

Instructions for Use
PLEGRIDY® (PLEGG-rih-dee)
(peginterferon beta-1a)
injection for intramuscular use

Titration Kit for use with the PLEGRIDY intramuscular Single-Dose Prefilled Syringe Only

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.

Important information: The tip of the cap of the Plegridy prefilled syringe is made of natural rubber latex. Tell your healthcare provider if you are allergic to rubber or latex.

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.
- 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.
- Do not use more than 1 Plegridy prefilled syringe every 14 days.

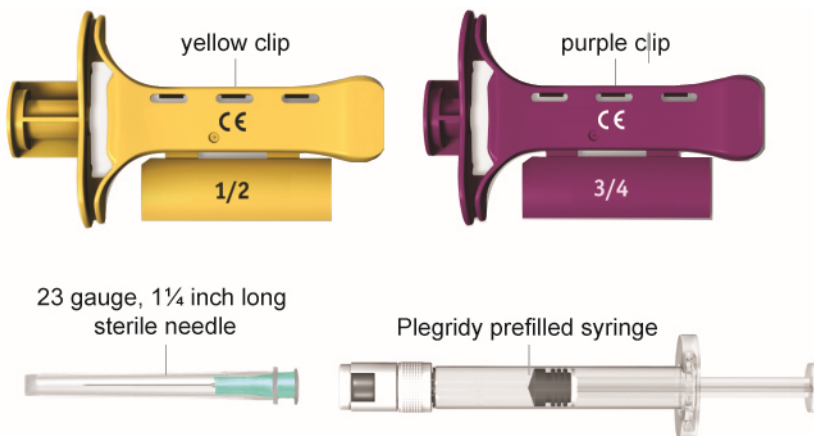
How should I store Plegridy?

- 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 a total of 30 days.
 - You can store your Plegridy prefilled syringes at room temperature and then put it back in the refrigerator.
- **Do not** freeze Plegridy. **Do not** use Plegridy that has been frozen.
- Store Plegridy in the original carton to protect it from light.

Keep the Plegridy Titration Kit, the Plegridy prefilled syringe, and all medicines out of the reach of children.

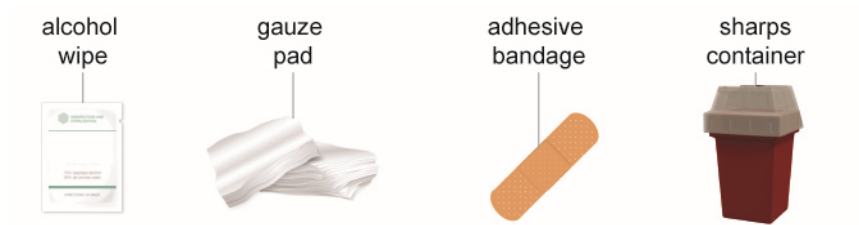
Supplies you will need for the Plegridy injection:

- 1 Plegridy Titration Kit that contains:
 - 1 yellow clip
 - 1 purple clip
- 1 Plegridy Administration Dose Pack that contains:
 - 1 Plegridy prefilled syringe
 - 23 gauge, 1¼ inch long sterile needle



Additional supplies not included in your Plegridy Titration Kit and Plegridy Administration Dose Pack:

- 1 alcohol wipe
- 1 gauze pad
- 1 adhesive bandage
- a sharps disposal container for throwing away used syringes and needles. See “**After the Plegridy injection**” at the end of these instructions.



Preparing the Plegridy Prefilled Syringe:

- Find a well-lit, clean, flat work surface like a table and collect all the supplies you will need to give yourself or receive an injection.
- Take 1 Plegridy Administration Dose Pack out of the refrigerator and let it come to room temperature for about 30 minutes. **Do not** use external heat sources such as hot water to warm the Plegridy prefilled syringe.
- Check the expiration date printed on the Plegridy prefilled syringe, Plegridy prefilled syringe Administration Dose Package carton, and the outer carton. **Do not** use the Plegridy prefilled syringe past the expiration date.
- Wash your hands with soap and water.

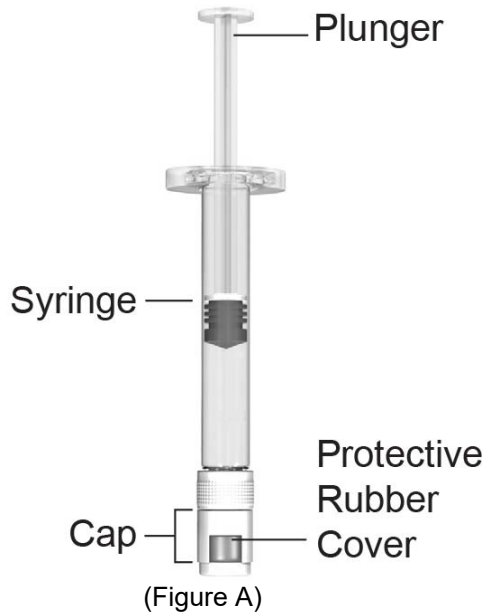
Identifying parts of the Plegridy prefilled syringe (See Figure A).

