

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

Important: Do not remove the Plegridy Pen cap until you are ready to inject.

How to Inject your Plegridy Pen

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 Pen for the first time**, your healthcare provider should show you or your caregiver how to prepare and inject your Plegridy Pen the right way.
- If you experience difficulty or have questions, call 1-800-456-2255.
- Plegridy Pen is for use under the skin only (subcutaneous).
- **Each Plegridy Pen can be used 1 time only. Do not** share your Plegridy Pen with anyone else. By sharing the Pen, you may give an infection to them or get an infection from them.
- **Take your Plegridy Pen 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 Pen every 14 days.
- **Do not** use your Plegridy Pen 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 Pens, needles, and all medicines out of the reach of children.**

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

- 1 Starter Pack for Plegridy Pen which contains:
 - 1 Plegridy 63 mcg Pen (orange pen)
 - 1 Plegridy 94 mcg Pen (blue pen)

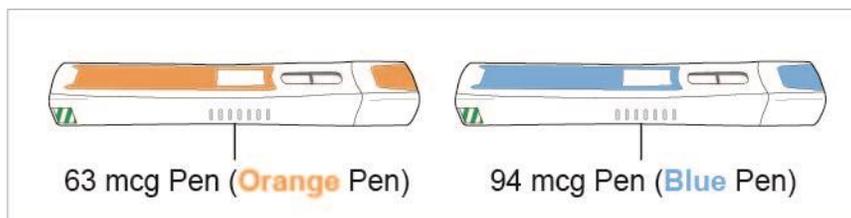


Figure A

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 Pens. See “**Disposing of your used Plegridy Pens**” at the end of these instructions.
- a well-lit area and a clean, flat surface to work on, like a table

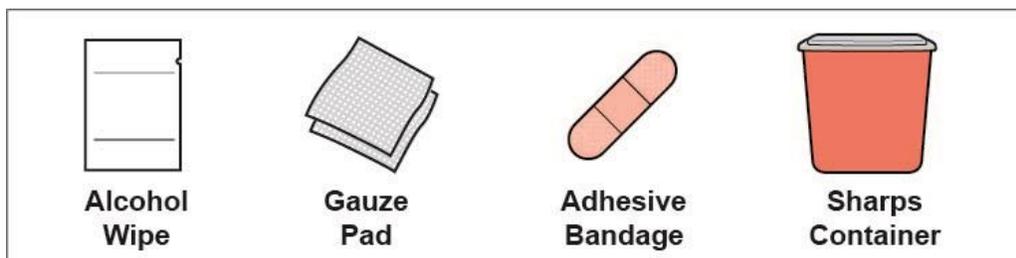
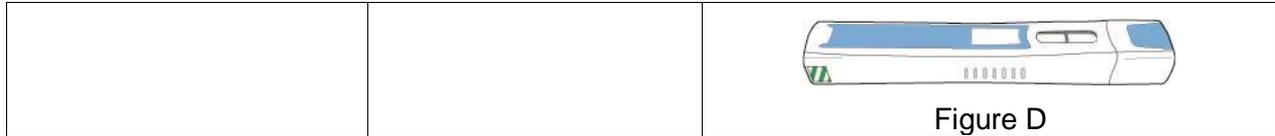


Figure B

Dose Schedule

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

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



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

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

Before Use – Parts of your Plegridy Pen before use (See Figure E):

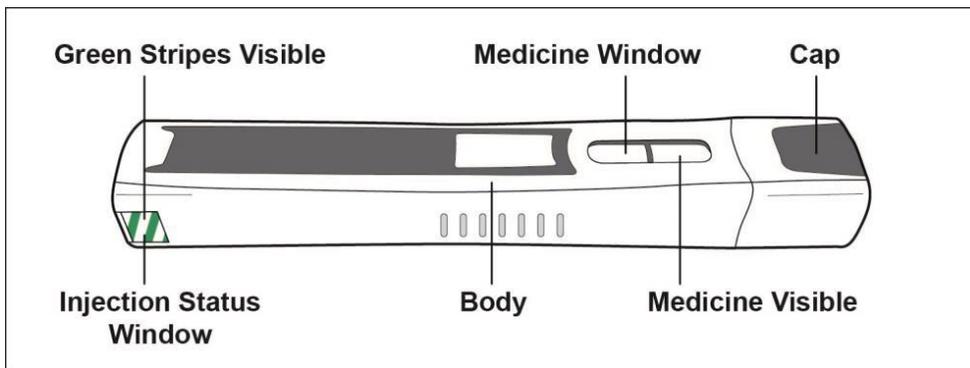


Figure E

Important: Do not remove the Plegridy Pen cap until you are ready to inject. If you remove the cap before you are ready to inject, do not re-cap the pen. Re-capping could cause the pen to lock.

