

INSTRUCTIONS FOR USE
PLEGRIDY® (PLEGG-rih-dee)
(peginterferon beta-1a) injection for Subcutaneous Use
Single-Dose Prefilled Syringe
Starter Pack

How to Inject your Plegridy Prefilled Syringe

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

Note:

- **Before you use your Plegridy Prefilled Syringe for the first time**, your healthcare provider should show you or your caregiver how to prepare and inject your Plegridy Prefilled Syringe the right way.
- If you experience difficulty or have questions, call 1-800-456-2255.
- Plegridy Prefilled Syringe is for use under the skin only (subcutaneous).
- **Each Plegridy Prefilled Syringe can be used 1 time only. Do not** share your Plegridy Prefilled Syringe with anyone else. By sharing the needle, you may give an infection to them or get an infection from them.
- **Take your Plegridy Prefilled Syringe out of the refrigerator and let it come to room temperature for at least 30 minutes before your injection.**
- **Do not** use more than 1 Plegridy Prefilled Syringe every 14 days.
- **Do not** use your Plegridy Prefilled Syringe if it has been dropped or is visibly damaged.

How should I store Plegridy?

- Store Plegridy in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If a refrigerator is not available, PLEGRIDY may be stored at room temperature up to 77°F (25°C) for up to 30 days in total.
- Keep Plegridy in the original carton to protect it from light.
- **Do not** freeze Plegridy.
- **Keep Plegridy Prefilled Syringes, needles, and all medicines out of the reach of children.**

Supplies needed for your Starter Pack for Plegridy Prefilled Syringe injection (See Figure A):

- 1 Starter Pack for Plegridy Prefilled Syringe which contains:
 - 1 Plegridy 63 mcg Prefilled Syringe (orange syringe)

- 1 Plegridy 94 mcg Prefilled Syringe (blue syringe)



Figure A

Additional supplies which are not included in the pack (See Figure B):


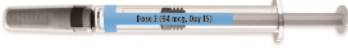
- alcohol wipe
- gauze pad
- adhesive bandage
- 1 sharps container for throwing away used needles and Plegridy Prefilled Syringes. See **“Disposing of your used Plegridy Prefilled Syringes”** at the end of these instructions.
- a well-lit area and a clean, flat surface to work on, like a table



Figure B

Dose Schedule

- **Choose the right Plegridy Prefilled Syringe for your dose.** The Starter Pack for Plegridy Prefilled Syringe contains your first 2 injections to slowly adjust your dose.

When	Which Dose	Choose
Day 1 (63 mcg)	First Dose: 63 mcg	Orange Syringe (See Figure C)  Figure C
Day 15 (94 mcg)	Second Dose: 94 mcg	Blue Syringe (See Figure D)  Figure D

- **Make sure you use the 63 mcg orange syringe for your first dose (on day 1).**
- **Make sure you use the 94 mcg blue syringe for your second dose (on day 15).**

Ask your healthcare provider which Plegridy Prefilled Syringe you should use for your correct dose if you are not sure.

Parts of your Plegridy Prefilled Syringe (See Figure E):

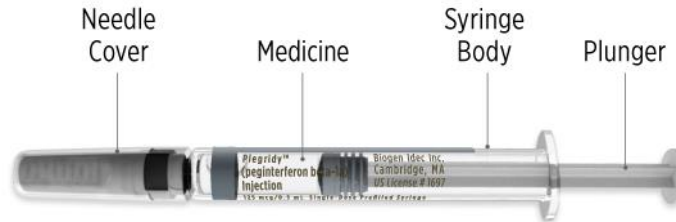


Figure E

Preparing for your injection:

Step 1: Take your Plegridy Prefilled Syringe out of the refrigerator and let it come to room temperature for at least 30 minutes.

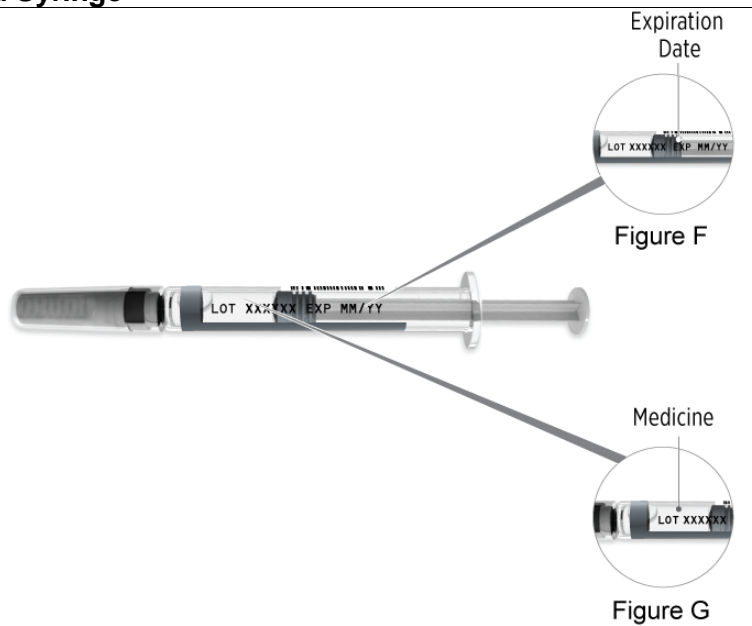
- **Do not** use external heat sources such as hot water to warm your Plegridy Prefilled Syringe.

