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

INSTRUCTIONS FOR USE

BESREMi [bez-reh-me]
(ropeginterferon alfa-2b-njft)
Injection, for subcutaneous use

Single-dose prefilled syringe

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 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 accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

PharmaEssentia™

Table of Contents

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

3 Important Information

4 Guide to Components and Storage

5 Gather and Check Supplies

7 Prepare Syringe for Injection

10 Inject BESREMi

11 Dispose of Used Syringe and Needle

12 Important Safety Information

Watch the Instructions for Use Video

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

Still have questions about using BESREMi?

- 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 accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

Important Information

You Need to Know Before Injecting with the Single-Dose BESREMi Prefilled Syringe

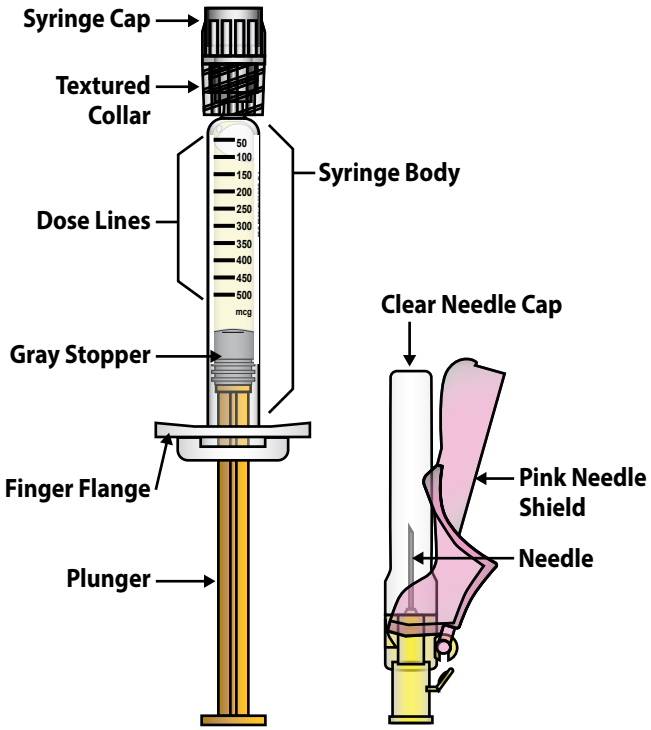
Read this Instructions for Use before using your single-dose BESREMi prefilled syringe and each time you get a new prescription. There may be new information. This resource does not take the place of talking with your healthcare provider about your medical condition or your treatment. Ask your healthcare 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 and the right amount of BESREMi to measure in the prefilled syringe for your dose. Each time you inject, be sure that you know the prescribed dose of BESREMi to inject. Your dose may change over time
- BESREMi is for subcutaneous (under the skin) injection only
- BESREMi is for one-time use only. **Do not** reuse your prefilled syringe or needle
- **Do not** use a prefilled syringe or needle that is damaged or broken. Contact your healthcare provider for a replacement prefilled syringe or additional needles
- Inject BESREMi into the top of the thighs or lower stomach-area just under the skin. **Do not** inject BESREMi into any other area of the body
- Throw away (dispose of) the BESREMi prefilled syringe with needle attached right away after use, even if there is medicine left in the prefilled syringe. See Step 10 in the section "Dispose of used prefilled syringes and needles"

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

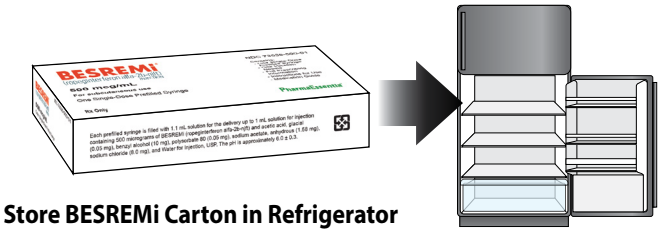
Guide to Components and Storage

Guide to Prefilled Syringe and Needle Parts



Storing BESREMi

- **Store the BESREMi carton in the refrigerator** between 36°F to 46°F (2°C to 8°C)
- Keep your BESREMi prefilled syringes in their original carton while stored
- **Do not** freeze the prefilled syringes
- **Do not** use a prefilled syringe that has been frozen or left in direct sunlight
- Keep BESREMi prefilled syringes, needles, and all medicines out of the reach of children



