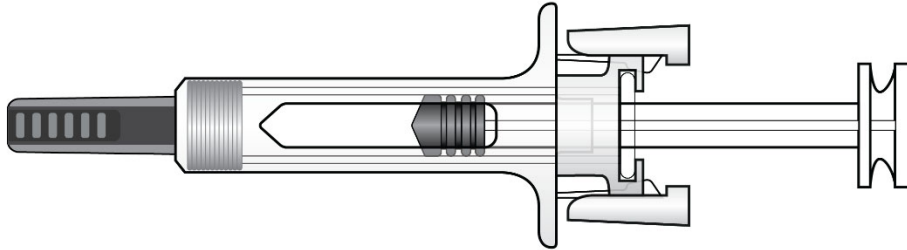


INSTRUCTIONS FOR USE
ROLVEDON® [roll veh don]
(eflapegrastim-xnst)
injection, for subcutaneous use
Single-Dose Prefilled Syringe

This Instructions for Use contains information on how to inject Rolvedon. Read this Instructions for Use before using Rolvedon and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.



Important Information You Need To Know Before Injecting Rolvedon

- It is important that you do not try to give the injection unless you or your caregiver have received training from your healthcare provider.
- Rolvedon is for use under the skin (subcutaneous injection) only.
- To help reduce needle stick injuries, each prefilled syringe has a needle guard that is automatically activated to cover the needle after the injection is complete.
- Make sure the name Rolvedon appears on the carton and prefilled syringe label.
- **Do not** use a Rolvedon prefilled syringe after the expiration date on the label.
- **Do not** use the Rolvedon prefilled syringe if it has been dropped on a hard surface. The prefilled syringe may be broken even if you cannot see the break. Use a new prefilled syringe.
- **Do not** use the Rolvedon prefilled syringe if the seal on the carton or the seal on the blister tray is broken.
- **Do not** shake the Rolvedon prefilled syringe.
- **Do not** touch the needle guard clips before use. Touching them may cause the needle guard to be activated too early.
- **Do not** remove the needle cap until just before you give the injection.

Rolvedon prefilled syringe parts

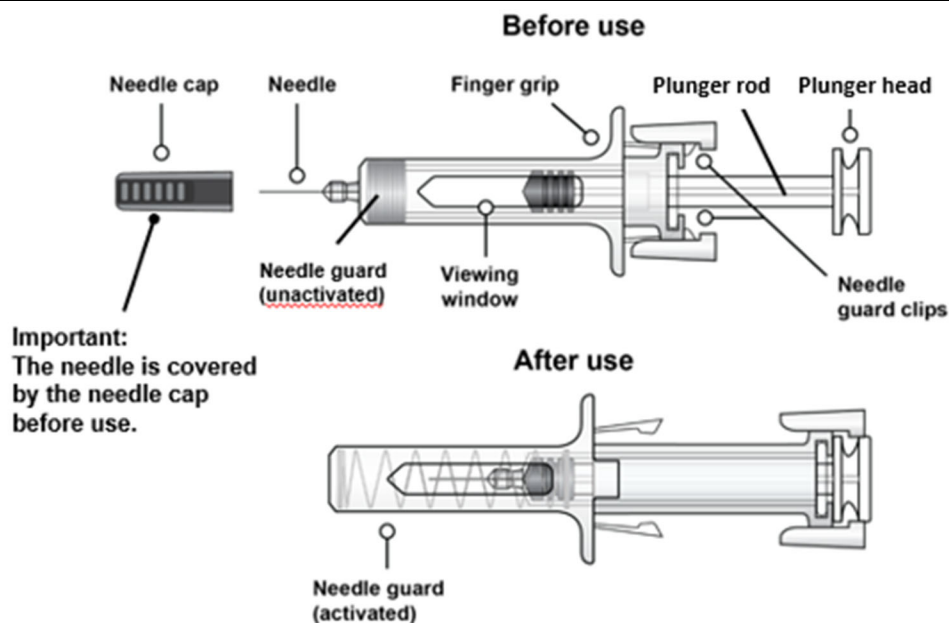


Figure A

Storing the Rolvedon prefilled syringe

- Store Rolvedon in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze Rolvedon. Throw away (dispose of) any Rolvedon that has been frozen.
- Store Rolvedon in the original carton to protect from light.
- Take the carton out of the refrigerator and place the sealed blister tray on a clean flat surface for at least 30 minutes to allow it to reach room temperature before use.
- Throw away (dispose of) any Rolvedon that has been left at room temperature, 68°F to 77°F (20°C to 25°C), for more than 12 hours.

