

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

Read this Instructions for Use before you start using Plegridy 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 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.

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

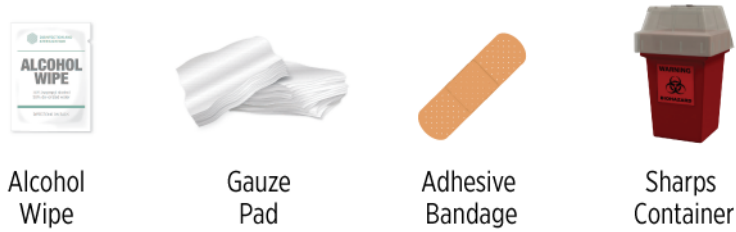




Figure B

Step 1: Choose your dose

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

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

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

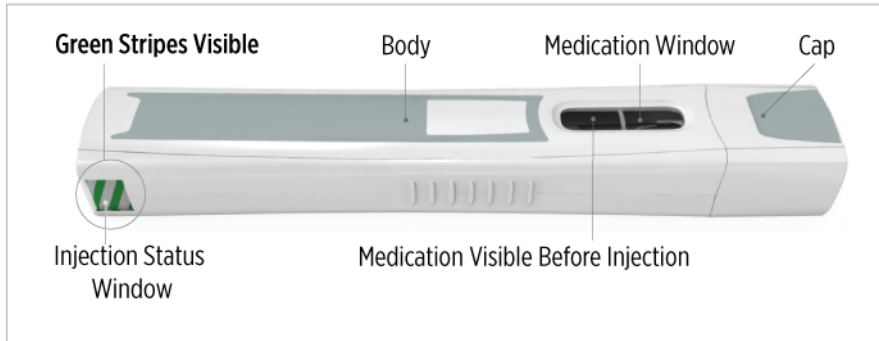


Figure E

Parts of your Plegridy Pen after use (See Figure F):

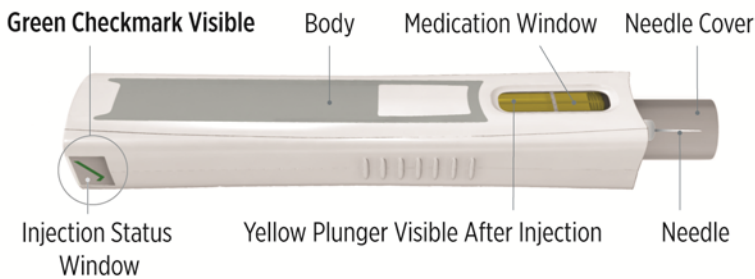


Figure F

Note: The needle is covered by the needle cover and the needle will not be seen (See Figure F). Do not touch or push on the needle cover, you could get a needle stick.

Note:

- **Before you prepare your injection, 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.
- **Do not** remove the cap until you are ready to inject.
- **Do not** use more than 1 Plegridy Pen every 14 days.

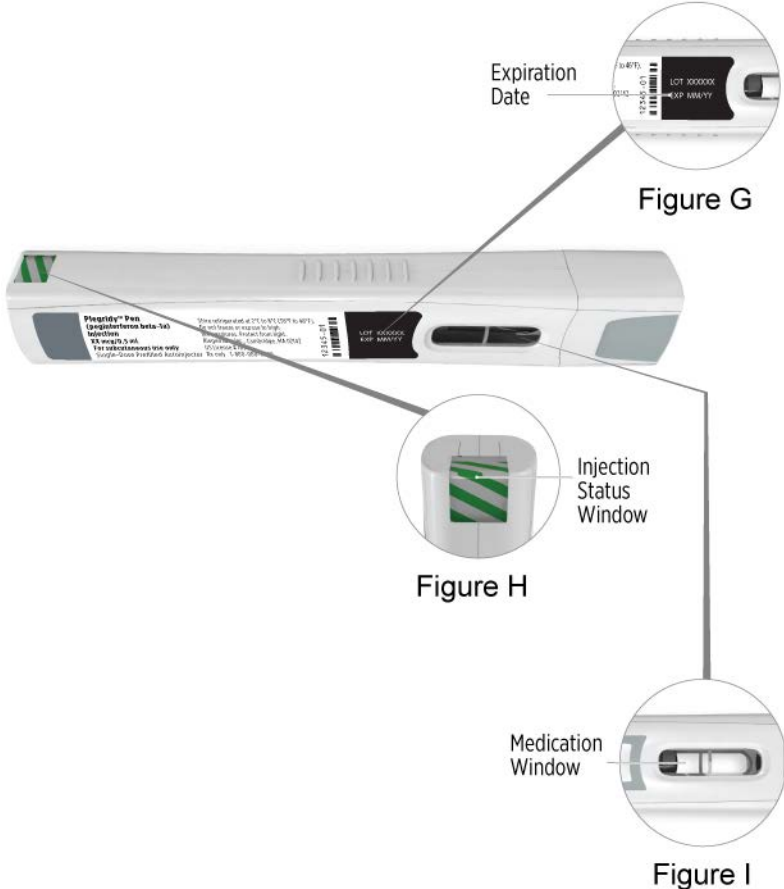
Preparing for your injection:

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

- If you experience difficulty or have questions, call 1-800-456-2255.