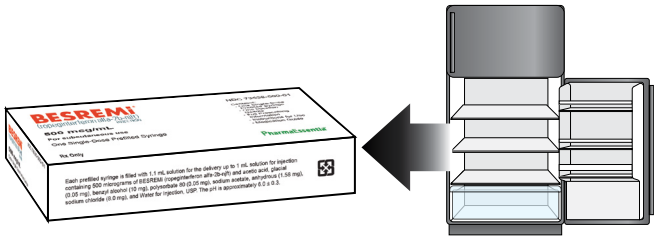
Store BESREMi Carton in Refrigerator

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

Gather and Check Supplies

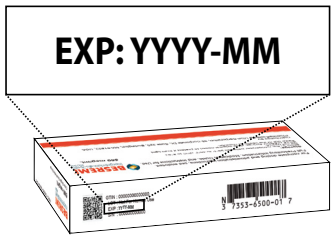
STEP 1 Prepare BESREMi Prefilled Syringe

1.1 Take the BESREMi carton out of the refrigerator.



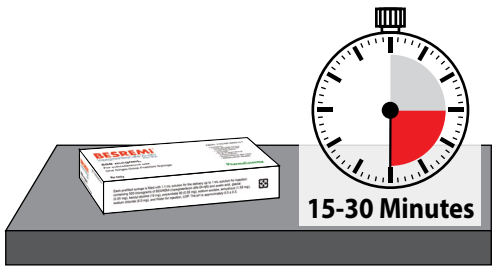
1.2 Check the expiration date ("EXP") on the top panel of the carton to make sure it has not passed.

Do not use the prefilled syringe if the expiration date has passed.



1.3 Let carton containing the BESREMi prefilled syringe sit on a clean work surface for **15 to 30 minutes** to allow it to come to room temperature.

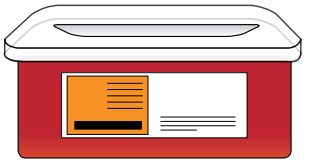
Do not warm the prefilled syringe any other way.

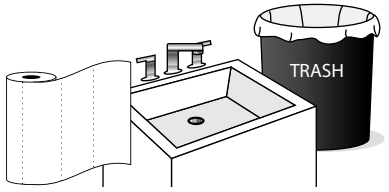


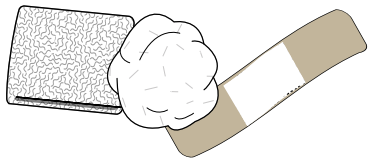
STEP 2 Gather Supplies for Injection

2.1 After allowing the prefilled syringe to come to room temperature for 15 to 30 minutes, gather the following additional supplies.

- **Alcohol swab**
- **FDA-cleared sharps disposal container**
- **A paper towel, sink, or trash can** to minimize mess during dose adjustment
- **Optional items:** Gauze or cotton ball and a small adhesive bandage







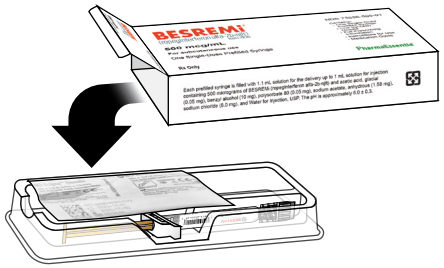
Please see additional Important Safety Information on pages 12-13 and accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

Gather and Check Supplies (continued)

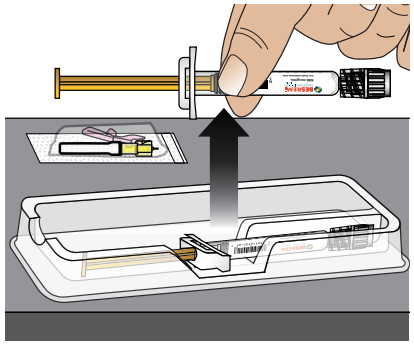
STEP 3 Wash Hands and Remove Syringe from Tray

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

3.2 Open the carton and remove the clear plastic tray that holds the BESREMi prefilled syringe and needle package.



3.3 Remove the needle package and BESREMi prefilled syringe from the plastic tray. Hold the prefilled syringe by the middle of the syringe body during removal.



