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

BESREMi Injection Training Guide

INDICATION

BESREMi is indicated for the treatment of adults with polycythemia vera

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DISORDERS

Interferon alfa products may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Therapy should be withdrawn in patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all cases, these disorders resolve after stopping therapy.

CONTRAINDICATIONS

- Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation, or suicide attempt
- Hypersensitivity to interferons including interferon alfa-2b or any of the inactive ingredients of BESREMi.
- Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment
- History or presence of active serious or untreated autoimmune disease
- Immunosuppressed transplant recipients

Please see additional Important Safety Information on pages 16 to 18 and full Prescribing Information, including Boxed Warning.

The purpose of this guide is to ensure that healthcare providers will be prepared to train patients how to self-inject with the single-dose BESREMi® (ropeginterferon alfa-2b-njft) prefilled syringe.

This training will cover how to communicate the following sections within the Instructions for Use (IFU):

- This guide follows the IFU step-by-step, and the IFU is intended to be read from the perspective of the patient.
- The tips within these boxes are not part of the IFU, but contain useful information that can help healthcare providers train patients to self-inject.

Please see additional Important Safety Information on pages 16 to 18 and full Prescribing Information, including Boxed Warning.

Important information you need to know before injecting BESREMi

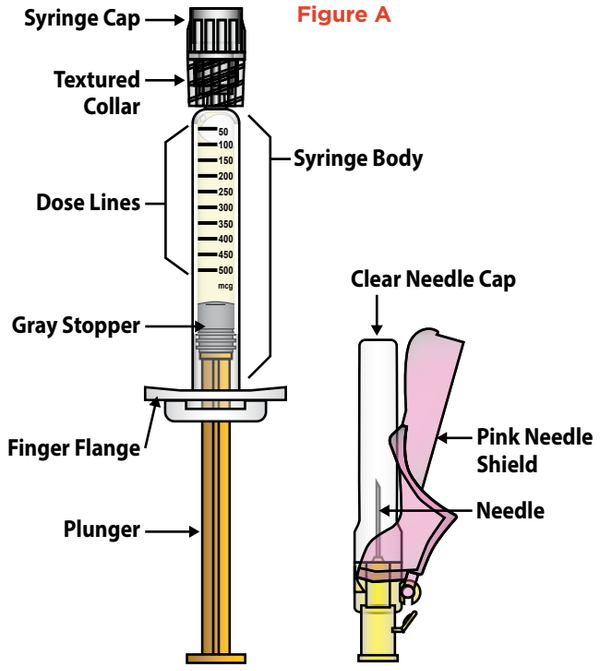
Read this Instructions for Use before using your single-dose BESREMi prefilled syringe for the first time and each time you get a new prescription. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment. 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**."

- After reviewing this important information, reinforce that the prefilled syringe is for one-time use only and cannot be used again.

Guide to Prefilled Syringe and Needle Parts (Figure A)

Figure A



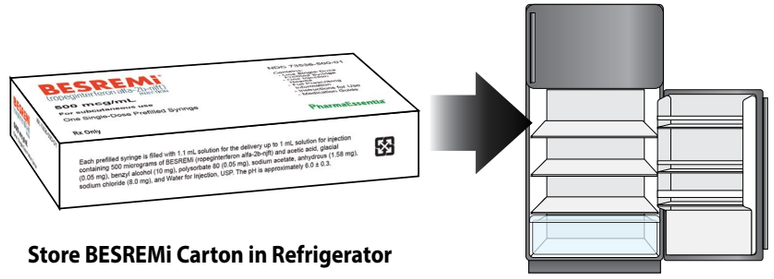
- Make sure the patient is familiar with the different parts of the syringe.
- Share this particular image, or have them turn to **Figure A** in the Large Print IFU, for reference. They should not be opening the carton at this time.
- Make sure the patient knows they should NEVER touch the yellow hub. It must remain sterile, since it is where the needle attaches to the syringe.

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

Store the BESREMi carton in the refrigerator between 36°F to 46°F (2°C to 8°C) (Figure B).

