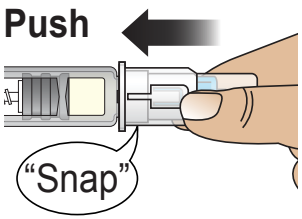


6.2 Peel off the protective seal from the needle and throw it away.

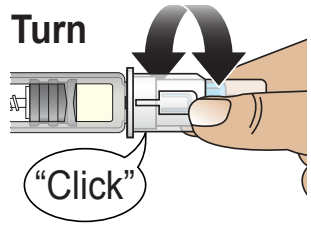


STEP 7 Attach the needle to the BESREMi Pen and remove the needle cover

7.1 Attach the capped needle by pushing it straight onto the BESREMi Pen **until you feel or hear it "snap"** into place.

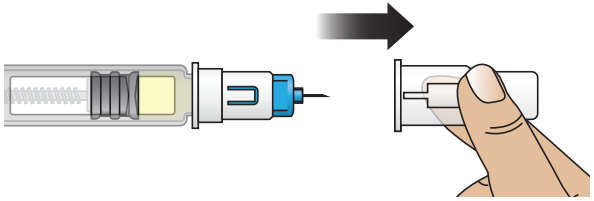


Turn or rotate the needle in either direction **until it "clicks"** into place. The needle is attached when it no longer turns or rotates freely.



7.2 Remove the needle cover by **pulling it off** and throw it away.

Do not recap the needle.



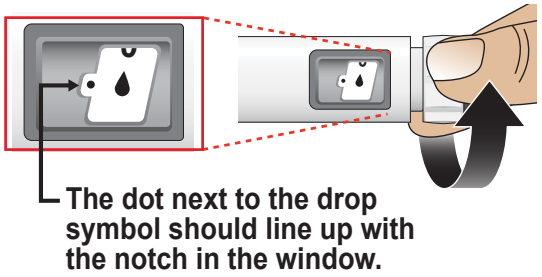
Please see additional Important Safety Information on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

CLICK: Remove Air

STEP 8 Remove air from the drug cartridge

8.1 Turn the dose selector until the flow check **drop symbol "💧" is centered** in the dose window.

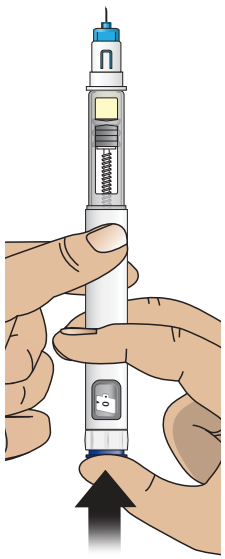
Do not dial your prescribed dose when doing the flow check. You will be instructed to in Step 10.1.



8.2 **Hold the BESREMi Pen with the needle pointing up.**

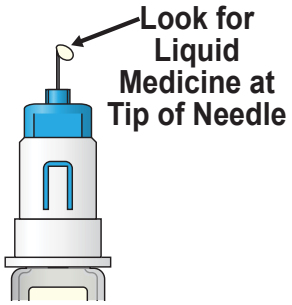
8.3 **Press and hold the injection button** all the way in until the dose window returns to "0."

8.4 **Repeat Steps 8.1 to 8.3** (dial to drop symbol and press injection button) **3 more times for a total of 4 cycles**.



STEP 9 Check needle for liquid medicine

9.1 After 4 cycles (see step 8.4), **check the tip of the needle** to make sure there is liquid medicine.



9.2 **If you do not see liquid at the tip of the needle, repeat Steps 8.1 to 8.3 again** (dial to drop symbol and press injection button) **up to 3 more times for a total of 7 cycles**.

Important: If you still do not see liquid at the tip of the needle after 7 cycles, get a new BESREMi Pen carton and start over from Step 1.

Please see additional Important Safety Information on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

PUSH: Inject BESREMi Pen

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

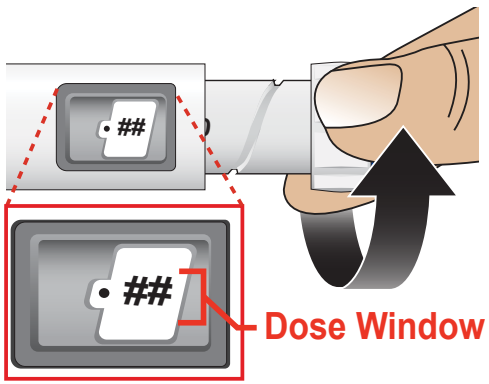
STEP 10 Set your dose

10.1 **Check your prescription to make sure you know your prescribed dose.** You will need to set your prescribed dose before giving the injection.