Keep Rolvedon and all medicines out of the reach of children.

Preparing to inject Rolvedon

Step 1. Remove the carton from refrigerator

- Remove the carton from the refrigerator (see Figure B).
 - Check the expiration date on the carton (see Figure C).
- Do not** use the prefilled syringe if it is expired or if the carton has been previously opened.
- Open the carton and remove the blister tray.

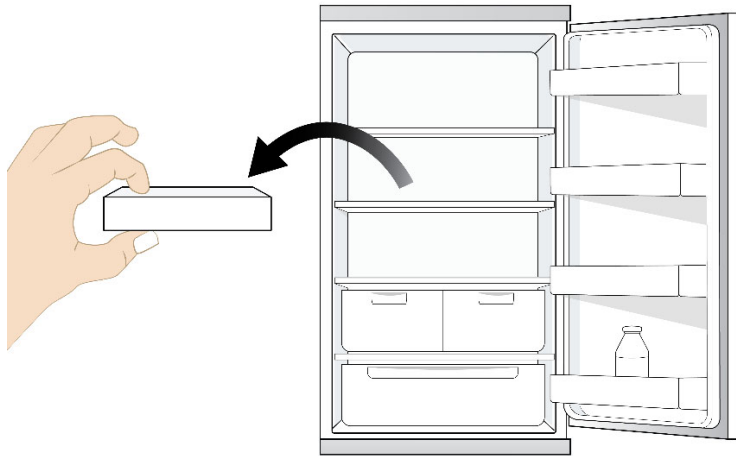


Figure B

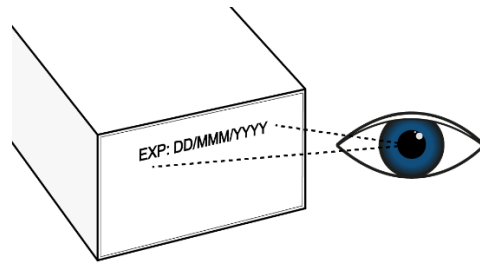


Figure C

Step 2. Allow Rolvedon to reach room temperature

Place the sealed blister tray on a clean flat surface and wait 30 minutes to reach room temperature (see Figure D). **Do not** warm up the prefilled syringe in any other way.



Figure D

Step 3. Gather the supplies needed for your injection

Gather the following supplies for the injection (see Figure E):

- 1 sterile cotton ball or gauze pad
- 1 alcohol wipe
- 1 sharps disposal container. See “**Disposing of used Rolvedon prefilled syringes**” at the end of this Instructions for Use.



Figure E

Step 4. Wash your hands

Wash your hands with soap and water.

Step 5. Remove the prefilled syringe from the blister tray

- Open the tray by peeling away the tray cover.
- To remove the prefilled syringe, grip the prefilled syringe by the center of the viewing window as shown in Figure F.
- **Do not** remove the prefilled syringe by the plunger rod, plunger head, or the needle cap.
- **Do not** touch the needle guard clips, as it could activate the needle guard.
- **Do not** remove the needle cap until you are ready to inject.