Preparing for your injection:

Step 1: Take your Plegridy Pen 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 Pen.

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 Pen (see Figure F)

- Check the injection status window on your Plegridy Pen. Before you give your injection, you should see green stripes in the injection status window.
 - **Do not** use Plegridy Pen if you do not see the green stripes in the injection status window.
- Check the expiration date printed on your Plegridy Pen.
 - **Do not** use Plegridy Pen past the expiration date.
- Check the medicine window on your Plegridy Pen and make sure the Plegridy medicine is clear and colorless.
 - **Do not** use Plegridy Pen if the liquid is colored, cloudy, or has floating particles in it.
 - You might see air bubbles in the medicine window. This is normal and will not affect your dose.

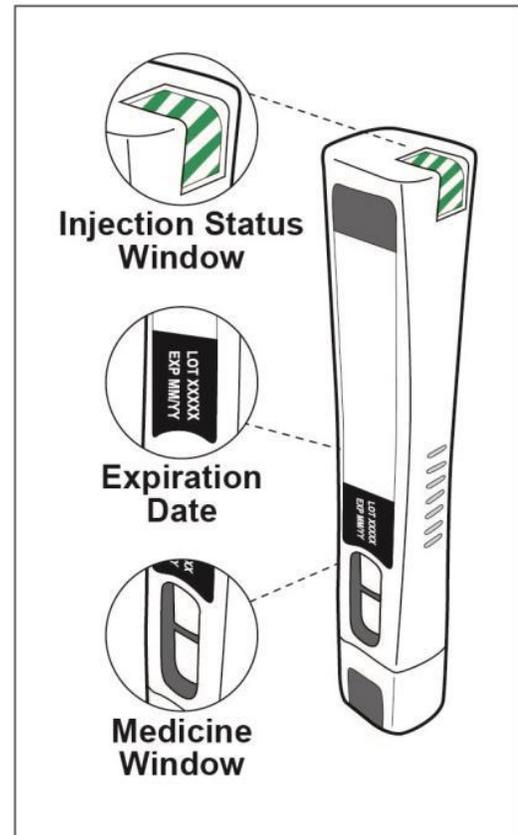


Figure F

Step 4: Choose and clean your injection site

- Plegridy Pen is for use under the skin only (subcutaneous).
- Plegridy Pen should be injected into your thigh, stomach area (abdomen) or the back of your upper arm (See Figure G).
 - **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.

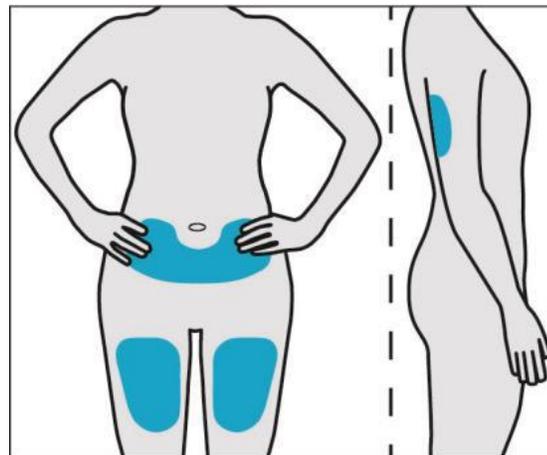


Figure G

- 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 your dose.

Giving your injection:

Step 5: Remove the Plegridy Pen cap

- Pull the Plegridy Pen cap straight off and set it aside (See Figure H).
 - The needle is covered by the needle cover and the needle will not be seen.
- **Important information:**
 - **Do not** touch or clean the needle cover. You could get a needle stick injury or the pen may lock.
 - **Do not** recap your Plegridy Pen. This could lock the pen.
- Your Plegridy Pen is ready to inject after the cap is removed.