Preparing the Plegridy injection:

Step 1: Check the Plegridy prefilled syringe (Figure A):

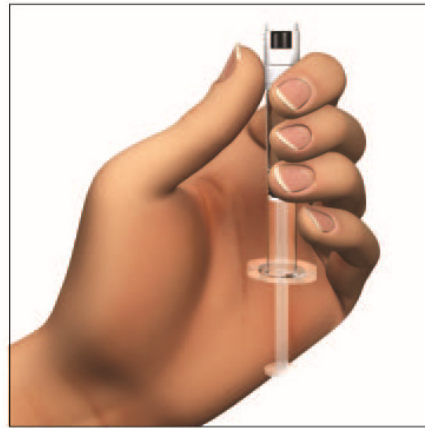
- The syringe should not have any cracks or damage.
- Check that the cap is intact and has not been removed.
- Plegridy should look slightly clear, colorless to slightly yellow, and should not have any particles in it.
- **Do not** use the Plegridy prefilled syringe if:
 - the syringe is cracked or damaged.
 - the solution is cloudy, colored other than slightly yellow, or has lumps or particles in it.
 - the cap has been removed or is not tightly attached.

If you cannot use that syringe, you will need to get a new syringe. Contact Biogen at 1-800-456-2255.



Step 2: With 1 hand, hold the Plegridy prefilled syringe right under the cap and with the cap pointing up (See Figure B).

- o Make sure you are holding the Plegridy prefilled syringe by the ridged part, directly under the cap.

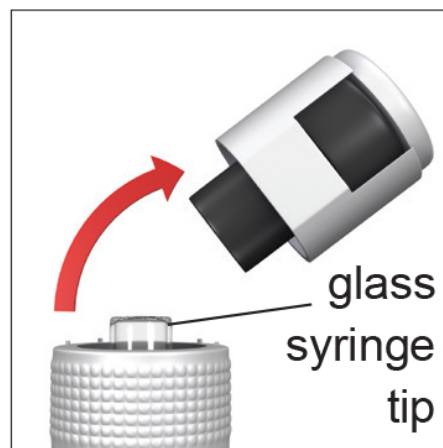


(Figure B)

Step 3: With the other hand, grasp the cap and bend it at a 90° angle until the cap snaps off (See Figure C and Figure D).

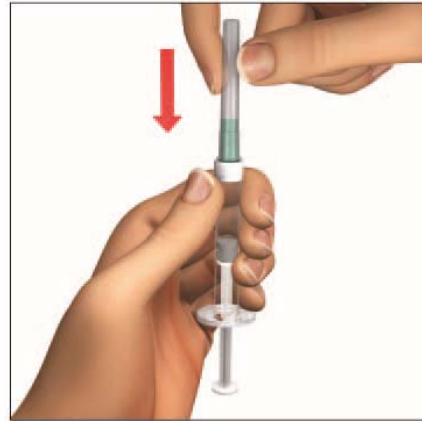


(Figure C)



(Figure D)

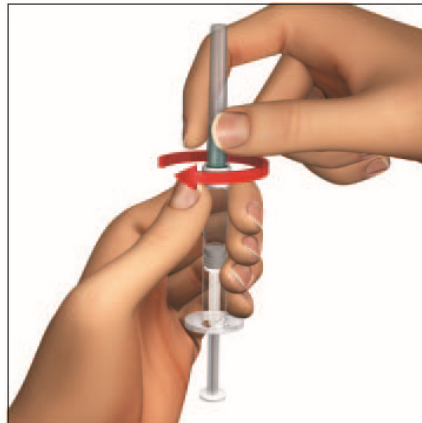
Step 4: Open the sterile needle package and take out the covered needle. Hold the Plegridy prefilled syringe with the glass syringe tip pointing up. Press the needle on the Plegridy prefilled syringe glass tip (See Figure E).



(Figure E)

Step 5: Gently turn the needle to the right (clockwise) until it is tight and firmly attached (See Figure F).

- If the needle is not firmly attached, it may leak and you may not get your full dose of Plegridy.
- **Do not** remove the protective cover from the needle.

