

## INSTRUCTIONS FOR USE

**BESREMI** [bez-reh-me]  
(ropeginterferon alfa-2b-njft)

This "Instructions for Use" contains information on how to prepare and subcutaneously inject BESREMI single-dose prefilled syringe.

## Guide to Prefilled Syringe and Needle Parts (Figure A)

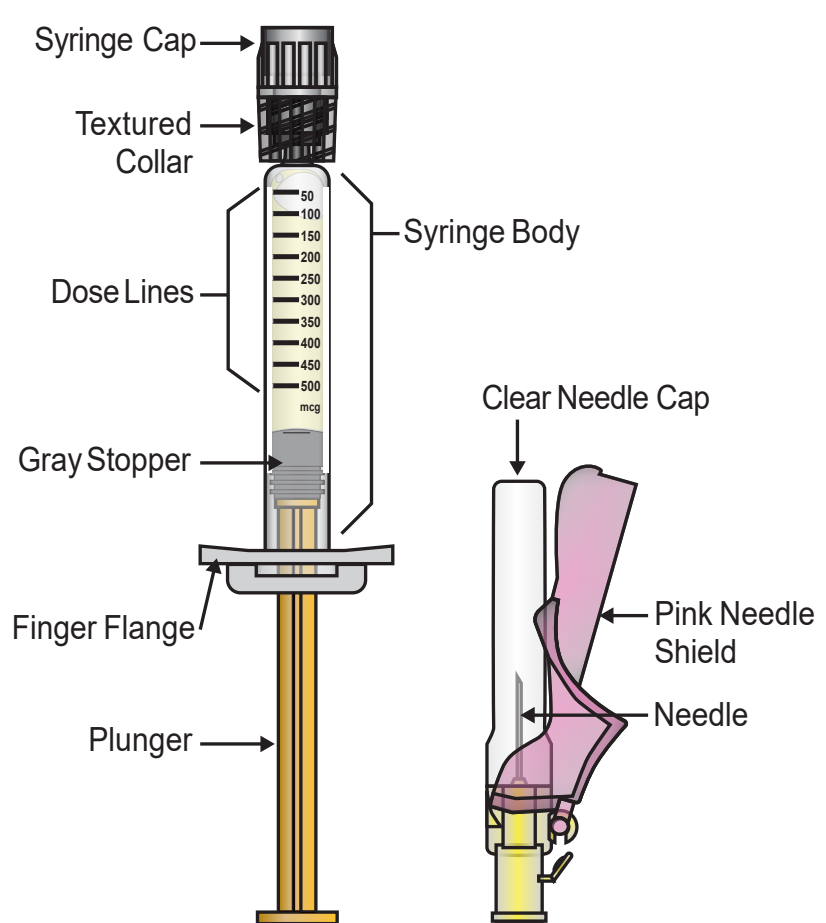
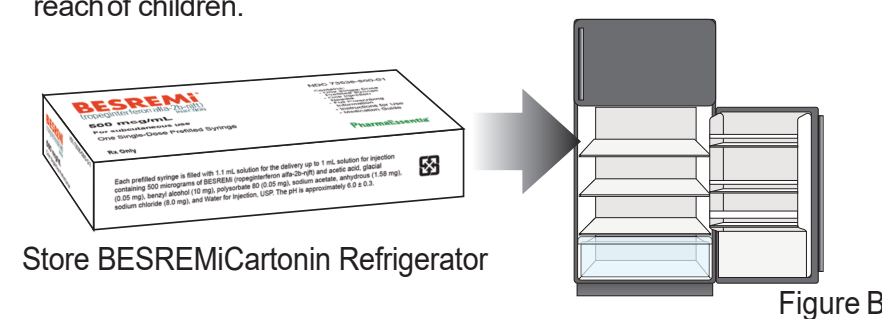


Figure A

## Storing BESREMI

- 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.



