

Instructions for Use

PEGINTRON® (peg-In-tron)

(Peginterferon alfa-2b)

REDIPEN® single-dose pre-filled pen

This Instructions for Use is only for use with the REDIPEN single-dose pre-filled pen.

Be sure that you read, understand, and follow these instructions before injecting PEGINTRON. Your healthcare provider should show you how to prepare and inject PEGINTRON properly using the REDIPEN single-dose pre-filled pen before you use it for the first time. Ask your healthcare provider if you have any questions.

Important:

- Make sure that you have the correct strength of REDIPEN pre-filled pen prescribed by your healthcare provider.
- Throw away REDIPEN after you use it. **Do not re-use your pre-filled pen or needle.** See “**Disposal of used needles and pre-filled pens**” in this Instructions for Use.

Before starting, collect all of the supplies that you will need to use for preparing and injecting PEGINTRON. For each injection you will need a package that contains:

- 1 PEGINTRON REDIPEN single-dose pre-filled pen
- 1 disposable needle
- 2 alcohol swabs
- dosing tray (the dosing tray is the bottom half of the REDIPEN package)
- You will need gauze or a cotton ball to press to the injection site after injecting. You will also need 1 sharps disposal container for throwing away your used pre-filled pen. See “**Disposal of used needles and pre-filled pens**” in this Instructions for Use.

The REDIPEN single-dose pre-filled pen should only be used with the injection needle that comes in the package. If you use other needles, the pen may not work the right way.

- Figures A and B below show the different parts of the REDIPEN single-dose pre-filled pen and the injection needle. Figure C below shows the dosing tray with the pre-filled pen. The parts of the pre-filled pen you need to know are:



Figure A

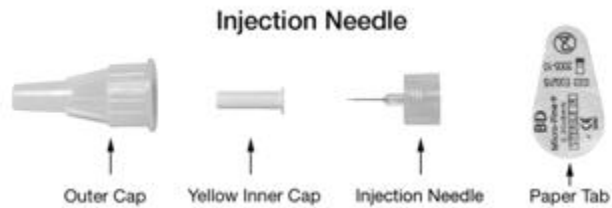


Figure B



Figure C

How should I prepare a dose of PEGINTRON using the REDIPEN single-dose pre-filled pen?

1. Find a clean, well-lit, flat work surface.
2. Take the pre-filled pen out of the refrigerator and allow the medicine to come to room temperature. Look at the date printed on the carton to make sure that the expiration date has not passed. Do not use if the expiration date has passed.
3. After taking the pre-filled pen out of the carton, look in the window of the pre-filled pen and make sure the PEGINTRON in the cartridge holder window is a white to off-white tablet that is whole, or in pieces, or powdered.

4. Wash your hands well with soap and water. It is important to keep your work area, your hands, and the injection site clean to decrease the risk of infection. See Figure D.



Figure D

Mix the PEGINTRON

5. **Place the pre-filled pen upright** in the dosing tray on a hard, flat, non-slip surface with the dosing button down. See Figure E. You may want to hold the pre-filled pen using the grip.



Figure E

6. To mix the powder and the liquid, keep the pre-filled pen upright in the dosing tray and press the top half of the pre-filled pen downward toward the hard, flat, non-slip surface **until you hear the "click" sound.** See Figure F. When you hear the click, you will notice in the window that both dark stoppers are now touching. The dosing button should be flat with the pen body.



Figure F

7. Wait several seconds for the powder to completely dissolve. Do not shake. If the solution does not dissolve, gently turn the pre-filled pen upside down two times. See Figure G.



Figure G

8. Keep the pre-filled pen **UPRIGHT**, with the dosing button down. Look through the pre-filled pen window to see that the mixed PEGINTRON solution is completely dissolved. The solution should be clear and colorless **before use**. It is normal to see some small bubbles in the pre-filled pen window, near the top of the solution. Do not use the REDIPEN pre-filled pen if the solution is discolored, or is not clear, or if it has particles in it.
9. Place the pre-filled pen back into the dosing tray provided in the packaging. See Figure H. The dosing button will be on the bottom.



