

Instructions for Use

SYLATRON™ (SY-LA-TRON)

(peginterferon alfa-2b)

for injection

Powder for Injection

Be sure that you read, understand and follow these instructions before injecting SYLATRON. Your healthcare provider should show you how to prepare, measure, and inject SYLATRON 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 SYLATRON. For each injection you will need a SYLATRON vial package that contains:

- 1 vial of SYLATRON powder
- 1 vial of sterile water for injection (diluent). The vial contains an excess amount of sterile water (5 mL). You will only need to withdraw 0.7 mL to prepare your single dose.
- 2 single-dose disposable syringes (BD Safety Lok syringes with a safety sleeve)
- 2 alcohol swabs

You will also need:

- 1 cotton ball or gauze
- 1 sharps disposal container to throw away (dispose of) used syringes, needles, and vials. See "How should I dispose of used syringes, needles, and vials?" at the end of this Instructions for Use.

Important:

- **Do not re-use or share syringes and needles.**
- The vial of mixed SYLATRON should be used right away. Do not mix more than 1 vial of SYLATRON 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 this Instructions for Use for information about "How should I store SYLATRON?"
- Make sure you have the right syringe and needle to use with SYLATRON. Your healthcare provider should tell you what syringes and needles to use to inject SYLATRON.

How should I prepare a dose of SYLATRON?

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

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

If you have already mixed the SYLATRON solution and stored it in the refrigerator, take it out of the refrigerator before use and allow the solution to come to room temperature.

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

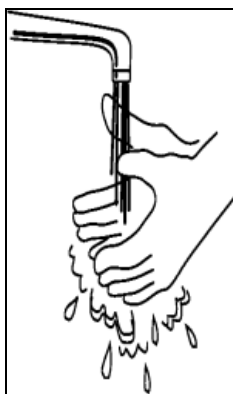


Figure A

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 B)

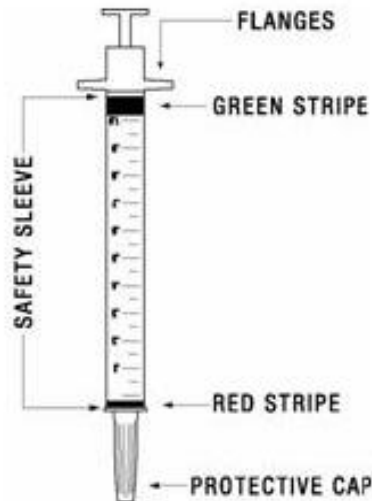


Figure B

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 B)
5. Remove the protective plastic cap from the tops of both the sterile water for injection (diluent) and the SYLATRON vials (See Figure C). Clean the rubber stopper on the top of both vials with an alcohol swab.

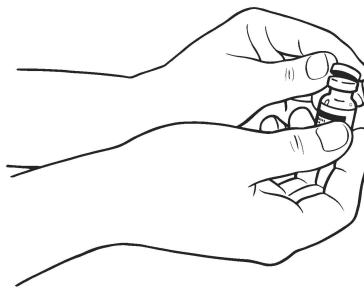


Figure C

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 D)

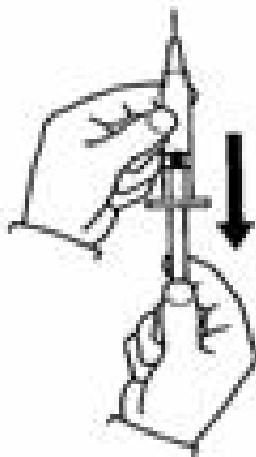


Figure D

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 E)
 - Slowly inject all the air from the syringe into the air space above the diluent in the vial. (See Figure F)

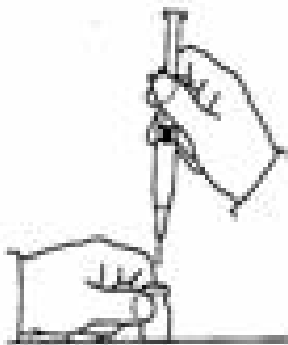


Figure E

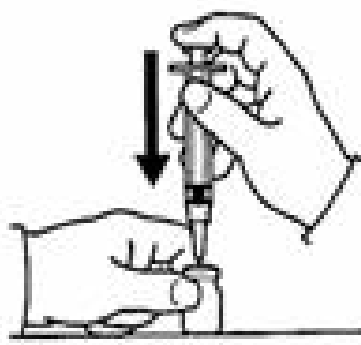


Figure F

9. Turn the vial upside down and make sure the tip of the needle is in the liquid.
 - Important: The sterile water for injection vial contains an excess amount of sterile water (5 mL). **You will only need to withdraw 0.7 mL to prepare your single dose.**
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 G)

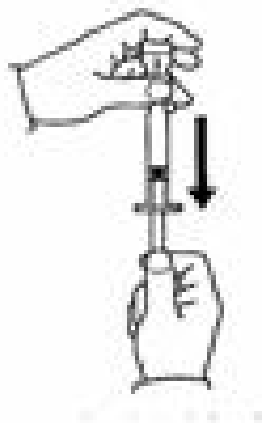


Figure G

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 H). Do not let the syringe touch anything.