Store BESREMI Carton in Refrigerator

Figure B

## 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 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.

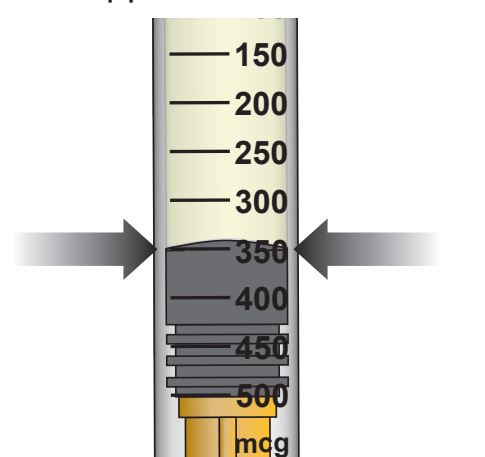
- Your healthcare provider will tell you the prescribed dose that you should take and the right amount of BESREMI to measure in the prefilled syringe for your dose. Each time you inject, be sure that you know the prescribed dose of BESREMI to inject. Your dose may change over time.
- BESREMI is for subcutaneous (under the skin) injection only. Do not inject into a vein.
- BESREMI must be injected immediately after preparing the dose.
- 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 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.

## 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).

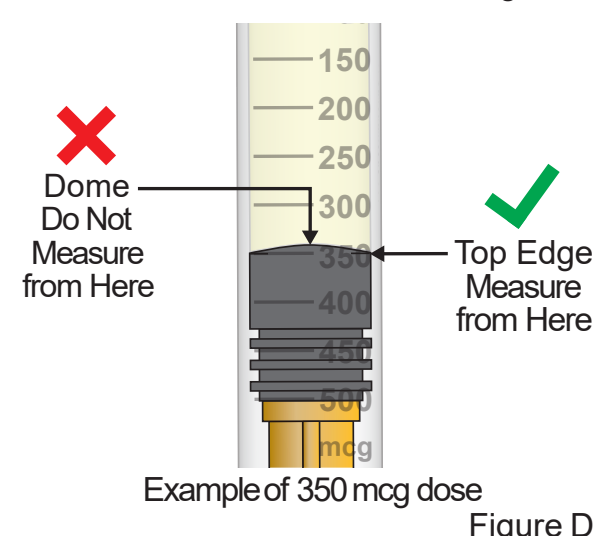
Do not line up the dome (at the top of the stopper) with the dose line (Figure D).

## Align Top Outer Edge of Stopper to Dose Line



Example of 350 mcg dose

Figure C



Example of 350 mcg dose

Figure D

## Gather and Check Supplies

## 1 Prepare BESREMI Prefilled Syringe

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

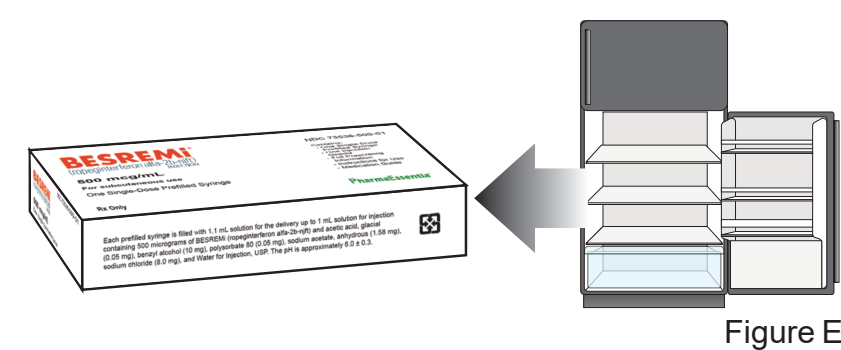


Figure E

- 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

- 1.3 Let BESREMI 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

## 2 Gather Supplies for Injection

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

- Alcohol Swab (Figure H).



Figure H

- Sharps Disposal Container (Figure I).

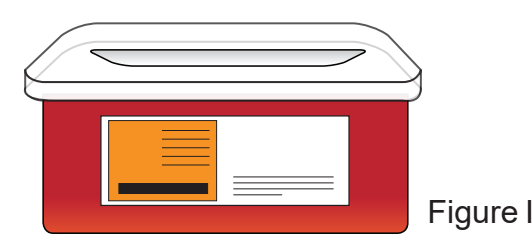


Figure I

- A paper towel, sink, or trash can to minimize mess during dose adjustment (Figure J).

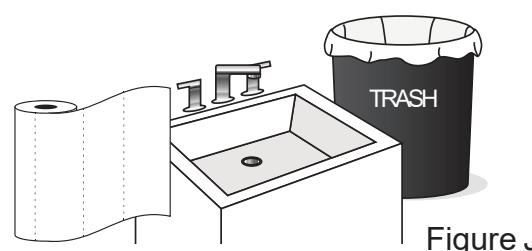


Figure J

- Optional Items: Gauze or Cotton Ball and a Small Adhesive Bandage (Figure K).