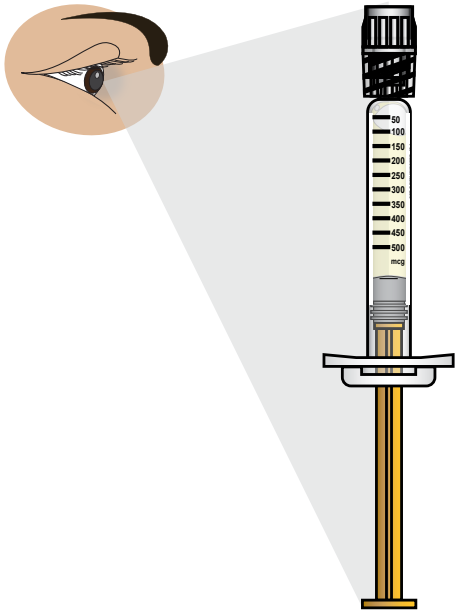
STEP 4 Check the Liquid Medicine in the BESREMi Prefilled Syringe

4.1 Check the liquid medicine in the prefilled syringe. The liquid should be clear and colorless to slightly yellow, and should not have particles.

Do not use the prefilled syringe if the liquid is cloudy, discolored, or contains particles. Contact your healthcare provider or pharmacist.

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

Do not use the prefilled syringe if it shows any signs of damage or breakage. Contact your healthcare provider or pharmacist.



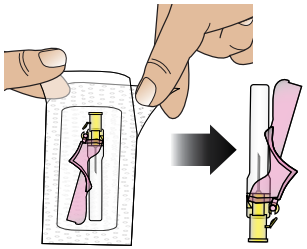
Please see additional Important Safety Information on pages 12-13 and accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

Prepare Syringe for Injection

STEP 5 Attach the Needle to the BESREMi Prefilled Syringe

5.1 Carefully open the needle package, remove the needle, and set it aside.

Throw away the packaging into household trash.

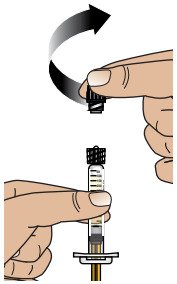


5.2 Hold the prefilled syringe as shown.

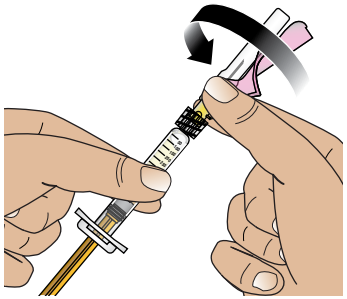
Remove the prefilled syringe cap by unscrewing it counter-clockwise.

Throw away the syringe cap into household trash.

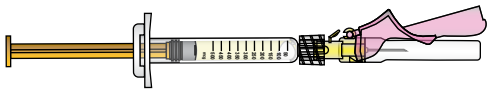
Do not allow the tip of the prefilled syringe to touch anything.



5.3 Attach the needle to the prefilled syringe by firmly pushing it into the collar of the syringe and then screwing (turn clock-wise) it on until it feels securely attached.



The needle should now be assembled to the prefilled syringe.



STEP 6 Choose and Clean Injection Site

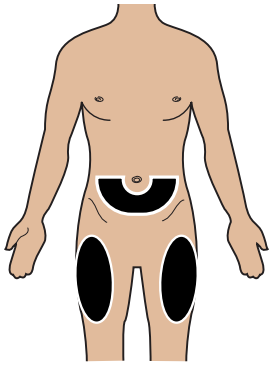
6.1 Choose one of the following injection sites:

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

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

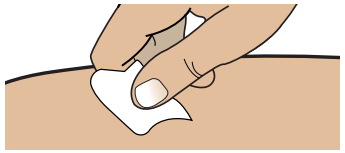
BESREMi is for subcutaneous (under the skin) injection only.

Rotate (change) the injection site for each injection.



6.2 Clean the chosen injection site with an alcohol swab and let it air dry.

Do not blow on or touch the injection site after it has been cleaned.