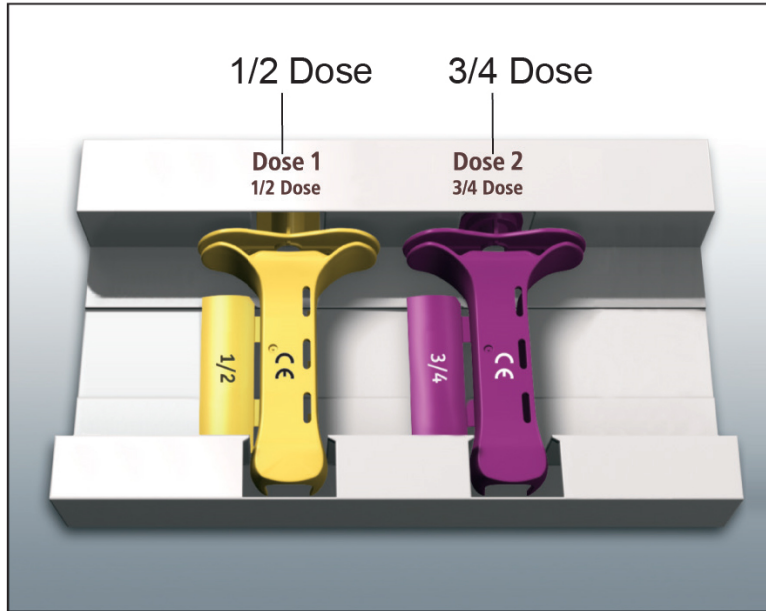


(Figure F)

Using the Plegridy prefilled syringe with the Plegridy Titration Kit:

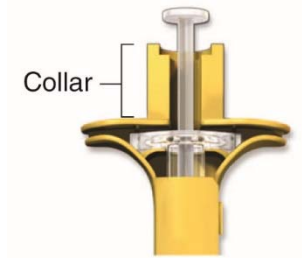
- You must prepare the Plegridy prefilled syringe and needle before you put it into the Plegridy titration clip. **Follow Step 1 to Step 5 above to prepare the Plegridy prefilled syringe.**
- Your Plegridy dose may be titrated over 2 doses by using the Plegridy prefilled syringe with the Plegridy Titration Kit.
 - **Dose 1 (Day 1):** ½ dose (yellow clip)
 - **Dose 2 (Day 15):** ¾ dose (purple clip)
 - **Dose 3 (Day 29):** a full dose (no clip needed)
- The 2 Plegridy titration clips are for single-use only with the Plegridy prefilled syringe. **Do not** re-use the Plegridy prefilled syringe or Plegridy titration clips.

Identifying the parts of Plegridy Titration Kit (See Figure G):



(Figure G)

- The Plegridy titration clip has a “collar” on top that will stop the syringe from injecting a full dose (See Figure H). The “collar” is to make sure that you receive the correct dose.



(Figure H)

Attaching the Plegridy titration clip:

Step 6: Choose the right titration clip for your dose.

- **Dose 1 (Day 1):** Choose the **yellow** clip to give $\frac{1}{2}$ dose (See Figure I).



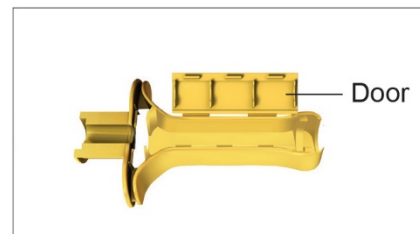
(Figure I)

- **Dose 2 (Day 15):** Choose the **purple** clip to give $\frac{3}{4}$ dose (See Figure J).



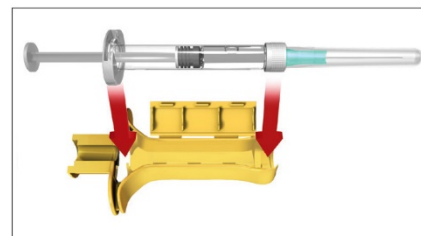
(Figure J)

Step 7: Put the correct titration clip on a flat surface with the door open (See Figure K).

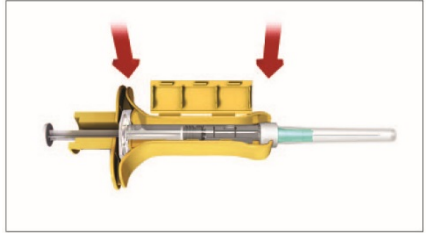
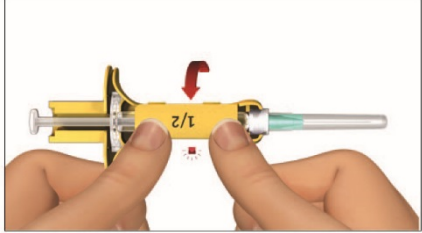



(Figure K)

Step 8: Line up the Plegridy prefilled syringe over the titration clip with the plunger pointing to the left and the needle pointing to the right (See Figure L).