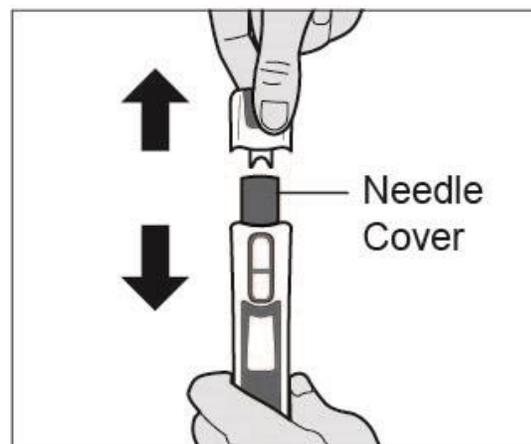


Figure H

Step 6: Give your injection

- Place your Plegridy Pen on your chosen injection site.
 - You should hold your Plegridy Pen at a 90° angle to your injection site so that you can see the green stripes in the injection status window (See Figure I).
 - **Do not** use your Plegridy Pen unless you see green stripes in the injection status window.

Note: Be ready to inject before you start pressing your Plegridy Pen down on your injection site. After you start pressing, the needle cover will lock when it is lifted from the site.

- **Firmly press and hold down your Plegridy Pen on your injection site.** This will insert the needle and start your injection (See Figure J).
 - **You will hear a clicking sound.**
- Continue to hold your Plegridy Pen firmly down on your injection site until the clicking sound has stopped (See figure K).
 - **Do not** lift your Plegridy Pen off your injection site until the clicking sound stops and you see green checkmarks in the injection status window.

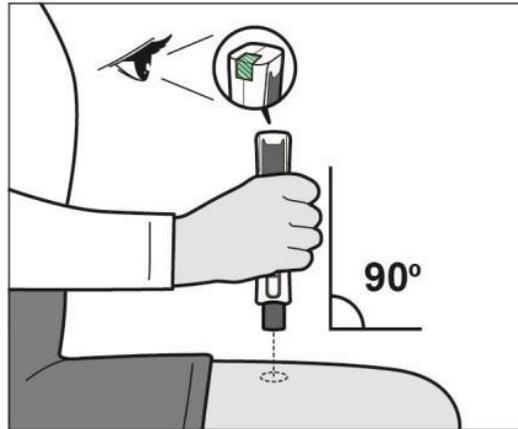


Figure I

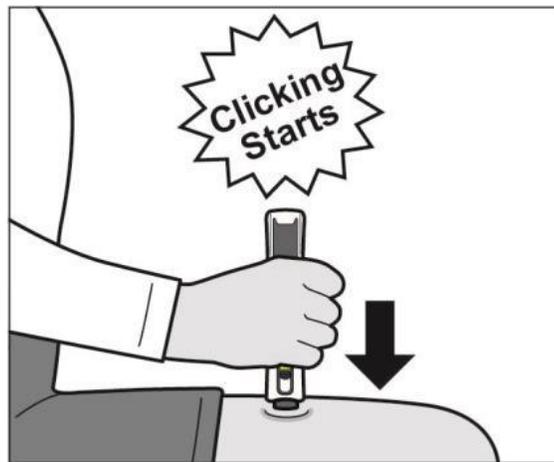


Figure J

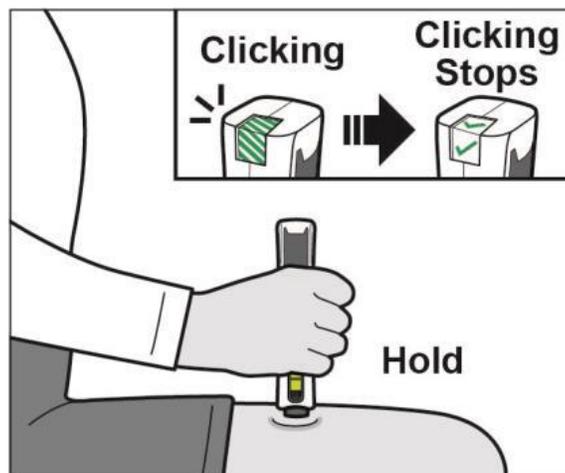


Figure K

If you do not hear clicking sounds, or you do not see green checkmarks in the injection status window after trying to give your injection, your Plegridy Pen may have locked and you should call 1-800-456-2255 for help.