- Keep your BESREMi prefilled syringes in their original carton (Figure B) 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.

Figure B

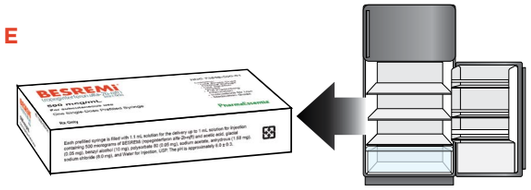


Store BESREMi Carton in Refrigerator

STEP 1 Prepare BESREMi Prefilled Syringe

1.1 Take the BESREMi carton out of the refrigerator (Figure E).

Figure E



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

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

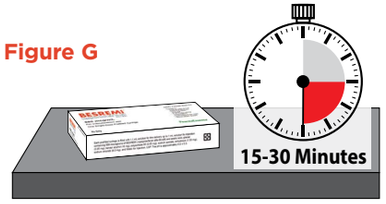
Figure F

- **If the patient uses reading glasses, this would be a good time to get them.**
- If the patient is **not** comfortable standing, make sure they can pull up a chair to the area and sit down.

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 (Figure G).

Do not warm the prefilled syringe any other way.

Figure G



- The patient can use a kitchen timer or a timer on their phone and set it to 15 to 30 minutes.
- While the medicine comes to room temperature, the supplies can be laid out and concerns can be identified and addressed using the assessment questionnaire that follows on page 7.

STEP 2 Gather Supplies for Injection

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

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

Figure H

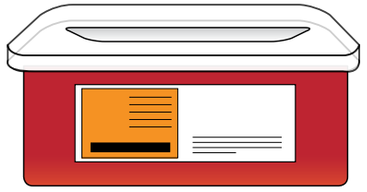


Figure I

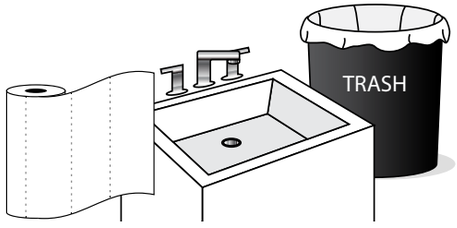


Figure J

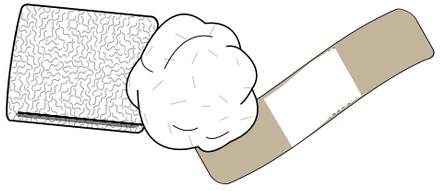


Figure K

- **The patient should be able to recognize each of the supplies before proceeding.**

Recommended Questions to Ask the Patient

- While you're waiting for the medicine to warm to room temperature, ask the questions below to determine concerns about self-injecting. The goal is to make patients feel comfortable about the process and let them know they'll have support from you along the way.

QUESTIONS	SAMPLE RESPONSES
How do you feel about self-injecting overall?	• Acknowledge any concerns: "It is natural to feel anxious about giving yourself a shot…" • If the patient is particularly worried about needles, let them know the needle is very small and the injection is given just under skin into a bit of fatty tissue. To put this into context, the needle is very thin and quite short (only ½"). Once you take it out of the carton, please notice how small it is. • Let the patient know that PharmaEssentia™ offers a variety of support services through PharmaEssentia SOURCE™ that may be able to help them address their questions or concerns about self-injection.
Do you have experience giving self-injections?	• Remind the patient that you and your staff are happy to help them and answer any questions they may have. You may also point out that PharmaEssentia offers a variety of support services to answer their questions.
Do you have concerns about giving yourself an injection because of a physical limitation, such as eyesight or hand dexterity? Tell me about these concerns.	• If the patient mentions having poor eyesight, ask whether they wear reading glasses and encourage their use, as precision is important when measuring the medicine. • If the patient is concerned about their motor skills, discuss the option of having someone help them by asking, "Do you have a support person living with or available to you? Would they be able or comfortable to assist you with your injections?"
Do you have a clean environment where you can safely perform an injection and a clean surface to set up your injection materials?	• Offer the patient suggestions about what to look for: a flat, clean surface in front of which they can sit comfortably. • If the patient needs to clean up the surface, reinforce that it should be clean and dried with a paper towel or clean towel (e.g., not a dirty dish rag).