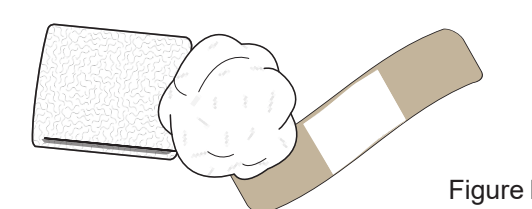


Figure K

## 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 prefilled syringe and needle package (Figure M).

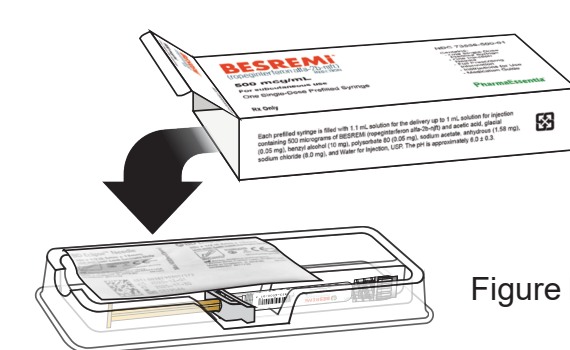


Figure M

- 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).

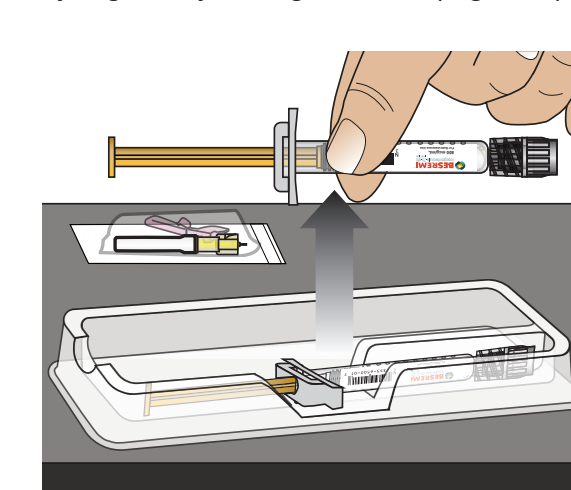


Figure N

## 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.

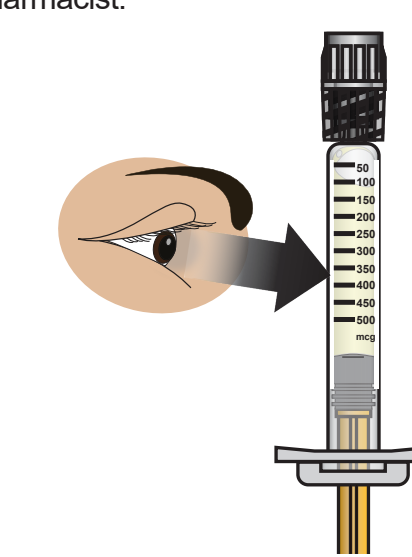


Figure O

## Prepare Syringe For Injection

## 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.

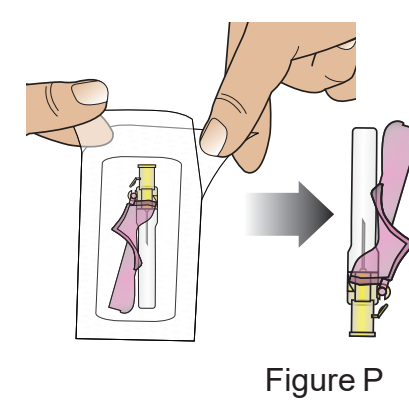


Figure P

- 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.

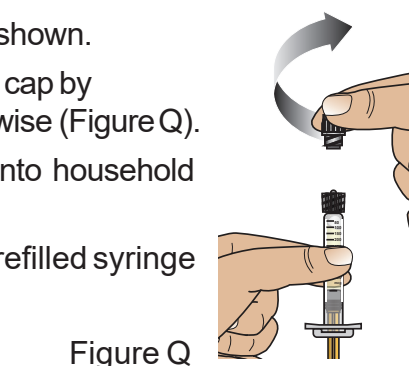


Figure Q

- 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).