Step 7: Remove your Plegridy Pen from your injection site

- After the clicking sound has stopped, lift your Plegridy Pen from your injection site. The needle will be covered by the needle cover and it will lock (see Figure L).

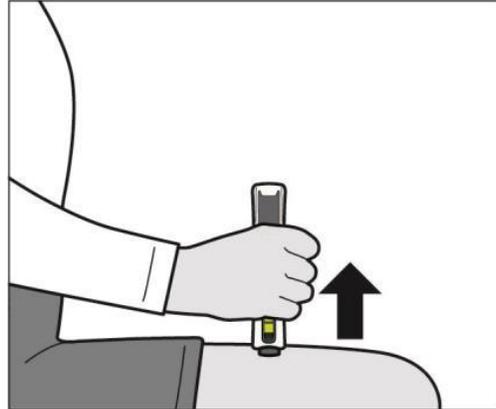


Figure L

Step 8: Check to make sure you have received your full dose of Plegridy (see Figure M)

- Check the injection status window. You should see green checkmarks in the injection status.
- Check the medicine window. You should see a yellow plunger in the medicine.
 - If you see blood at your injection site, wipe it off with the gauze pad and apply an adhesive bandage.

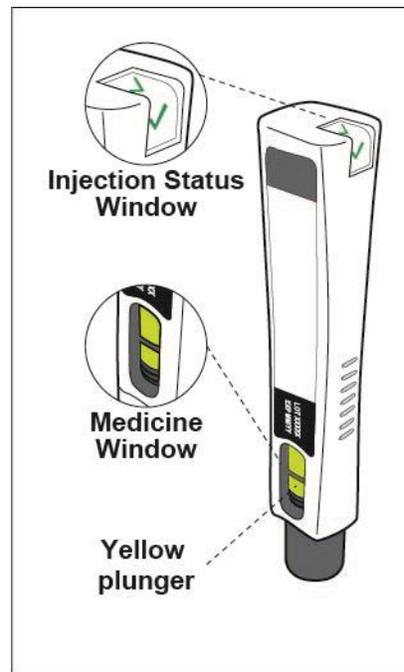


Figure M

After your injection:

After Use – Parts of your Plegridy Pen (Figure N)

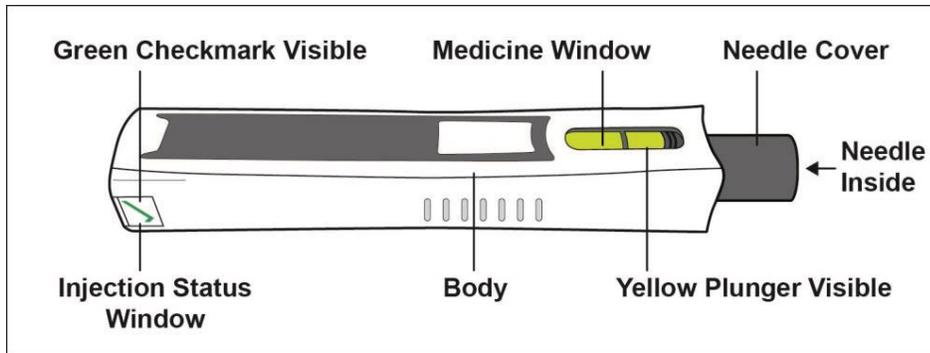


Figure N

Important: Do not touch the needle cover in any way. You could get a needle stick injury.

Note: After the pen has been removed from the injection site, the needle cover will lock to protect against needle stick injury. **Do not** recap your Plegridy Pen.

Step 9: Disposing of your used Plegridy Pens

- Put your used Plegridy Pens in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) Plegridy Pens 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 pens. 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.
- **Do not** recap your Plegridy Pen.

Step 10: 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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