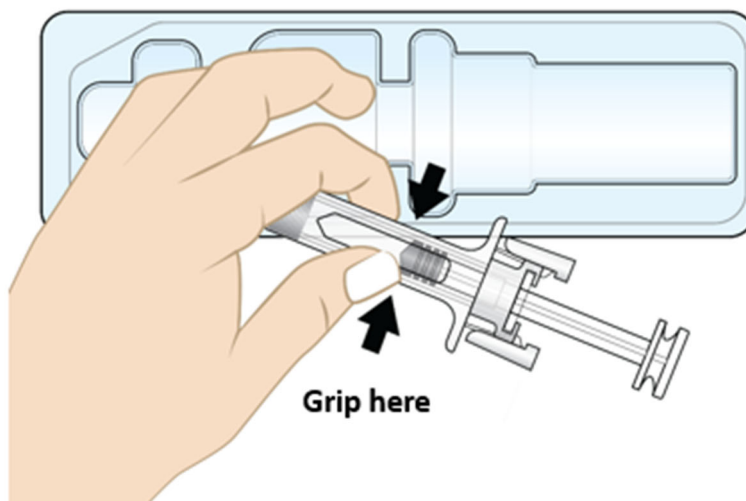


Figure F

Step 6. Inspect the prefilled syringe and medicine

- Visually inspect the prefilled syringe. **Do not** use the prefilled syringe if it appears damaged (for example, if the syringe is cracked or broken, or if the plunger rod is detached or broken) or if the needle cap is missing.
- Check the expiration date on the prefilled syringe label. **Do not** use if the expiration date has passed.
- Check the medicine inside the prefilled syringe through the viewing window (see Figure G). The medicine inside should be clear and colorless. It is normal to see small air bubbles in the medicine. It does not need to be removed.
- **Do not** use the prefilled syringe if:
 - the medicine appears discolored or cloudy.
 - the medicine contains lumps, flakes, or particles.

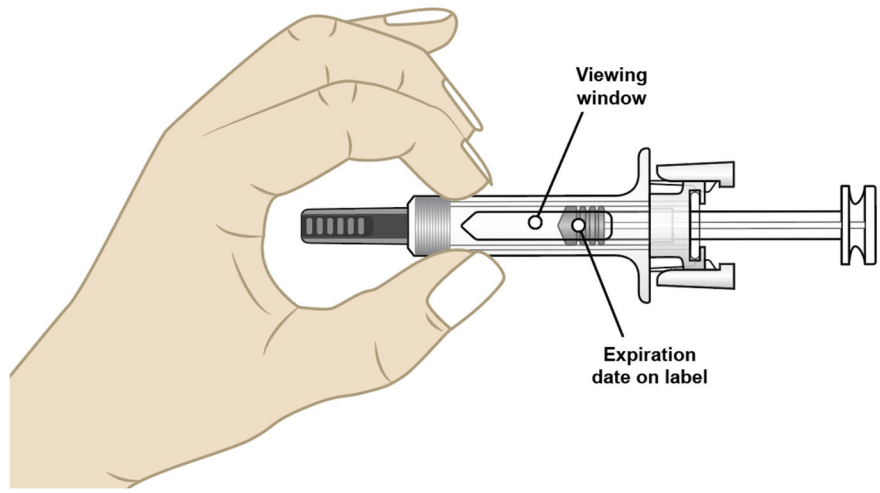


Figure G

Step 7. Select the injection site

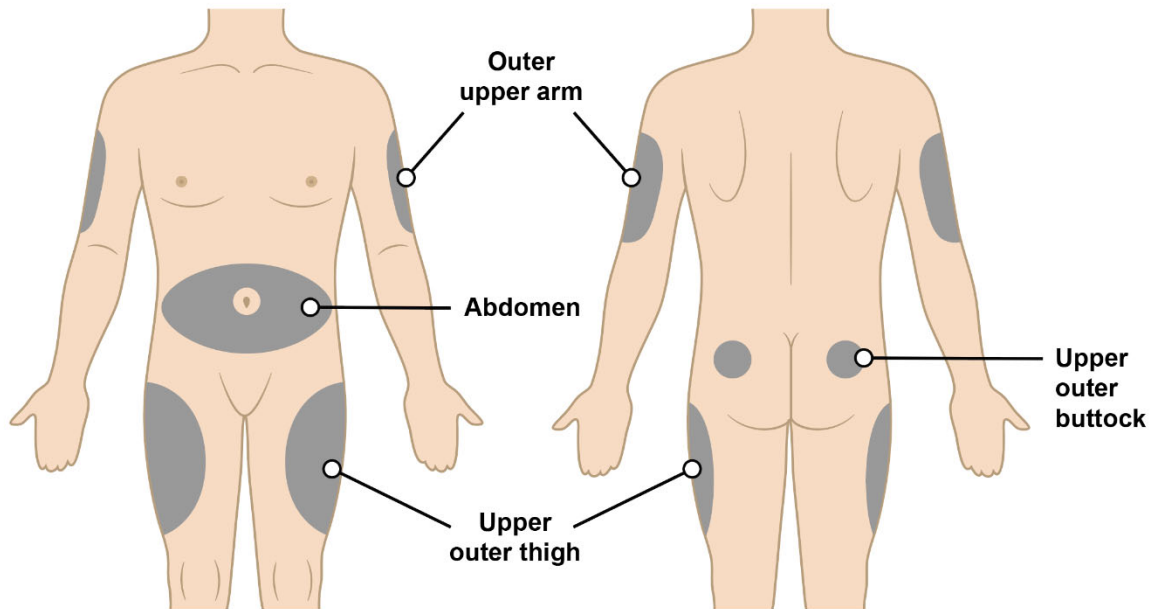


Figure H

- The recommended injection sites for a subcutaneous injection are the (see Figure H):
 - Abdomen (except for a two-inch area surrounding the navel)
 - Upper outer thigh
 - Outer upper arm (only if someone else is giving you the injection)
 - Upper outer buttock (only if someone else is giving you the injection)
- **Do not** inject into area of the skin that is tender, damaged, bruised, scarred or hard.
- **Do not** inject into moles, scars, birthmarks or stretchmarks.
- If you want to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.