Please see additional Important Safety Information on pages 16 to 18 and full Prescribing Information, including Boxed Warning.

STEP 3 Wash Hands and Remove Syringe from Tray

3.1 Wash your hands with soap and water, then dry your hands (Figure L).

Figure L

3.2 Open the carton and remove the clear plastic tray that holds the BESREMi® (ropeginterferon alfa-2b-njft) prefilled syringe and needle package (Figure M).

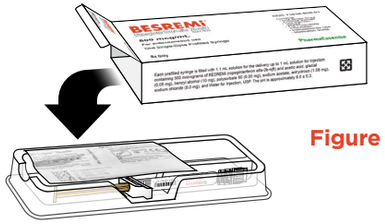


Figure M

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 (Figure N).

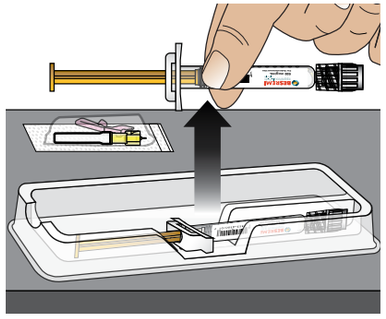


Figure N

STEP 4 Check the Liquid Medicine in the BESREMi Prefilled Syringe

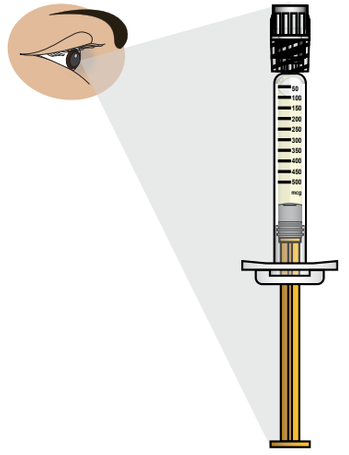
4.1 Check the liquid medicine in the prefilled syringe (Figure O). The liquid should be clear and colorless to slightly yellow, and should not have particles.

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 (Figure O).

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

Figure O



- If the patient asks about particles, these are defined as solids, clumps, or flakes that might be floating in the liquid.
- If there is something wrong with the liquid or syringe, the patient should get another carton and redo this step. If they don't have another, they should order a new one and reschedule the training.

STEP 5 Attach the Needle to the BESREMi Prefilled Syringe

5.1 Carefully open the needle package, remove the needle, and set it aside (Figure P).

Throw away the packaging into household trash.

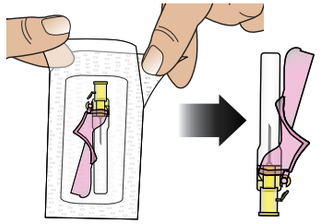


Figure P

- **Make sure to instruct the patient not to touch the yellow needle hub with their fingers, as it must remain sterile. This is where the needle attaches to the syringe. Lay the needle carefully on its side on the clean surface.**
- **If the patient expresses concern about keeping the needle sterile, trainers may consider teaching them to carefully peel back the needle package and set it aside. The package will be open, but the needle will still be sitting in the package.**
- **Make sure the patient understands not to take the pink needle shield off or to lock it in place. Once locked, it cannot be removed.**

5.2 Hold the prefilled syringe as shown. Remove the prefilled syringe cap by unscrewing it counter-clockwise (Figure Q).

Throw away the syringe cap into household trash.

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

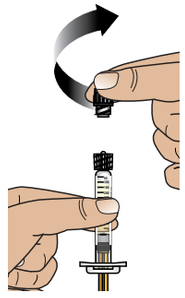


Figure Q

- **Be sure the patient is familiar with the parts of the syringe. They can always return to page 4 of this training guide, or Figure A in the Large Print IFU, if they need a reminder.**
- **Make sure the patient is holding the syringe in whichever hand is most comfortable.**

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

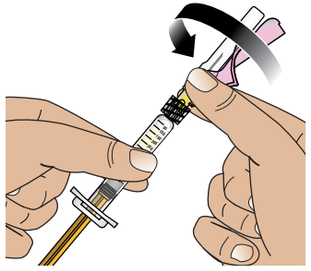


Figure R

The needle should now be assembled to the prefilled syringe (Figure S).