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

Prepare Syringe for Injection (continued)

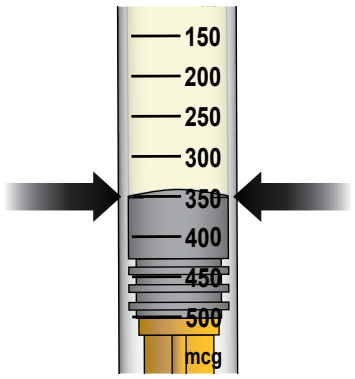
Read Me

How to Adjust the Medicine Level for Your Prescribed Dose

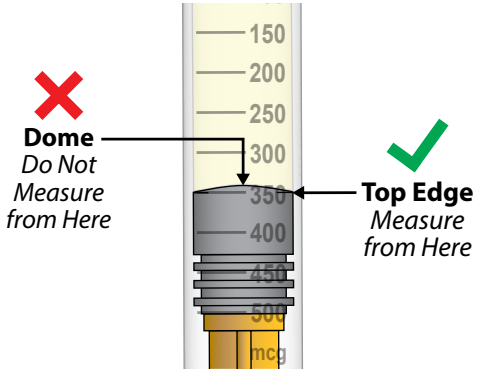
When setting your dose in Step 8, you will need to line up the top outer edge of the gray stopper with the specific dose line and number on the syringe that matches your prescribed dose.

Do not line up the dome (at the top of the stopper) with the dose line.

Align Top Outer Edge of Stopper to Dose Line



Example of 350 mcg dose



Example of 350 mcg dose

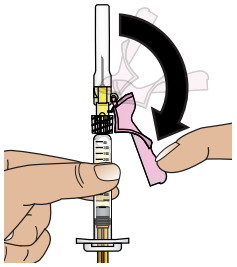
Please see additional Important Safety Information on pages 12-13 and accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

Prepare Syringe for Injection (continued)

STEP 7 Uncap Needle and Move Air Bubbles to Top

7.1 Pull the pink needle shield back.

Note: The pink needle shield will be used after the injection to cover the needle and protect you from needle-stick injuries.

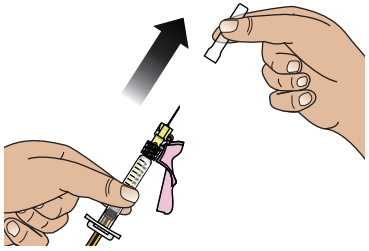


7.2 Hold the syringe from the syringe body.

Remove the clear needle cap by pulling it straight off.

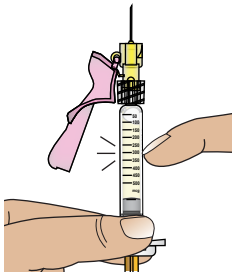
Throw away the needle cap into household trash.

Do not recap needle.



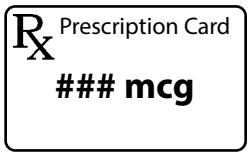
7.3 Hold the prefilled syringe with the needle pointing up.

Tap on the body of the prefilled syringe to move any air bubbles to the top.



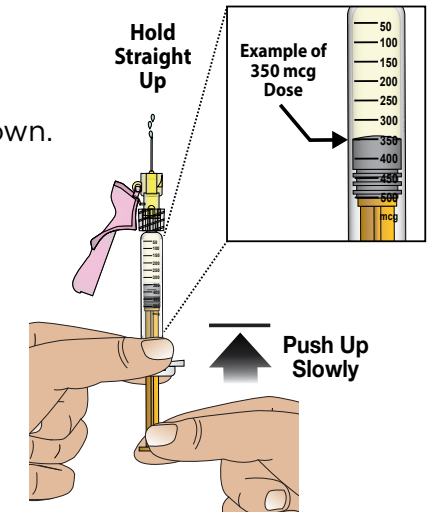
STEP 8 Set Your Dose

8.1 **Check your prescription to identify your prescribed dose.** Depending on your prescribed dose, you may have to adjust the dose in the syringe by getting rid of (discarding) some medicine from the prefilled syringe before you inject the medicine.



8.2 **To set your dose follow the 4 steps below:**

1. **Hold** the prefilled syringe at eye level with the needle **pointing straight up** over a paper towel, sink, or trash can.
2. **Check** that you can see the dose lines and number markings on the prefilled syringe.
3. **Pinch** the end of the plunger as shown.
4. **Slowly push up** on the plunger to remove liquid medicine until the top edge of the gray stopper lines up with the marking for **your prescribed dose. Keep holding straight up as you set the dose.**



Important: If you accidentally remove too much liquid medicine, **do not** inject. Contact your healthcare provider or pharmacist.