Step 8. Clean the injection site

- Clean the injection site with an alcohol wipe (see Figure I).
- Allow the area of skin to dry before injecting.

Do not touch or blow on the cleaned area before injecting.



Figure I

Injecting Rolvedon

Step 9. Remove needle cap

- **Do not** remove the needle cap until you are ready to inject. When ready for the injection, carefully remove the needle cap by pulling it straight off (see Figure J).
- When removing the needle cap, hold the prefilled syringe as shown in Figure J.
- Throw away (dispose of) the needle cap in the sharps disposal container.
- **Do not** put the needle cap back onto the prefilled syringe after it has been removed. This can damage the needle and cause needle stick injuries.
- **Do not** hold the prefilled syringe by the plunger rod or touch the needle guard clips when removing the needle cap.

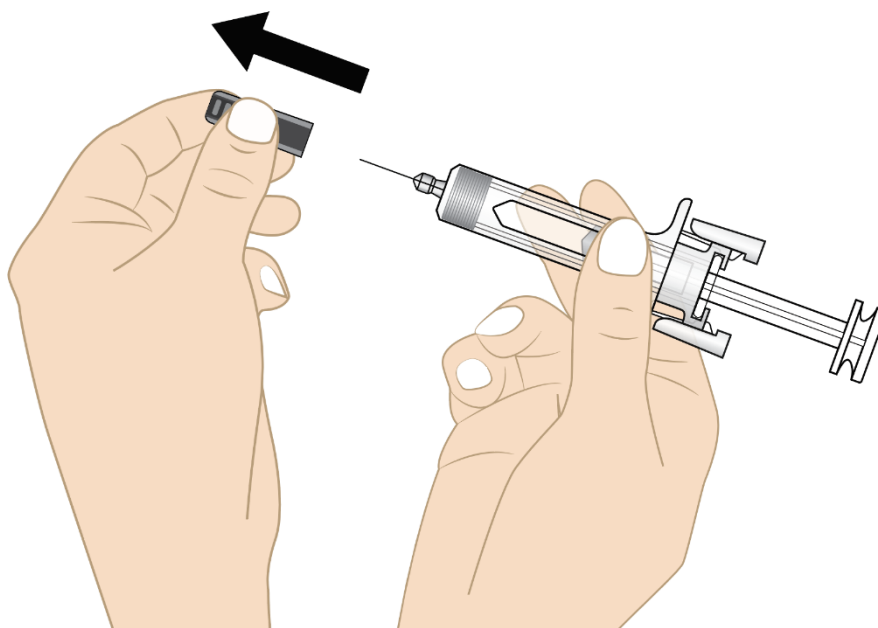


Figure J

Step 10. Insert the needle

- Hold the prefilled syringe at a 45 to 90-degree angle (see Figure K).
- Using your other hand, gently pinch the cleaned injection site as shown in Figure K.
- Fully insert the needle into the skin in a quick “dart-like” motion.

Do not touch the plunger head while inserting the needle into the skin.