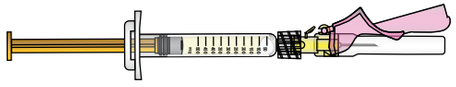


Figure S

- **Remind the patient not to touch the yellow needle hub or the collar (or tip) of the syringe. Indicate that they should hold the needle just above the yellow hub. They will be connecting the yellow needle hub to the syringe collar (or tip).**

STEP 6 Choose and Clean Injection Site

6.1 Choose one of the following injection sites (Figure T):

- 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® (ropeginterferon alfa-2b-njft) is for subcutaneous (under the skin) injection only.

Rotate (change) the injection site for each injection.

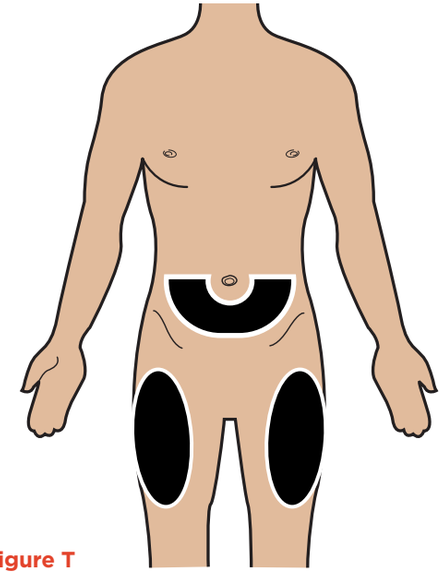


Figure T

- Explain what it means to "rotate the injection site." Each time the patient injects a dose of BESREMi, which is usually every 2 weeks, they must choose a different site for the injection. For example, they may want to use the right upper stomach today and the right upper thigh 2 weeks later for the next injection. Next month, they can use their left upper stomach and then left upper thigh.
- The patient can track the injection site and date in a notepad so they don't have to remember.

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

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

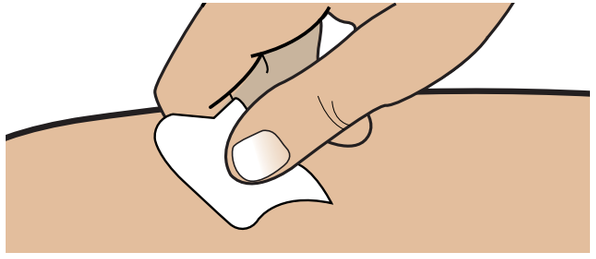


Figure U

- To ensure the site is truly clean, suggest that the patient lightly swab the area for 30 seconds in a circular motion.

STEP 7 Uncap Needle and Move Air Bubbles to Top

7.1 Pull the pink needle shield back (Figure V).

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

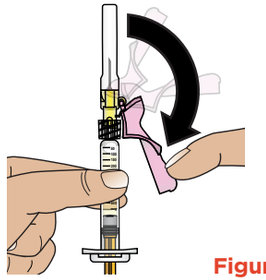


Figure V

7.2 Hold the syringe from the syringe body.

Remove the clear needle cap by pulling it straight off (Figure W). Throw away the needle cap into household trash.

Do not recap needle.

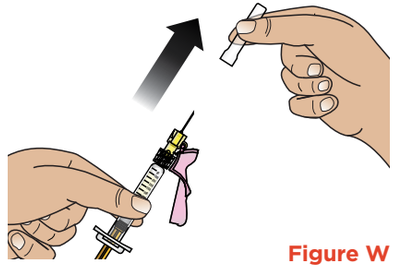


Figure W

- If the patient is particularly worried about needle-sticks, consider doing the following:
  - —Have the patient hold the needle with the syringe body in one hand and the cap in the other, then pull apart gently and slowly.
  - —Also, **make sure the patient does not try** to remove the pink needle shield or throw it away.

