

Instructions for Use

PegIntron[®] (peg-In-tron)

(Peginterferon alfa-2b)

Powder for Solution

Be sure that you read, understand and follow these instructions before injecting PegIntron Solution. Your healthcare provider should show you how to prepare, measure, and inject PegIntron properly before you use it for the first time. Ask your healthcare provider if you have any questions.

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 PegIntron vial package that contains:

- 1 vial of PegIntron powder for solution
- 1 vial of sterile water for injection (diluent)
- 2 single-use disposable syringes (BD Safety Lok syringes with a safety sleeve)
- 2 alcohol swabs

You will also need:

- 1 cotton ball or gauze
- a puncture-proof disposable container to throw away used syringes, needles, and vials.

Important:

- **Never re-use disposable syringes and needles.**
- The vial of mixed PegIntron should be used right away. Do not mix more than 1 vial of PegIntron at a time. If you do not use the vial of the prepared solution right away, store it in a refrigerator and use within 24 hours. See the end of these Instructions for Use for information about "How should I store PegIntron?"
- Make sure you have the right syringe and needle to use with PegIntron. Your healthcare provider should tell you what syringes and needles to use to inject PegIntron.

How should I prepare a dose of PegIntron?

Before you inject PegIntron, the powder must be mixed with 0.7 mL of the sterile water for injection (diluent) that comes in the PegIntron vial package.

1. Find a clean, well-lit, flat work surface.

2. Get 1 of your PegIntron vial packages. Check the date printed on the PegIntron carton. Make sure that the expiration date has not passed. Do not use your PegIntron vial packages if the expiration date has passed. The medicine in the PegIntron vial should look like a white to off-white tablet that is whole, or in pieces, or powdered.

If you have already mixed the PegIntron solution and stored it in the refrigerator, take it out of the refrigerator before use and allow the solution to come to room temperature. See the Medication Guide section "How should I store PegIntron?"

3. Wash your hands well with soap and water, rinse and towel dry (see Figure 1). Keep your work area, your hands, and injection site clean to decrease the risk of infection.

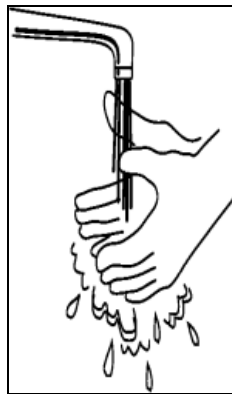


Figure 1

The disposable syringes have needles that are already attached and cannot be removed. Each syringe has a clear plastic safety sleeve that is pulled over the needle for disposal after use. The safety sleeve should remain tight against the flange while using the syringe and moved over the needle only when ready for disposal. (See Figure 2.)

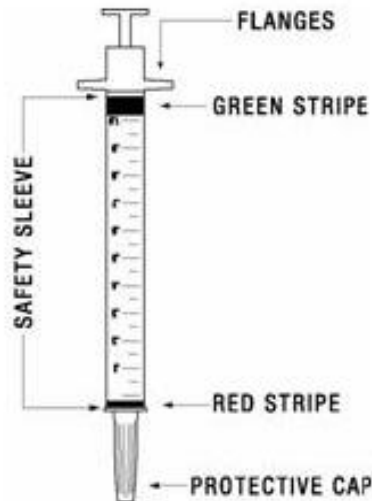


Figure 2

4. Remove the protective wrapper from one of the syringes provided. Use the syringe for steps 4 through 15. Make sure that the syringe safety sleeve is sitting against the flange. (See Figure 2.)
5. Remove the protective plastic cap from the tops of both the sterile water for injection (diluent) and the PegIntron vials (see Figure 3). Clean the rubber stopper on the top of both vials with an alcohol swab.

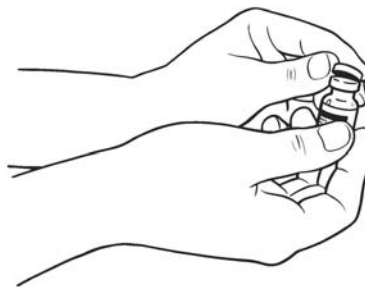


Figure 3

6. Carefully remove the protective cap straight off of the needle to avoid damaging the needle point.
7. Fill the syringe with air by pulling back on the plunger to 0.7 mL. (See Figure 4.)