<ul style="list-style-type: none"> • Check the expiration date printed on your Plegridy Pen (See Figure G). <ul style="list-style-type: none"> ○ Do not use Plegridy Pen past the expiration date. 	 <p>The diagram shows a Plegridy Pen with three callout boxes. The top callout, labeled 'Expiration Date', points to a circular inset showing the pen's label with 'EXP 12/2015' and 'LOT 100000X'. The middle callout, labeled 'Injection Status Window', points to a circular inset showing a window with three green stripes. The bottom callout, labeled 'Medication Window', points to a circular inset showing a window with a clear liquid inside.</p>
<ul style="list-style-type: none"> • Check the injection status window on your Plegridy Pen. You should see green stripes in the injection status window (See Figure H). <ul style="list-style-type: none"> ○ Do not use Plegridy Pen if you do not see the green stripes in the injection status window. 	
<ul style="list-style-type: none"> • Check the medication window on your Plegridy Pen and make sure the Plegridy medicine is clear and colorless (See Figure I). <ul style="list-style-type: none"> ○ Do not use Plegridy Pen if the liquid is colored, cloudy, or has floating particles in it. ○ You might see air bubbles in the medication window. This is normal and will not affect your dose. 	

Giving your injection:

<h3>Step 4: Choose your injection site</h3>	
<ul style="list-style-type: none"> • Plegridy Pen is for use under the skin only (subcutaneous). 	

- Plegridy Pen should be injected into your thigh, abdomen or the back of your upper arm (See Figure J).
 - **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.
- Let your injection site dry on its own before injecting your dose.
 - **Do not** touch this area again before giving your injection.
- **Do not** take off the Plegridy Pen cap until you are ready to inject.

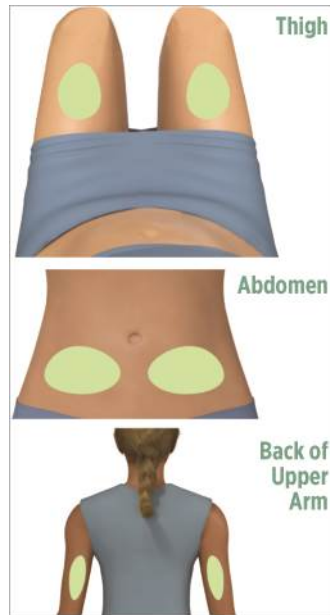


Figure J

Step 5: Remove the Plegridy Pen cap

- Pull the Plegridy Pen cap straight off and set it aside (See Figure K).
 - **Do not** recap your Plegridy Pen.
 - The needle is covered by the needle cover and the needle will not be seen (See Figure K).
 - **Do not** touch or push down on the needle cover, you could get a needle stick.

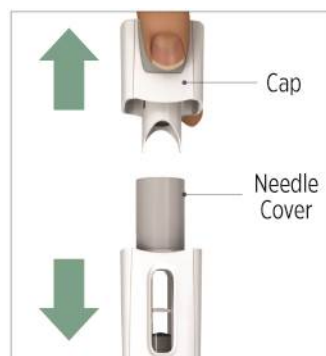


Figure K

- Your Plegridy Pen is ready to inject after the cap is removed.

Step 6: Place your Plegridy Pen on your injection site

- 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 L).
 - **Do not** use your Plegridy Pen unless you see green stripes in the injection status window.

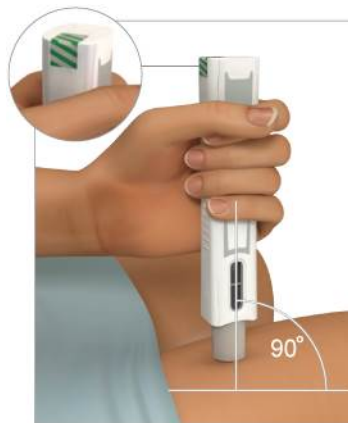


Figure L

Step 7: Give your Plegridy Pen injection

- **Firmly press and hold down your Plegridy Pen on your injection site.** This will insert the needle and start your injection (See Figure M).
 - **You will hear a “clicking” sound.**
- Hold your Plegridy Pen firmly down on your injection site until the “clicking” sound has stopped.
 - **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.

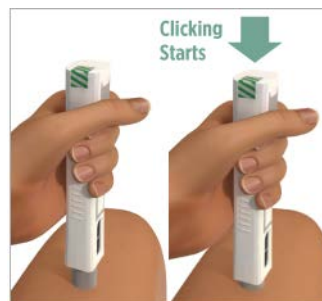


Figure M

- After the “clicking” sound has stopped, check the injection status window. You should see green checkmarks in the injection status window (See Figure N).

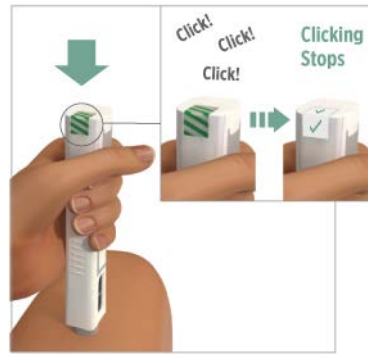


Figure N

Step 8: Remove your Plegridy Pen from your injection site

- Lift your Plegridy Pen from your injection site. The needle cover will be covering all of the needle (See Figure O).



Figure O

Step 9: Check to make sure you have received your full dose of Plegridy

- Check the injection status window. You should see green checkmarks in the injection status window (See Figure P).
- Check the medication window. You should see a yellow plunger in the medication window (See Figure Q).
 - If you see blood at your injection site, wipe it off with gauze and apply an adhesive bandage.
- If you experience difficulty or have questions, call 1-800-456-2255.



Figure P

Figure Q

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After your injection:

Step 10: 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.

Step 11: Check your injection site

- Plegridy may commonly cause redness, pain or swelling of your skin at the injection site.
- 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.

How should I store Plegridy?

- Store Plegridy in the refrigerator between 36°F to 46°F (2°C to 8°C).
- If needed, Plegridy may be stored between 36°F to 77°F (2°C to 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.**

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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