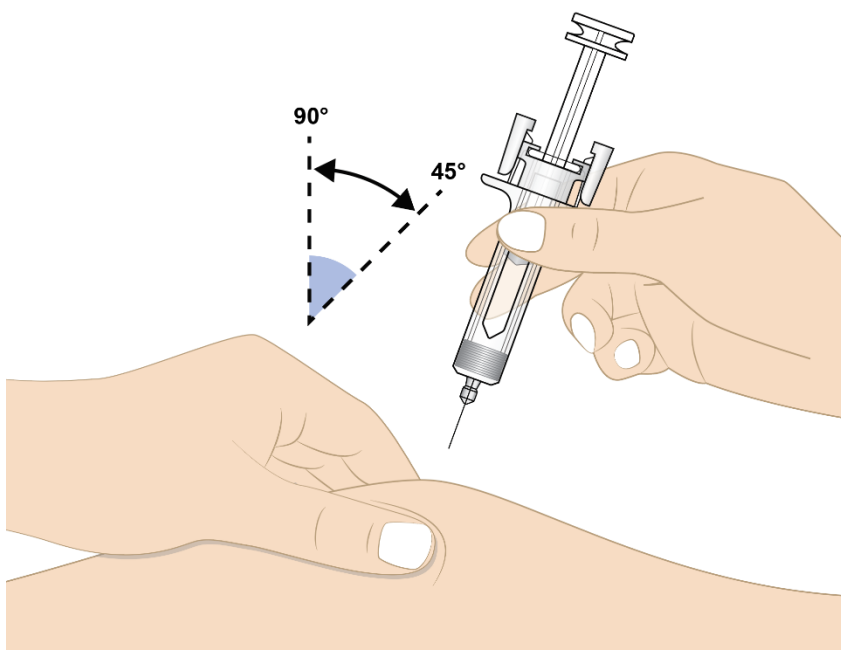


Figure K

Step 11. Inject Rolvedon

- Release the pinched skin.
- Hold the prefilled syringe as shown in Figure L with your thumb on the plunger head ready to inject.
- Slowly press the plunger head down to inject the medicine.
- Hold the syringe steadily in place while the needle is inserted.

Note: You may feel some resistance, this is normal.

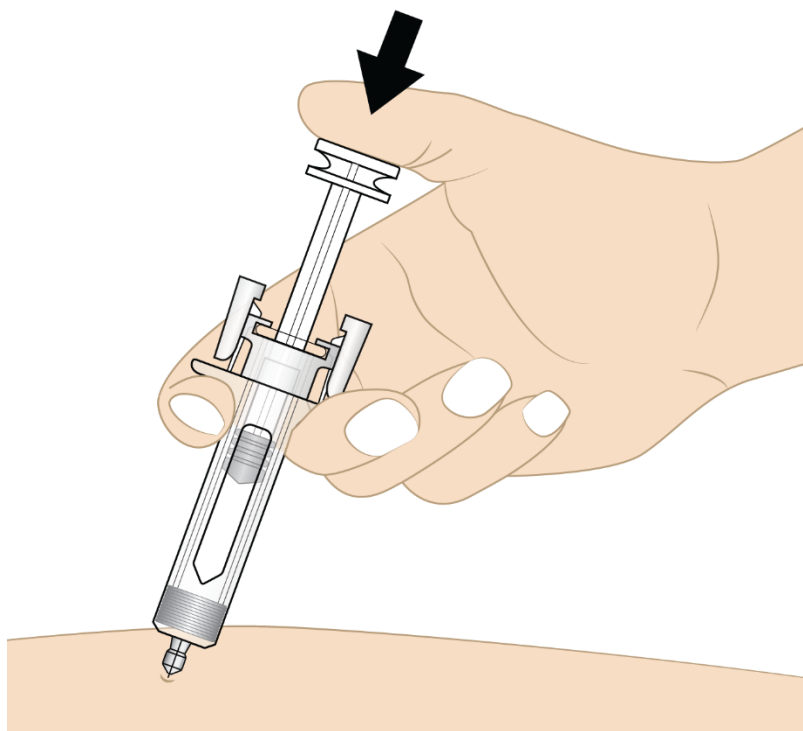


Figure L

- Push the plunger head down until it reaches the bottom to make sure all of the medicine is injected (see Figure M).
- You may hear a click when the plunger head reaches the bottom.