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 (Figure X).

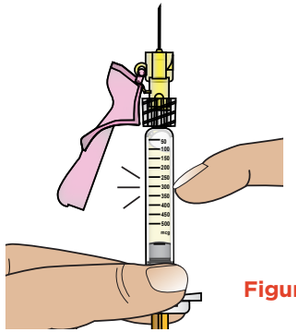


Figure X

READ ME

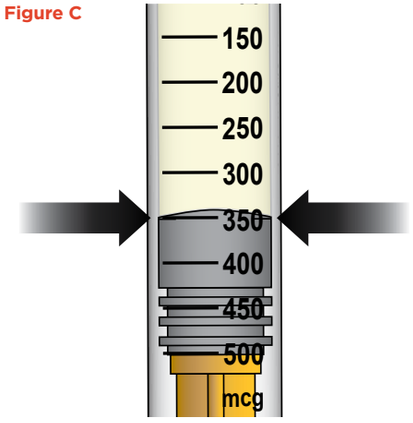
How to Adjust the Medicine Level for Your Prescribed Dose

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 (Figure C).

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

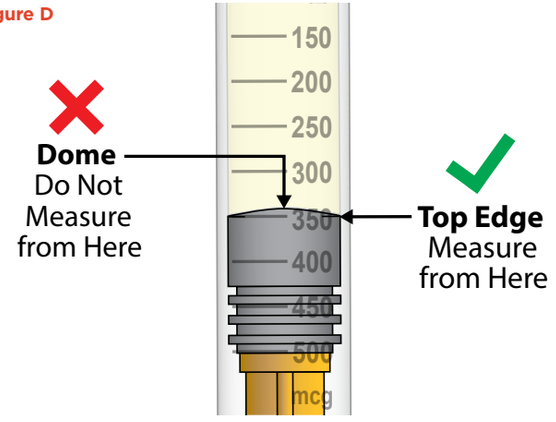
Align Top Outer Edge of Stopper to Dose Line

Figure C



Example of 350 mcg dose

Figure D



Example of 350 mcg dose

- Make sure the patient understands where the top edge of the stopper is, and confirm they know not to measure from the top of the dome.

- If the patient needs a break, now would be a good time. Just make sure they wash and dry their hands prior to resuming this training.

STEP 8 Set Your Dose

8.1 Check your prescription to identify your prescribed dose (Figure Y). 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.

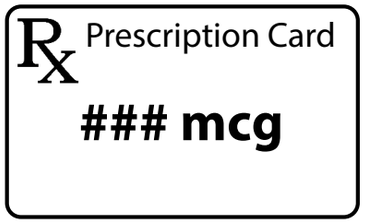


Figure Y

- The patient can confirm their dose by contacting their physician's office. PharmaCord® and specialty pharmacies should have the doses on record. The starting dose will either be 50 or 100 mcg, depending on cytoreductive therapy, but the patient will want to confirm with their prescribing physician.
- When confirming the prescribed dose with the patient, it might be a good time to reinforce that there is a total of 500 mcg of drug in the syringe.

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 (Figure Z).
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** (Figure Z). **Keep holding straight up as you set the dose.**

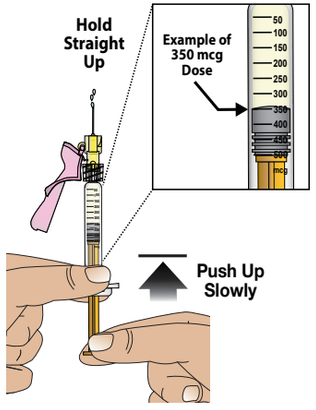


Figure Z

- Encourage the patient to do this slowly to avoid removing too much liquid medicine. If they accidentally remove too much liquid medicine, they should not inject. The trainer should offer to get them a new supply. They may need to send a new refill or contact the patient's healthcare provider.
- **Make sure to emphasize: DO NOT** save or store the extra liquid medicine for future use. It must be disposed of over a paper towel, sink, or trash can.
- If the patient reports getting the liquid on their hands, suggest they wipe the liquid off with a paper towel and wash their hands with soap and water when they are finished.