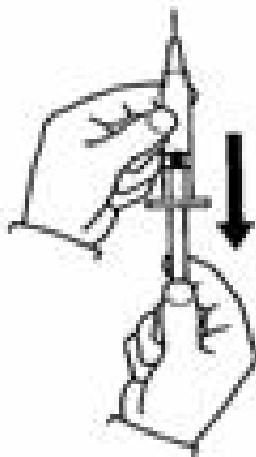


Figure 4

8. Hold the diluent vial upright. Do not touch the cleaned top of the vial with your hands.
 - Push the needle through the center of the rubber stopper of the diluent vial. (See Figure 5.)
 - Slowly inject all the air from the syringe into the air space above the diluent in the vial. (See Figure 6.)

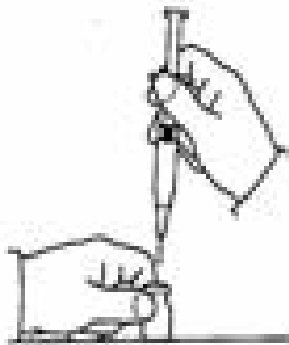


Figure 5

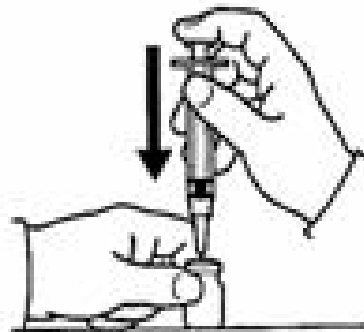


Figure 6

9. Turn the vial upside down and make sure the tip of the needle is in the liquid.
10. Withdraw only 0.7 mL of diluent by pulling the plunger back to the 0.7 mL mark on the side of the syringe. (See Figure 7.)

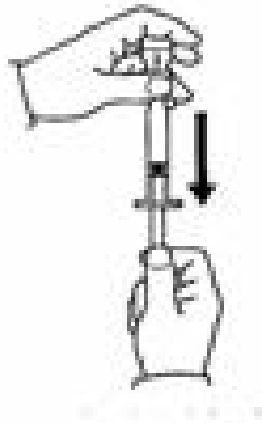


Figure 7

11. With the needle still inserted in the vial, check the syringe for air bubbles.
 - If there are any air bubbles, gently tap the syringe with your finger until the air bubbles rise to the top of the syringe.
 - Slowly push the plunger up to remove the air bubbles.
 - If you push diluent back into the vial, slowly pull back on the plunger to draw the correct amount of diluent back into the syringe.
12. Remove the needle from the vial. (See Figure 8.) Do not let the syringe touch anything.

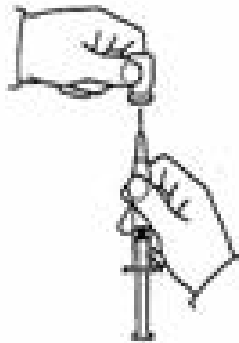


Figure 8

13. Throw away any diluent that is left over in the vial.
14. Insert the needle through the center of the rubber stopper of the PegIntron powder vial. Do not touch the cleaned rubber stopper.
 - Place the needle tip, at an angle, against the side of the vial. (See Figure 9.)

- Slowly push the plunger down to inject the 0.7 mL diluent. The stream of diluent should run down the side of the vial.
- To prevent bubbles from forming, do not aim the stream of diluent directly on the medicine in the bottom of the vial.

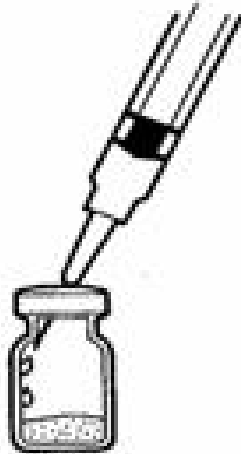


Figure 9

15. Remove the needle from the vial.
 - Firmly grasp the safety sleeve and pull it over the exposed needle until you hear a click (see Figure 10). The green stripe on the safety sleeve will completely cover the red stripe on the needle. Discard the syringe, needle, and vial in the puncture-proof container.