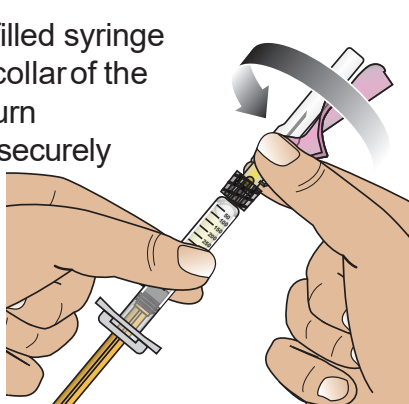


Figure R

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

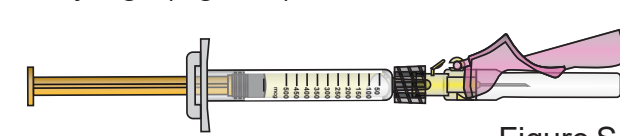


Figure S

## 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.

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

Rotate (change) the injection site for each injection.

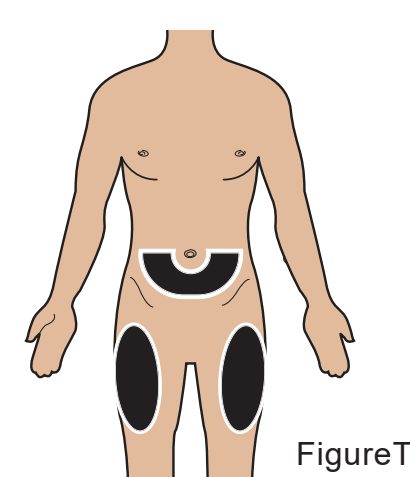


Figure T

- 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.

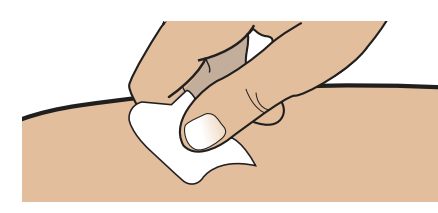


Figure U

## 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 from needle-stick injuries.

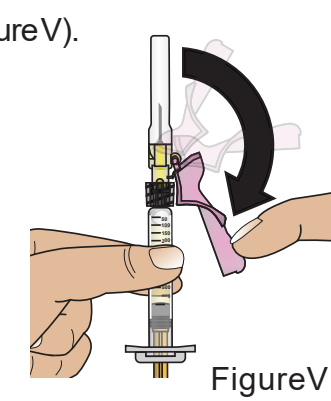


Figure V

- 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.

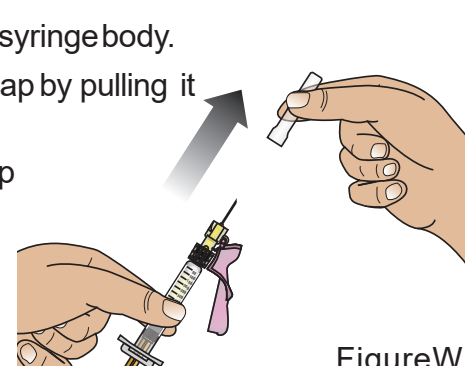


Figure W

- 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).

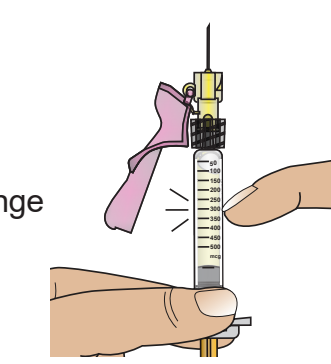


Figure X

## 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.

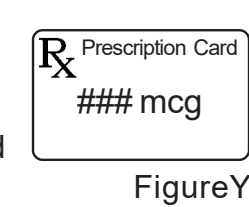


Figure Y

- 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.

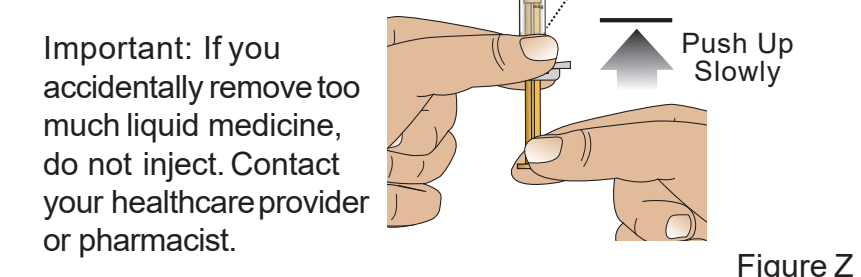


Figure Z

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

Note: BESREMI must be injected immediately after preparing the dose.