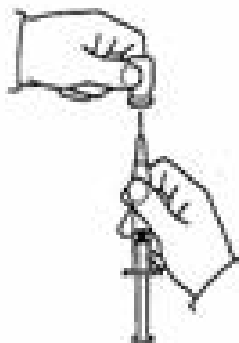


Figure H

13. Throw away the diluent that is left over in the vial. Do not save any leftover diluent or use it again. See "How should I dispose of used syringes, needles, and vials?" at the end of this Instructions for Use.
14. Insert the needle through the center of the rubber stopper of the SYLATRON powder vial. Do not touch the cleaned rubber stopper.
 - Place the needle tip, at an angle, against the side of the vial. (See Figure I)

- 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.

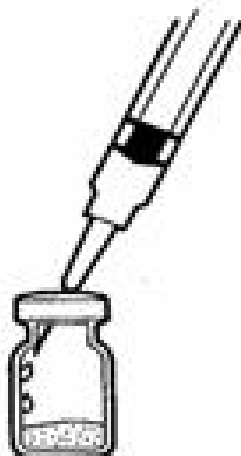


Figure I

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 J). The green stripe on the safety sleeve will completely cover the red stripe on the needle. Dispose of the syringe, needle, and vial in the sharps disposal container. See "How should I dispose of used syringes, needles, and vials?" at the end of this Instructions for Use.

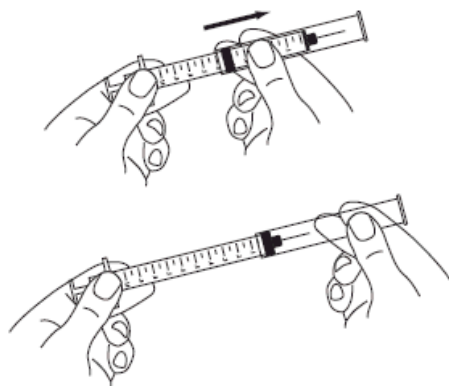


Figure J

16. Gently swirl the vial in a gentle circular motion, until the SYLATRON is completely dissolved (mixed together). (See Figure K)
 - 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 K

17. After the SYLATRON 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. Dispose of the syringe and needle in the sharps disposal container. See the section "How should I dispose of used syringes, needles, and vials?" at the end of this Instructions for Use. Then, repeat steps 1 through 17 with a new vial of SYLATRON and diluent to prepare a new syringe.
18. After the SYLATRON 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.
 - 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 L)

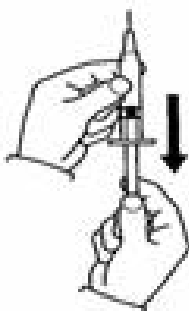


Figure L

- Hold the SYLATRON vial upright. Do not touch the cleaned top of the vial with your hands. (See Figure M)

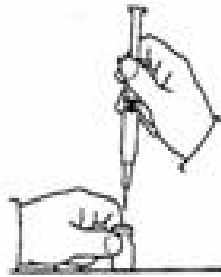


Figure M

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



Figure N

20. Turn the SYLATRON vial upside down. Be sure the tip of the needle is in the SYLATRON solution.

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

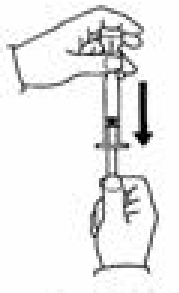


Figure O

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 SYLATRON back into the syringe. When you are

ready to inject the medicine, remove the needle from the vial. (See Figure P)

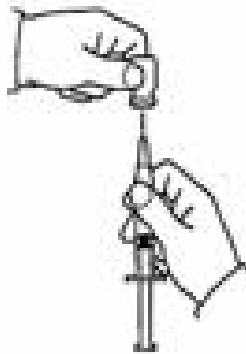


Figure P

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 Q). 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 Q

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

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 B)

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 R)

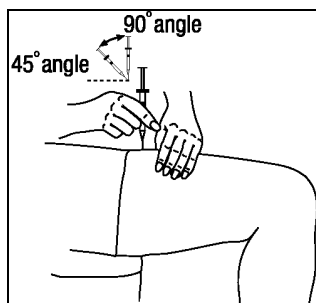


Figure R

- 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 dispose of the syringe and needle in the sharps disposal container. (See the section "How should I dispose of used syringes, needles, and vials?" at the end of this Instructions for Use.)
 - If there is bleeding, cover the injection site with a bandage.
 - Then, repeat steps 1 through 23 with a new vial of SYLATRON 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:
- 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)

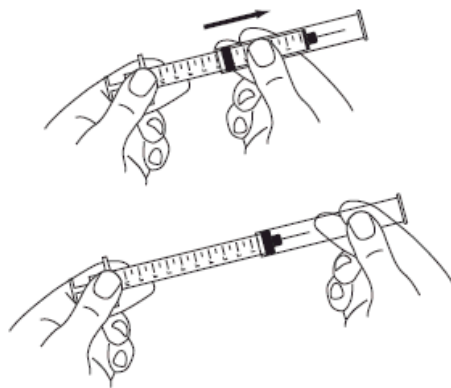


Figure S

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

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

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

- Before mixing, store SYLATRON vials at 59°F to 86°F (15°C to 30°C).
- After mixing, use SYLATRON right away or store it in the refrigerator for up to 24 hours between 36°F to 46°F (2°C to 8°C). Throw away any mixed SYLATRON that is not used within 24 hours.
- Do not freeze SYLATRON.
- Keep SYLATRON away from heat.

Keep SYLATRON 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:

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