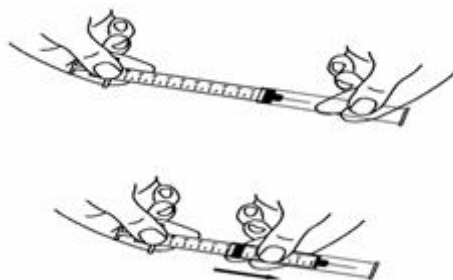


Figure 10

16. Gently swirl the vial in a gentle circular motion, until the PegIntron is completely dissolved (mixed together). (See Figure 11.)
 - Do not shake the vial. If any powder remains undissolved in the vial, gently turn the vial upside down until all of the powder is dissolved.
 - The solution may look cloudy or bubbly for a few minutes. If air bubbles form, wait until the solution settles and all bubbles rise to the top.



Figure 11

17. After the PegIntron completely dissolves, the solution should be clear, colorless and without particles. It is normal to see a ring of foam or bubbles on the surface.

Do not use the mixed solution if you see particles in it, or it is not clear and colorless. Throw away the syringe and needle in the puncture-proof container. (See the section "How should I dispose of the used syringes, needles, and vials?") Then, repeat steps 1 through 23 with a new vial of PegIntron and diluent to prepare a new syringe.

18. After the PegIntron powder completely dissolves, clean the rubber stopper again with an alcohol swab before you withdraw your dose.
19. Unwrap the second syringe provided. You will use it to give yourself the injection.
 - o Carefully remove the protective cap from the needle. Fill the syringe with air by pulling the plunger to the number on the side of the syringe (mL) that matches your prescribed dose. (See Figure 12.)

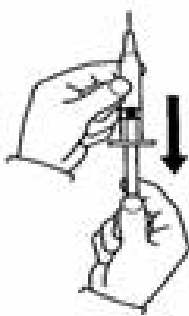


Figure 12

- o Hold the PegIntron vial upright. Do not touch the cleaned top of the vial with your hands. (See Figure 13.)

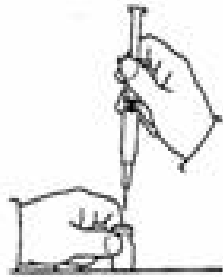


Figure 13

- Insert the needle into the vial containing the PegIntron solution. Inject the air into the center of the vial. (See Figure 14.)

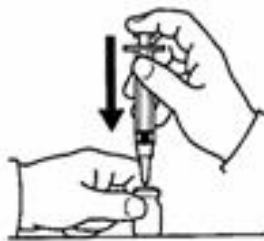


Figure 14

20. Turn the PegIntron vial upside down. Be sure the tip of the needle is in the PegIntron solution.
 - Hold the vial and syringe with one hand. Be sure the tip of the needle is in the PegIntron Solution. With the other hand, slowly pull the plunger back to fill the syringe with the exact amount of PegIntron into the syringe your healthcare provider told you to use. (See Figure 15.)

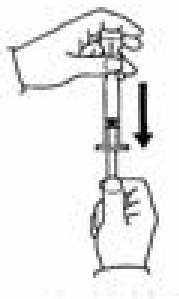


Figure 15

21. Check for air bubbles in the syringe. If you see any air bubbles, hold the syringe with the needle pointing up. Gently tap the syringe until the air bubbles rise. Then, slowly push the plunger up to remove any air bubbles. If you push solution into the vial, slowly pull back on the plunger again to

draw the correct amount of PegIntron back into the syringe. When you are ready to inject the medicine, remove the needle from the vial. (See Figure 16.)

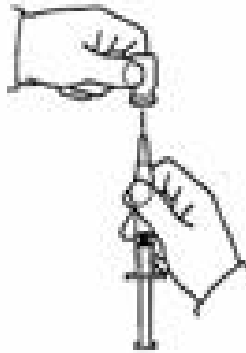


Figure 16

How should I choose a site for injection?

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 17). Do not inject yourself in the area near your navel or waistline. If you are very thin, you should only use the thigh or outer surface of the arm for injection.



Figure 17

You should use a different site each time you inject PegIntron to avoid soreness at any one site. Do not inject PegIntron solution 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?