Step 2: Collect your supplies and wash your hands

- Find a well-lit area and a clean, flat surface like a table and collect all the supplies you will need to give yourself or to receive an injection.
- Wash your hands with soap and water.

Step 3: Check your Plegridy Prefilled Syringe

- Check the expiration date printed on your Plegridy Prefilled Syringe (See Figure F).
 - **Do not** use Plegridy Prefilled Syringe past the expiration date.
- Check that your Plegridy medicine is clear and colorless (See Figure G).
 - **Do not** use Plegridy Prefilled Syringe if the liquid is colored, cloudy, or has floating particles in it.
 - You might see air bubbles in your Plegridy medicine. This is normal and will not affect your dose.



Step 4: Choose and clean your injection site

- Plegridy Prefilled Syringe is for use under the skin only (subcutaneous).
- Plegridy Prefilled Syringe should be injected into your thigh, stomach area (abdomen) or the back of your upper arm (See Figure H).
 - **Do not** inject directly into your belly button.
 - **Do not** inject into an area of your body where the skin is irritated, reddened, bruised, infected or scarred.
- **Change (rotate) your injection site** for each injection. **Do not** use the same injection site for each injection.
- Choose an injection site and wipe your skin with an alcohol wipe.
 - Do not touch this area again before giving your injection.
- Let your injection site dry on its own before injecting the dose.
- **Do not** take off the Plegridy Prefilled Syringe needle cover until you are ready

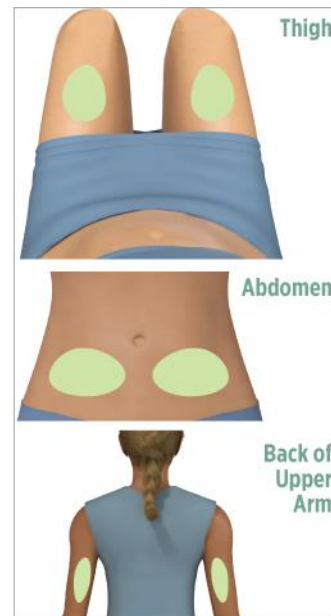


Figure H

to inject.

Giving Your Injection:

Step 5: Remove the Plegridy Prefilled Syringe needle cover

- With 1 hand, hold your Plegridy Prefilled Syringe. With your other hand, firmly hold the needle cover and pull the needle cover straight off the needle (See Figure I).
 - **Be careful** when removing the needle cover to avoid getting a needle stick injury.
 - **Do not** touch the needle.
 - **Important: Do not** recap the Plegridy Prefilled Syringe. You could get a needle stick injury.
 - Throw away the needle cover after your injection.

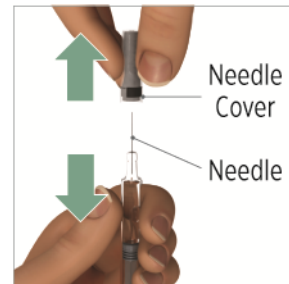


Figure I

Step 6: Gently pinch the injection site

- With 1 hand, use your thumb and first finger and pinch the skin around your cleaned injection site (See Figure J).

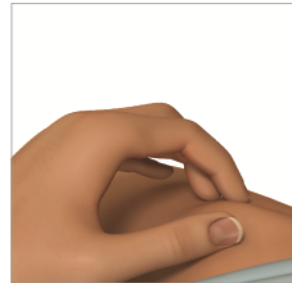


Figure J

Step 7: Give your Plegridy Prefilled Syringe injection

- With your other hand, hold your Plegridy Prefilled Syringe like a pencil. **Use a quick dart-like motion and insert the needle at a 90° angle into your skin (See Figure K).**
- After the needle is in, let go of your skin.

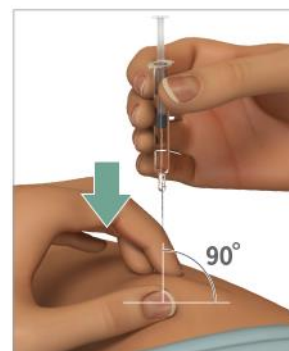


Figure K

- Slowly push the plunger down until the syringe is empty (See Figure L).
 - **Do not** take your Plegridy Prefilled Syringe out of your injection site until you have slowly pushed the plunger all the way down.



Figure L

- Pull the needle straight out of your skin (See Figure M).
 - If you see blood at your injection site, wipe it off with the gauze pad and apply an adhesive bandage.
- **Important: Do not** recap your Plegridy Prefilled Syringe. You could get a needle stick injury.
- **Do not** reuse your Plegridy Prefilled Syringe.



Figure M

After Your Injection:

Step 8: Disposing of your used Plegridy Prefilled Syringes

- Put your used Plegridy Prefilled Syringes in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) Plegridy Prefilled Syringes in your household trash.**
- 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.

Step 9: Check your injection site

- Plegridy may commonly cause redness, pain or swelling of your skin at the injection site.
- After 2 hours check your injection site for redness, swelling or tenderness.
- Call your healthcare provider right away if your injection site becomes swollen and painful or the area looks infected and does not heal within a few days.

Questions?

For product or service-related questions, call 1-800-456-2255 or go to www.plegridy.com.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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