10.2 **Set your dose** by turning the dose selector clockwise until the prescribed dose is centered in the dose window.

It is normal to hear a clicking sound as you dial.

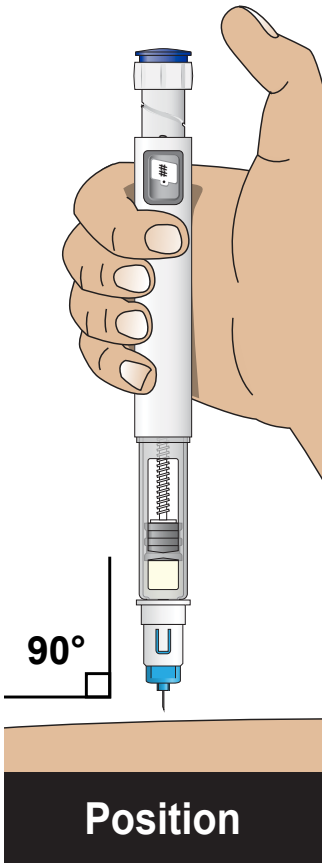
Check to make sure the number in the dose window is the correct prescribed dose before giving the injection.



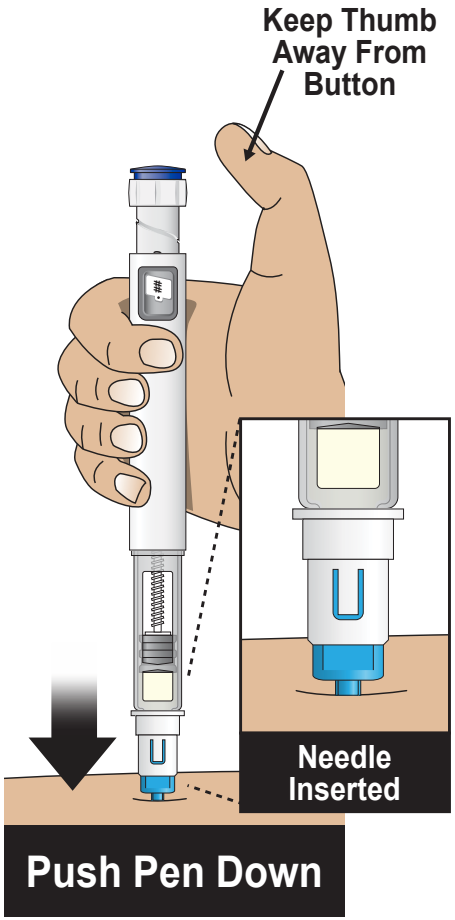
If you accidentally turn the dose selector past the prescribed dose, turn the dose selector back to the correct dose.

STEP 11 Insert the needle

11.1 **Hold the BESREMi Pen** over the cleaned injection site at a 90-degree angle.



11.2 Without touching the injection button, **push the BESREMi Pen down to fully insert the needle into the skin**.



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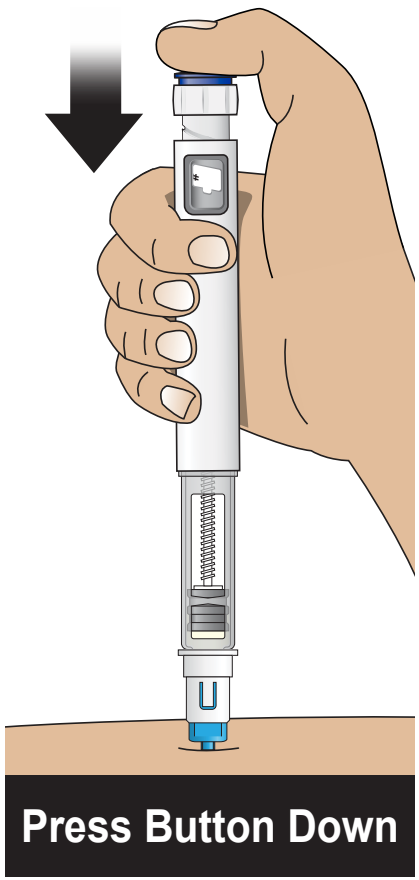
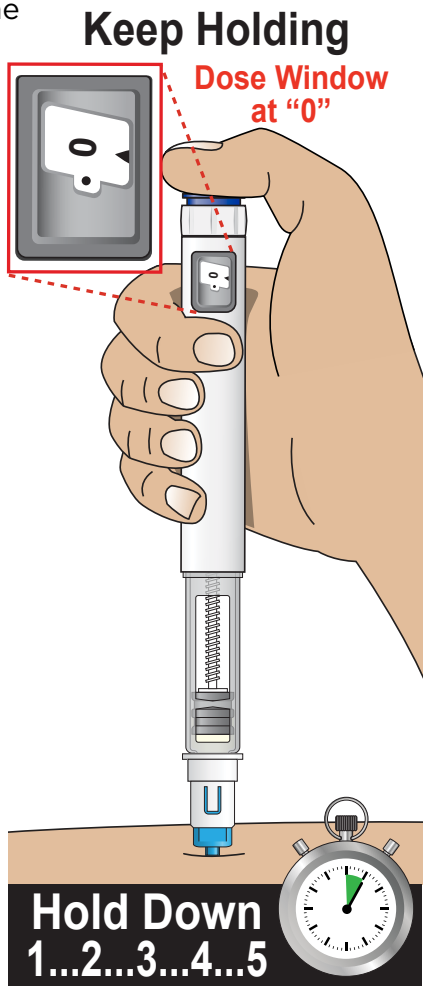
STEP 12 **Give injection**