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.**

STEP 9 Give Injection

9.1 Pinch the chosen injection site (Figure AA).

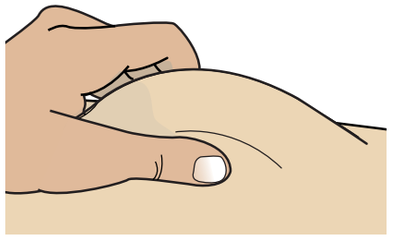


Figure AA

9.2 While pinching the skin, insert the needle at a 45 to 90 degree angle into the pinched skin (Figure AB).Then release the pinched skin.

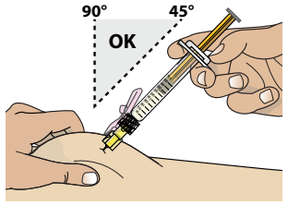


Figure AB

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

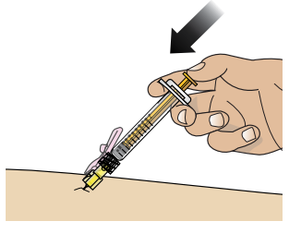


Figure AC

- Before starting, make sure the patient practices pinching their skin.
- Also make sure the patient understands what a 45 to 90 degree angle is and, if they don't, demonstrate the angle.

9.4 After all the liquid medicine is injected, remove the needle from the skin (Figure AD).

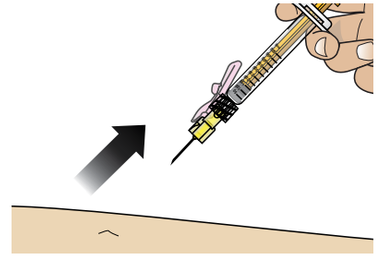


Figure AD

9.5 **Cover needle**
Carefully push the pink needle shield over the needle until it snaps into place and covers the needle (Figure AE). 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.

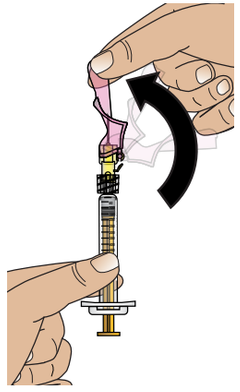


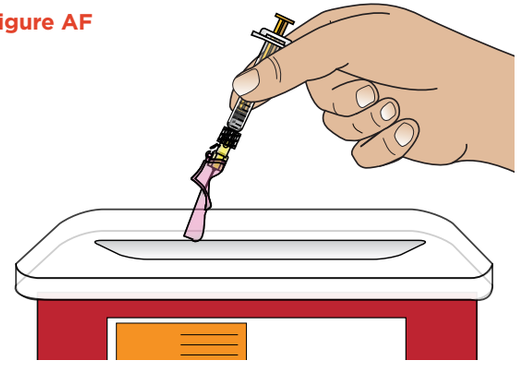
Figure AE

STEP 10 Dispose of Used Prefilled Syringes and Needles

10.1 Dispose of used prefilled syringes and needles.

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

Figure AF



- **After completing Step 10, reinforce that the prefilled syringe is for single use only and cannot be used again.**

- If you do not have a 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, 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.

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 (Figure AG).

Figure AG

11.2 **Do not** rub the injection site. If needed, you may apply a small adhesive bandage.

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

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IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

- Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation, or suicide attempt
- Hypersensitivity to interferons including interferon alfa-2b or any of the inactive ingredients of BESREMi.
- Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment
- History or presence of active serious or untreated autoimmune disease
- Immunosuppressed transplant recipients

WARNINGS AND PRECAUTIONS

- Depression and Suicide: Life-threatening or fatal neuropsychiatric reactions have occurred in patients receiving interferon alfa-2b products, including BESREMi. These reactions may occur in patients with and without previous psychiatric illness.