22. Clean the skin where the injection is to be given with an alcohol swab. Wait for the area to dry.
- Make sure the safety sleeve of the syringe is pushed firmly against the syringe flange so that the needle is fully exposed. (See Figure 2.)
23. With one hand, pinch a fold of skin. With your other hand, pick up the syringe and hold it like a pencil.
- Insert the needle into the pinched skin at a 45- to 90-degree angle with a quick dart-like motion (see Figure 18).

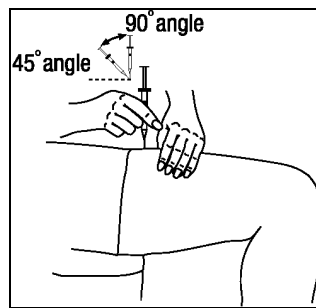


Figure 18

- After the needle is inserted, remove the hand that you used to pinch your skin. Use it to hold the syringe barrel.
 - Pull the plunger of the syringe back very slightly.
 - **If no blood is present in the syringe**, inject the medicine by gently pressing the plunger all the way down the syringe barrel, until the syringe is empty.
 - **If blood comes into the syringe**, the needle has entered a blood vessel. Do not inject.
 - Withdraw the needle and throw away the syringe and needle in the puncture-proof container. (See step 24 and the disposal steps below.)
 - Then, repeat steps 1 through 23 with a new vial of PegIntron and diluent to prepare a new syringe, and inject the medicine at a new site.
24. When the syringe is empty, pull the needle out of the skin.
- Place a cotton ball or gauze over the injection site and press for several seconds. Do not massage the injection site.
 - If there is bleeding, cover it with a bandage.

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 19).

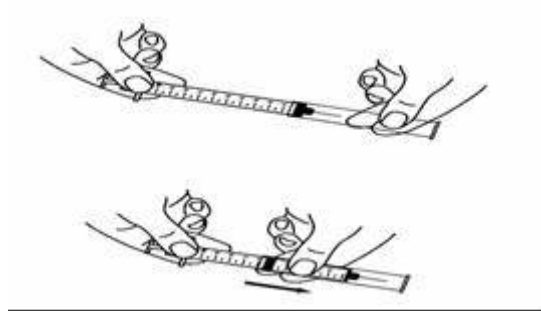


Figure 19

26. Throw away the used syringe, needle, and vials in the puncture-proof disposable container. (See "How should I dispose of the used syringes, needles, and vials?")

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

- Throw away used syringes, needles, and vials in a puncture-proof container, sharps container, or a hard container like a metal can with a lid. Always place needles facing down. Do not use glass or clear plastic containers. **Always keep the puncture-proof container out of the reach of children.**
- Do not throw away used needles, syringes, or the puncture-proof container in household trash and do not recycle them.
- Check with your healthcare provider for instructions about the right way to throw away used needles and syringes. There may be local or state laws about how to throw away used needles and syringes. Always follow the instructions of your healthcare provider.

How should I store PegIntron?

- Before mixing, store PegIntron vials at room temperature, between 59°F to 86°F (15°C to 30°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.**

Manufactured by: Schering Corporation, a subsidiary of **Merck & Co., Inc.**,
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Instructions for Use

PegIntron[®] (peg-In-tron)
(Peginterferon alfa-2b)

Solution for Injection REDIPEN

How to Use the PegIntron[®] REDIPEN[®] Single-dose Delivery System.

Be sure that you read, understand, and follow these instructions before injecting PegIntron Solution. Your healthcare provider should show you how to prepare, measure, and inject PegIntron properly before you use it for the first time. Ask your healthcare provider if you have any questions.

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 PegIntron REDIPEN package that contains:

- the PegIntron REDIPEN single-dose delivery system
 - 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 a puncture-proof disposable container to throw away your used REDIPEN.

Important:

- **Never re-use needles.**
- Make sure that you have the correct PegIntron REDIPEN prescribed by your healthcare provider. The PegIntron REDIPEN system is for a single use, by one person only, 1 time a week. **The REDIPEN must not be shared.**

The PegIntron REDIPEN should only be used with the injection needle that is provided in the packaging for the PegIntron REDIPEN system. If you use other needles, the pen may not work the right way.