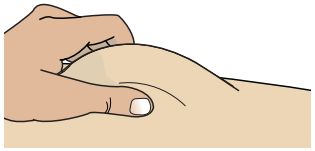
Caution: The example shown in this figure may not be your prescribed dose. **Always adjust the medicine level in the syringe to match your prescribed dose.**

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

Inject BESREMi

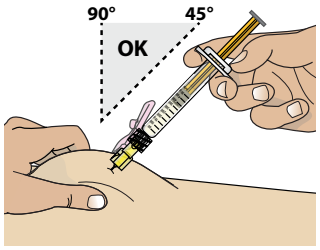
STEP 9 Give Injection

9.1 Pinch the chosen injection site.

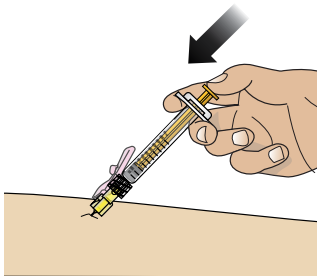


9.2 While pinching the skin, insert the needle at a **45 to 90 degree** angle into the pinched skin.

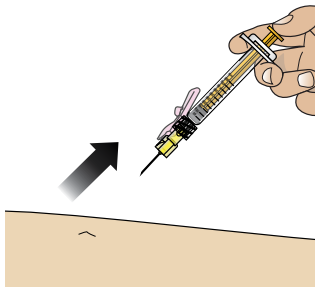
Then release the pinched skin.



9.3 Inject the medicine by slowly pressing down on the plunger all the way until it stops.



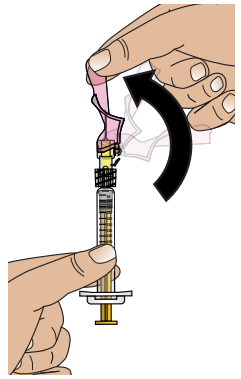
9.4 After all the liquid medicine is injected, remove the needle from the skin.



9.5 Cover needle

Carefully push the pink needle shield over the needle until it snaps into place and covers the needle. This helps prevent needle-stick injuries.

Do not recap the needle using the needle cap. Only use the pink needle shield to cover the needle.



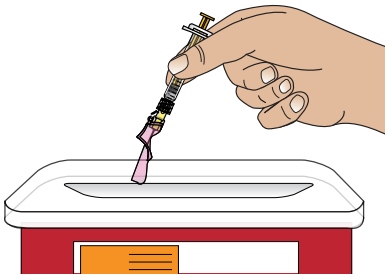
Do not reuse the prefilled syringe and needle.

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

Dispose of Used Syringe and Needle

STEP 10 Dispose of Used Prefilled Syringes and Needles

10. Put your used prefilled syringes and needles in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose prefilled syringes and needles in the household trash.**



If you do not have an FDA-cleared 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
- Properly labeled to warn of hazardous waste inside the container

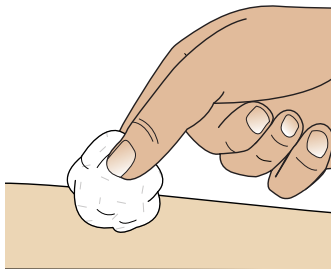
When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, 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.

STEP 11 Check Injection Site

11.1 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.



11.2 **Do not** rub the injection site.

If needed, you may apply a small adhesive bandage.

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

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

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

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

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

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

Manufactured by:
PharmaEssentia Corporation
2F-5 No. 3 YuanQu Street
Nangang Dist. Taipei, Taiwan
U.S. License number: 2155

Distributed by:
PharmaEssentia USA Corporation
35 Corporate Drive, Suite 325
Burlington, MA 01803

© 2025 PharmaEssentia Corporation. All rights reserved.
BESREMi, the BESREMi logo, and PharmaEssentia are registered trademarks of PharmaEssentia Corporation, and the PharmaEssentia logo is a trademark of PharmaEssentia Corporation.
US-BSRM-2500073 (v1.0) 06/2025

PharmaEssentia™