  Other central nervous system effects, including suicidal ideation, attempted suicide, aggression, bipolar disorder, mania and confusion have been observed with other interferon alfa products.

  Closely monitor patients for any symptoms of psychiatric disorders and consider psychiatric consultation and treatment if such symptoms emerge. If psychiatric symptoms worsen, it is recommended to discontinue BESREMi therapy.

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

BESREMi®
(ropeginterferon alfa-2b-njft)
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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Endocrine Toxicity: These toxicities may include worsening hypothyroidism and hyperthyroidism. Do not use BESREMi in patients with active serious or untreated endocrine disorders associated with autoimmune disease. Evaluate thyroid function in patients who develop symptoms suggestive of thyroid disease during BESREMi therapy. Discontinue BESREMi in patients who develop endocrine disorders that cannot be adequately managed during treatment with BESREMi.
- Cardiovascular Toxicity: Toxicities may include cardiomyopathy, myocardial infarction, atrial fibrillation and coronary artery ischemia. Patients with a history of cardiovascular disorders should be closely monitored for cardiovascular toxicity during BESREMi therapy. Avoid use of BESREMi in patients with severe or unstable cardiovascular disease, (e.g., uncontrolled hypertension, congestive heart failure (≥ NYHA class 2), serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina) or recent stroke or myocardial infarction.
- Decreased Peripheral Blood Counts: These toxicities may include thrombocytopenia (increasing the risk of bleeding), anemia, and leukopenia (increasing the risk of infection). Monitor complete blood counts at baseline, during titration and every 3-6 months during the maintenance phase. Monitor patients for signs and symptoms of infection or bleeding.
- Hypersensitivity Reactions: Toxicities may include serious, acute hypersensitivity reactions (e.g., urticaria, angioedema, bronchoconstriction, anaphylaxis). If such reactions occur, discontinue BESREMi and institute appropriate medical therapy immediately. Transient rashes may not necessitate interruption of treatment.
- Pancreatitis: Pancreatitis has occurred in 2.2% of patients receiving BESREMi. Symptoms may include nausea, vomiting, upper abdominal pain, bloating, and fever. Patients may experience elevated lipase, amylase, white blood cell count, or altered renal/hepatic function. Interrupt BESREMi treatment in patients with possible pancreatitis and evaluate promptly. Consider discontinuation of BESREMi in patients with confirmed pancreatitis.
- Colitis: Fatal and serious ulcerative or hemorrhagic/ischemic colitis have occurred in patients receiving interferon alfa products, some cases starting as early as 12 weeks after start of treatment. Symptoms may include abdominal pain, bloody diarrhea, and fever. Discontinue BESREMi in patients who develop these signs or symptoms. Colitis may resolve within 1 to 3 weeks of stopping treatment.
- Pulmonary Toxicity: Pulmonary toxicity may manifest as dyspnea, pulmonary infiltrates, pneumonia, bronchiolitis obliterans, interstitial pneumonitis, pulmonary hypertension, and sarcoidosis. Some events have resulted in respiratory failure or death. Discontinue BESREMi in patients who develop pulmonary infiltrates or pulmonary function impairment.
- Ophthalmologic Toxicity: These toxicities may include severe eye disorders such as retinopathy, retinal hemorrhage, retinal exudates, retinal detachment and retinal artery or vein occlusion which may result in blindness. During BESREMi therapy, 23% of patients were identified with an eye disorder. Eyes disorders ≥5% included cataract (6%) and dry eye (5%). Advise patients to have eye examinations before and during BESREMi therapy, specifically in those patients with a retinopathy-associated disease such as diabetes mellitus or hypertension. Evaluate eye symptoms promptly. Discontinue BESREMi in patients who develop new or worsening eye disorders.
- Hyperlipidemia: Elevated triglycerides may result in pancreatitis. Monitor serum triglycerides before BESREMi treatment and intermittently during therapy and manage when elevated. Consider discontinuation of BESREMi in patients with persistently, markedly elevated triglycerides.
- Hepatotoxicity: These toxicities may include increases in serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT) and bilirubin. Liver enzyme elevations have also been reported in patients after long-term BESREMi therapy. Monitor liver enzymes and hepatic function at baseline and during BESREMi treatment. Discontinue BESREMi in patients who develop evidence of hepatic decompensation (characterized by jaundice, ascites, hepatic encephalopathy, hepatorenal syndrome or variceal hemorrhage) during treatment
- Renal Toxicity: Monitor serum creatinine at baseline and during therapy. Avoid use of BESREMi in patients with eGFR <30 mL/min. Discontinue BESREMi if severe renal impairment develops during treatment.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Dental and Periodontal Toxicity: These toxicities may include dental and periodontal disorders, which may lead to loss of teeth. In addition, dry mouth could have a damaging effect on teeth and mucous membranes of the mouth during long-term treatment with BESREMi. Patients should have good oral hygiene and regular dental examinations.
- Dermatologic Toxicity: These toxicities have included skin rash, pruritus, alopecia, erythema, psoriasis, xeroderma, dermatitis acneiform, hyperkeratosis, and hyperhidrosis. Consider discontinuation of BESREMi if clinically significant dermatologic toxicity occurs.
- Driving and Operating Machinery: BESREMi may impact the ability to drive and use machinery. Patients should not drive or use heavy machinery until they know how BESREMi affects their abilities. Patients who experience dizziness, somnolence or hallucination during BESREMi therapy should avoid driving or using machinery.
- Embryo-Fetal Toxicity: Based on the mechanism of action, BESREMi can cause fetal harm when administered to a pregnant woman. Pregnancy testing is recommended in females of reproductive potential prior to treatment with BESREMi. Advise females of reproductive potential to use an effective method of contraception during treatment with BESREMi and for at least 8 weeks after the final dose.