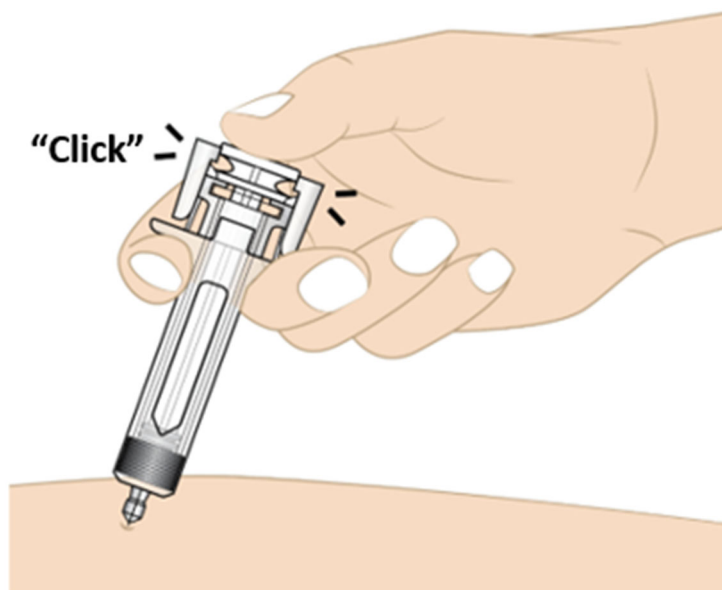


Figure M

Step 12. Activate the needle guard

- Gently lift your thumb to release the plunger until the entire needle is covered by the needle guard. Then remove the prefilled syringe from the injection site at the same angle as inserted as shown in Figure N.
- If there is bleeding, lightly press a cotton ball or gauze on the injection site.

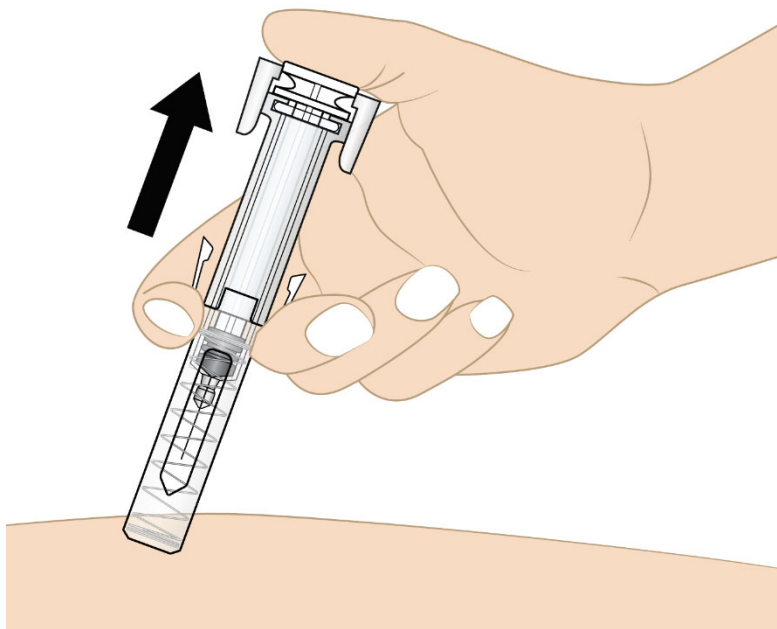


Figure N

Disposing of used Rolvedon prefilled syringes

- Put the used prefilled syringe and needle cap in an FDA-cleared sharps disposal container right away after use (see Figure O). Do not throw away (dispose of) the prefilled syringe in your 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, 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** reuse the prefilled syringes or throw them into household waste.
- **Do not** recycle prefilled syringes or sharps disposal container.
- **Do not** attempt to remove the needle from the prefilled syringe.

Important: Keep the sharps disposal container out of the reach of children.

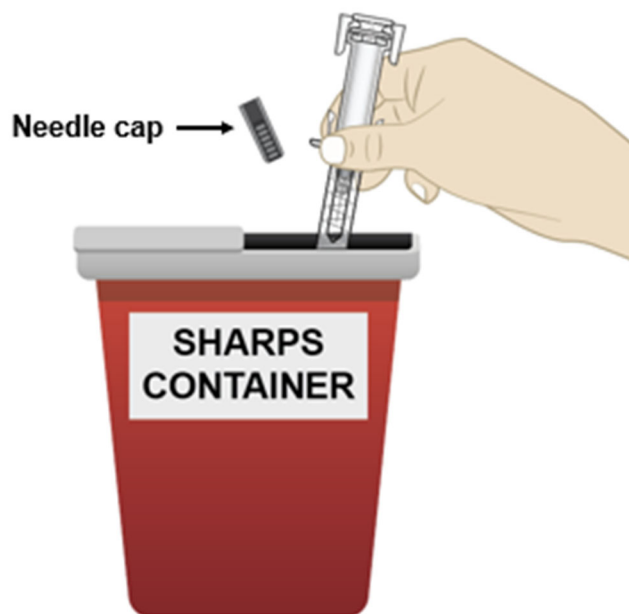


Figure O

Manufactured by: Spectrum Pharmaceuticals, Inc. Lake Forest, IL 60045

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For more information, go to www.rolvedon.com or call 1-888-713-0688.

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Issued: 11/2023