- Figures 1 and 2 below show the different parts of the PegIntron REDIPEN Delivery System and the injection needle. Figure 3 below shows the dosing tray with the REDIPEN. The parts of the pen you need to know are:



Figure 1

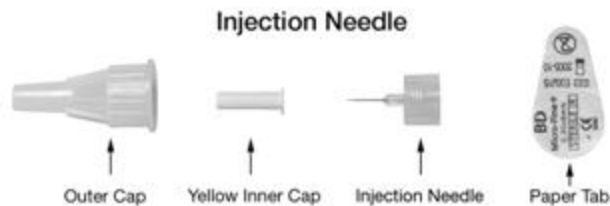


Figure 2



Figure 3

How should I prepare a dose of PegIntron using the REDIPEN?

1. Find a clean, well-lit, flat work surface.
2. Take the PegIntron REDIPEN out of the refrigerator and allow the medicine to come to room temperature. Look at the date printed on the PegIntron REDIPEN carton to make sure that the expiration date has not passed. Do not use if the expiration date has passed.
3. After taking the PegIntron REDIPEN out of the carton, look in the window of the REDIPEN 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 4).



Figure 4

Mix the Drug

5. **Place the PegIntron REDIPEN upright** in the dosing tray on a hard, flat, non-slip surface with the dosing button down (see Figure 5). You may want to hold the REDIPEN using the grip.



Figure 5

6. To mix the powder and the liquid, keep the REDIPEN upright in the dosing tray and press the top half of the REDIPEN downward toward the hard, flat, non-slip surface **until you hear the “click” sound** (see Figure 6). 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 6

7. Wait several seconds for the powder to completely dissolve. Do not shake. If the solution does not dissolve, gently turn the PegIntron REDIPEN upside down two times (see Figure 7).



Figure 7

8. Keep the PegIntron REDIPEN **UPRIGHT**, with the dosing button down. Look through the REDIPEN 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 REDIPEN window, near the top of the solution. Do not use the PegIntron REDIPEN solution if it is discolored, or not clear, or if it has particles in it.
9. Place the PegIntron REDIPEN back into the dosing tray provided in the packaging (see Figure 8). The dosing button will be on the bottom.



Figure 8

Attach the Needle

10. Before you attach the needle to the PegIntron REDIPEN, wipe the rubber membrane of the PegIntron REDIPEN 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 PegIntron REDIPEN upright in the dosing tray and push the injection needle straight into the REDIPEN rubber membrane. Screw the needle onto the PegIntron REDIPEN by turning it in a clockwise direction (see Figure 9).
 - Remember to leave the needle caps in place when you attach the needle to the REDIPEN. Pushing the needle through the rubber membrane "primes" the needle and allows the extra liquid and air in the pen to be removed.



Figure 9

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 REDIPEN, but leave the yellow cap on (see Figure 10).



Figure 10

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

Dial the Dose

13. Holding the PegIntron REDIPEN firmly, pull the dosing button out as far as it will go (see Figure 11). You will see a dark band.

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



Figure 11

14. Turn the dosing button until your prescribed dose is lined up with the dosing tab (see Figure 12). 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 13).



Figure 12

Figure 13

15. Carefully lay the PegIntron REDIPEN 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 14). Do not inject yourself in the area near your navel or waistline. If you are very thin, you should only use the thigh or outer surface of the arm for injection.



Figure 14

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 15). This is normal.



Figure 15

18. Remove the **yellow** inner needle cap when the injection site is dry (see Figure 16). You are now ready to inject.



Figure 16

19. Hold the PegIntron REDIPEN with your fingers wrapped around the pen body barrel and your thumb on the dosing button (see Figure 17).



Figure 17

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 18).



Figure 18

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 REDIPEN.

How do I dispose of the REDIPEN?

- Throw away the REDIPEN and needle and any solution remaining in the REDIPEN in a puncture-proof container, sharps container, or a hard container like a metal can with a lid. Always place needles facing down. Do not use glass or clear plastic containers. **Always keep the puncture-proof container out of reach of children.**
- Do not throw away used REDIPENS and needles in household trash and do not recycle them.
- Check with your healthcare provider for instructions about the right way to throw away used REDIPENS and needles. There may be local or state laws about how to throw away used REDIPENS and needles. Always follow the instructions of your healthcare provider.

How should I store PegIntron?

- Before mixing, store PegIntron REDIPEN 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 the reach of children.**

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