Figure H

Attach the Needle

10. Before you attach the needle to the pre-filled pen, wipe the rubber membrane of the pre-filled pen with an alcohol swab.
11. Remove the protective paper tab from the injection needle, but do not remove either the outer cap or the yellow inner cap from the injection needle.
12. Keep the pre-filled pen upright in the dosing tray and push the injection needle straight into the pre-filled pen rubber membrane. Screw the needle onto the pre-filled pen by turning it in a clockwise direction. See Figure I.
 - Remember to leave the needle caps in place when you attach the needle to the pre-filled pen. Pushing the needle through the rubber membrane "primes" the needle and allows the extra liquid and air in the pen to be removed.



Figure I

NOTE: Some fluid will trickle out. This is **normal**. The dark stoppers move up and you will no longer see the fluid in the window once the needle is successfully primed.

- Remove the outer clear needle cap on the pre-filled pen, but leave the yellow cap on. See Figure J.



Figure J

How should I set the dose prescribed by my healthcare provider?

Dial the Dose

13. Holding the pre-filled pen firmly, pull the dosing button out as far as it will go. See Figure K. You will see a dark band.

Do not push the dosing button in until you are ready to self-inject the PEGINTRON dose.



Figure K

14. Turn the dosing button until your prescribed dose is lined up with the dosing tab. See Figure L. The dosing button will turn freely. If you have trouble dialing your dose, check to make sure the dosing button has been pulled out **as far** as it will go. See Figure M.



Figure L

Figure M

15. Carefully lay the pre-filled pen down on the dosing tray or on a hard, flat, non-slip surface. Do not remove the yellow needle cap and do not push the dosing button in until you are ready to self-inject the PEGINTRON dose.

Choosing an Injection Site

The best sites for giving yourself an injection are those areas with a layer of fat between the skin and muscle, like your thigh, the outer surface of your upper arm, and abdomen. See Figure N. Do not inject yourself in the area near your belly-button (navel) or waistline. If you are very thin, you should only use the thigh or outer surface of the arm for injection.

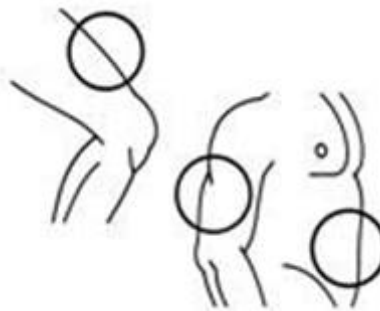


Figure N

You should use a different site each time you inject PEGINTRON to avoid soreness at any one site. Do not inject PEGINTRON into an area where the skin is irritated, red, bruised, infected, or has scars, stretch marks, or lumps.

How should I Inject a dose of PEGINTRON?

16. Clean the skin where the injection is to be given with the second alcohol swab provided, and wait for the skin to dry.
17. There may be some liquid around the yellow inner needle cap. See Figure O. This is normal.



Figure O

18. Remove the **yellow** inner needle cap when the injection site is dry. See Figure P. You are now ready to inject.



Figure P

19. Hold the pre-filled pen with your fingers wrapped around the pen body barrel and your thumb on the dosing button. See Figure Q.



Figure Q

20. With your other hand, pinch the skin in the area you have cleaned for injection.
21. Insert the needle into the pinched skin at an angle of 45° to 90°. See Figure R.



Figure R

22. Press the dosing button down slowly and firmly until you can not push it any further. Keep your thumb pressed down on the dosing button for an additional 5 seconds to make sure that you get the complete dose.
23. Slowly release the dosing button and remove the needle from your skin.

24. Gently press the injection site with a small bandage or sterile gauze if needed for a few seconds but do not massage the injection site. If there is bleeding, cover with an adhesive bandage. Do not recap the needle and do not reuse the pre-filled pen.

Disposal of the used needles and pre-filled pens

- Put your used needles and pre-filled pens in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and pre-filled 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, syringes and pre-filled 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.

Always keep the sharps disposal container out of the reach of children.

How should I store PEGINTRON REDIPEN pre-filled pen?

- Before mixing, store PEGINTRON REDIPEN pre-filled pen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- After mixing, use PEGINTRON right away or store it in the refrigerator for up to 24 hours between 36°F to 46°F (2°C to 8°C).
- Do not freeze PEGINTRON.
- Keep PEGINTRON away from heat.

Keep PEGINTRON and all medicines out of reach of children.

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

Manufactured by:

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