

25. After injecting your dose:

- o Firmly grasp the safety sleeve and pull it over the exposed needle until you hear a click, and the green stripe on the safety sleeve covers the red stripe on the needle. (See Figure S)

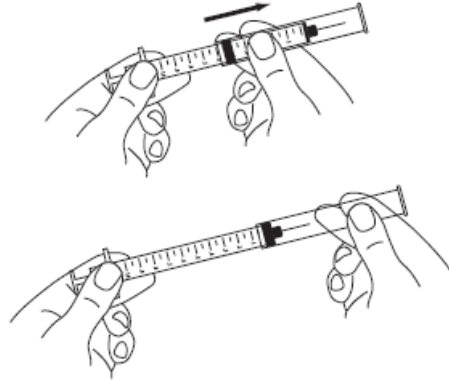


Figure S

26. Dispose of used syringes, needles, and vials in the sharps disposal container. (See “How should I dispose of the used syringes, needles, and vials?” below).

How should I dispose of the used syringes, needles, and vials?

- Put your used needles, syringes and vials in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles, syringes and vials in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - o made of a heavy-duty plastic,
 - o can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - o upright and stable during use,
 - o leak-resistant, and
 - o 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 syringes and needles. 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?

- Before mixing, store PegIntron vials at room temperature, between 68°F to 77°F (20°C to 25°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 the reach of children.

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

Manufactured by:

Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.**, Whitehouse Station, NJ 08889, USA

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Instructions for Use

PegIntron[®] (peg-In-tron)

(Peginterferon alfa-2b)

REDIPEN[®] single-use pre-filled pen

This Instructions for Use is only for use with the REDIPEN single-use 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-use 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-use 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-use 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-use 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

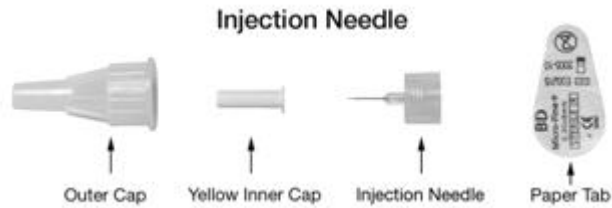


Figure B



Figure C

How should I prepare a dose of PegIntron using the REDIPEN single-use 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

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