ADVERSE REACTIONS

The most common adverse reactions reported in > 40% of patients in the PEGINVERA study (n=51) were influenza-like illness, arthralgia, fatigue, pruritis, nasopharyngitis, and musculoskeletal pain. In the pooled safety population (n=178), the most common adverse reactions greater than 10%, were liver enzyme elevations (20%), leukopenia (20%), thrombocytopenia (19%), arthralgia (13%), fatigue (12%), myalgia (11%), and influenza-like illness (11%).

DRUG INTERACTIONS

Patients on BESREMi who are receiving concomitant drugs which are CYP450 substrates with a narrow therapeutic index should be monitored to inform the need for dosage modification for these concomitant drugs. Avoid use with myelosuppressive agents and monitor patients receiving the combination for effects of excessive myelosuppression. Avoid use with narcotics, hypnotics or sedatives and monitor patients receiving the combination for effects of excessive CNS toxicity.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on mechanism of action and the role of interferon alfa in pregnancy and fetal development, BESREMi may cause fetal harm and should be assumed to have abortifacient potential when administered to a pregnant woman. There are adverse effects on maternal and fetal outcomes associated with polycythemia vera in pregnancy. Advise pregnant women of the potential risk to a fetus.
- Lactation: There are no data on the presence of BESREMi in human or animal milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children from BESREMi, advise women not to breastfeed during treatment and for 8 weeks after the final dose.
- Females of Reproductive Potential: BESREMi may cause embryo-fetal harm when administered to a pregnant woman. Pregnancy testing prior to BESREMi treatment is recommended for females of reproductive potential. Advise female patients of reproductive potential to use effective contraception during treatment with BESREMi and for at least 8 weeks after the final dose.
- Pediatric Use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric Use: In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other therapy.

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Get Your Patients Started on BESREMi

PharmaEssentia SOURCE™ can guide your patients through the access and reimbursement process and offer personalized support throughout their BESREMi treatment. Learn more at PharmaEssentiaSOURCE.com.

Discover more at BESREMiHCP.com

INDICATION

BESREMi is indicated for the treatment of adults with polycythemia vera

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DISORDERS

Interferon alfa products may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Therapy should be withdrawn in patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all cases, these disorders resolve after stopping therapy.

Please see additional Important Safety Information on pages 16 to 18 and full Prescribing Information, including Boxed Warning.

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