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.

## Inject BESREMI

## 9 Give Injection

- 9.1 Pinch the chosen injection site (Figure AA).

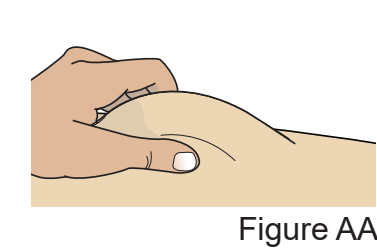


Figure AA

- 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.

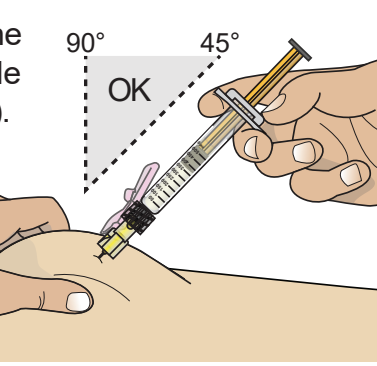


Figure AB

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

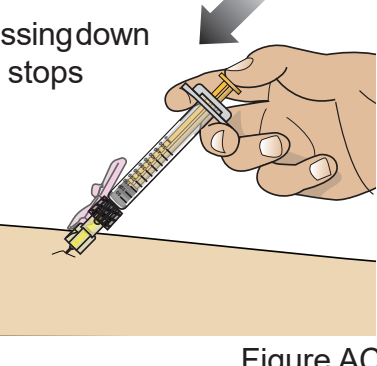


Figure AC

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

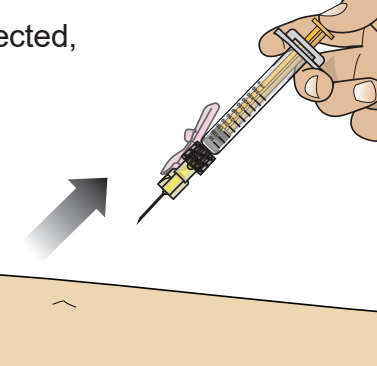


Figure AD

## Dispose of Used Syringe

## 10 Cover Needle, Throw Away (Dispose of) Syringe, and Treat Injection Site

- 10.1 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.

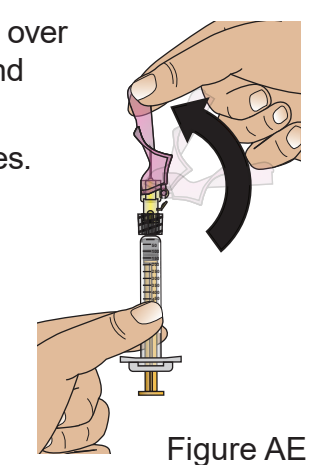


Figure AE

- 10.2 Throw away the used prefilled syringe, with the needle still attached, into an FDA-cleared sharps disposal container right away (Figure AF).

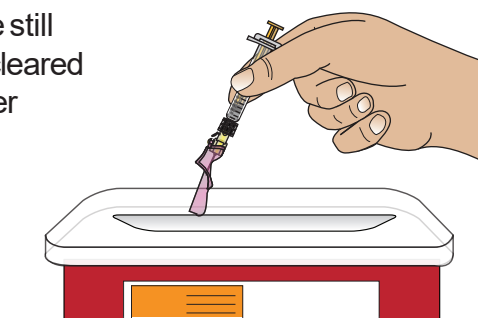


Figure AF

- 10.3 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).

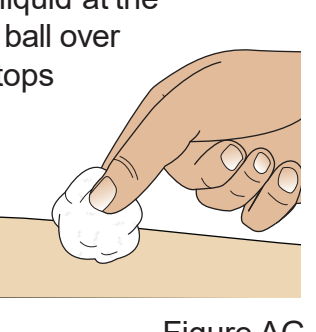


Figure AG

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

## Additional Disposal Information

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, 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 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.

## Additional Information

For additional information about BESREMI and a video demonstration on how to use BESREMI, go to: [www.BESREMI.com](http://www.BESREMI.com)

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