(Figure L)

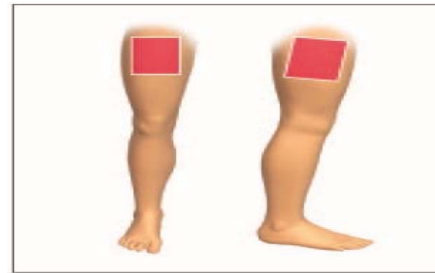
<p>Step 9: Push the Plegridy prefilled syringe down into the titration clip until both ends “snap” into place (See Figure M).</p>	 <p>(Figure M)</p>
<p>Step 10: Using 2 fingers, push the door down until it closes over the Plegridy prefilled syringe (See Figure N).</p> <ul style="list-style-type: none"> You will hear a “snap” when the door is closed the right way. Do not open door after it is closed. 	 <p>(Figure N)</p>
<p>Step 11: Check to make sure that the Plegridy prefilled syringe is in the titration clip the right way and that the door is tightly closed.</p>	 <p>(Figure O)</p>

Giving the Plegridy injection:

- Your healthcare provider should show you or a caregiver how to prepare and inject the dose of Plegridy before the Plegridy prefilled syringe is used for the first time. Your healthcare provider should watch you inject the dose of Plegridy the first time the Plegridy prefilled syringe is used.
- Inject your Plegridy exactly as your healthcare provider has shown you.
- Plegridy is injected into the muscle (intramuscularly).
- Plegridy should be injected into the thigh (See Figure P).
- Change (rotate) your injection sites for each dose. **Do not** use the same injection site for each injection.
- Do not** inject into an area of the body where the skin is irritated, reddened, bruised, infected or scarred in any way.

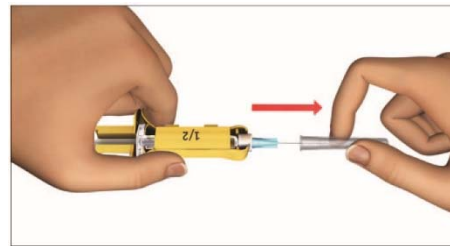
Step 12: Choose your left or right thigh and wipe the skin with an alcohol wipe (See Figure P). Let the injection site dry before injecting the dose.

- **Do not** touch this area again before giving the injection.



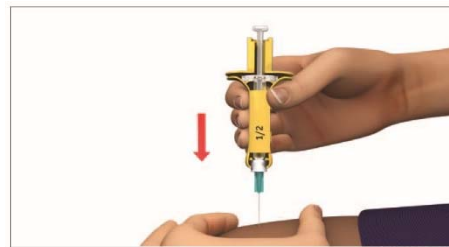
(Figure P)

Step 13: Pull the protective cover straight off the needle (See Figure Q). **Do not** twist the cover off.



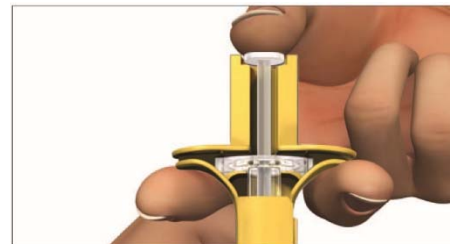
(Figure Q)

Step 14: With 1 hand, stretch the skin out around the injection site. With the other hand, hold the syringe like a pencil. Use a quick dart-like motion and insert the needle at a 90° angle, through the skin and into the muscle (See Figure R). After the needle is in, let go of the skin.



(Figure R)

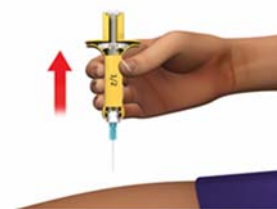
Step 15: Slowly push the plunger all the way down until it touches the collar (See Figure S).



(Figure S)

Step 16: Pull the needle out of the skin (See Figure T). Press down on the injection site with the gauze pad for a few seconds or rub gently in a circular motion.

- If you see blood after you press the injection site for a few seconds, wipe it off with the gauze pad and apply an adhesive bandage.



(Figure T)

After the Plegridy injection:

- **Do not** recap the needle. Recapping the needle can lead to a needle stick injury.
- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and 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 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.

Check the injection site:

- After 2 hours, check the injection site for redness, pain, itching, swelling, tenderness, a break in your skin that becomes blue and black, or drains fluid. If you have a skin reaction and it does not clear up in a few days, contact your healthcare provider.

General information about the safe and effective use of Plegridy

- Always use a new Plegridy prefilled syringe, titration clip, and needle. **Do not** re-use your Plegridy prefilled syringe, titration clip, or needle.
- **Do not** share your Plegridy prefilled syringe, titration clip, or needle.
- You can use the table below to keep track of your injections.

Day	Dose	Use Titration Clip	Date/Time
Day 1	1/2 Dose	Yellow	
Day 15	3/4 Dose	Purple	
Day 29	Full Dose	None	

Manufactured for:

Biogen Inc.

Cambridge, MA 02142 USA

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1-800-456-2255

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

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