12.1 **Press and hold the injection button** all the way down until it stops. The number in the dose window will go back to "0."



12.2 **Keep holding the injection button down after the dose window returns to "0" and count to 5** to make sure the full dose is delivered.

Note: There may still be liquid remaining in the pen cartridge after the injection. This is normal.



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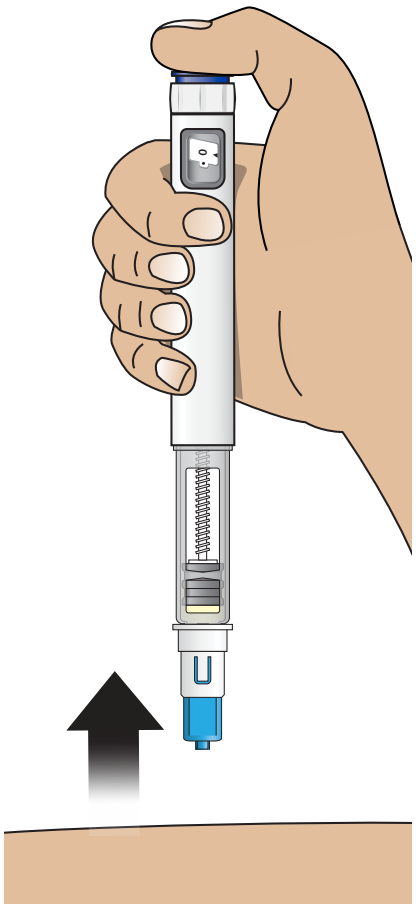
Dispose of Used BESREMi Pen

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

STEP 13 Remove needle from skin

13.1 Remove the needle from the skin by lifting the pen straight up.

The blue needle shield will cover the needle.

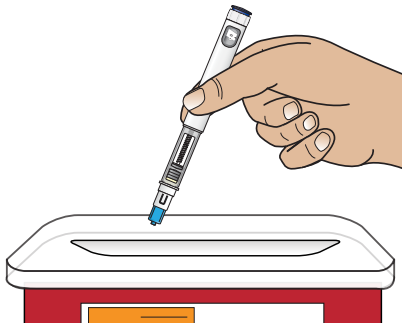


STEP 14 Throw away (dispose of) pen and treat injection site

14.1 Put the used BESREMi Pen, **with the needle still attached**, into a sharps disposal container right away after use.

Important: Do not recap the needle or attempt to remove it.

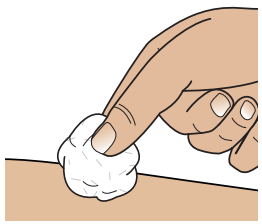
Do not reuse the BESREMi Pen. **Throw it away in a sharps disposal container after use**, even if there is still medicine left in the BESREMi Pen.



14.2 If there is a small amount of blood or liquid at the injection site, press a gauze or cotton ball over the injection site until the bleeding stops.

If needed, you may apply a small adhesive bandage.

Do not rub the injection site.



Additional Sharps Disposal Information:

If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out
- upright and stable during use
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

Always keep the sharps disposal container out of the reach of children.

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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.

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

Please see additional Important Safety Information on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

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
- 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**.

Please see full Prescribing Information, including Boxed Warning and Medication Guide.

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

PREP. CLICK. PUSH.

Please see additional Important Safety Information on pages 12-13, and full Prescribing Information, including Boxed Warning and Medication Guide.

For additional information about BESREMi Pen and a video demonstration on how to use BESREMi Pen, go to **BESREMi.com**.

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