Instructions for Use INTRON® A (In-tron-aye)

(Interferon alfa-2b, recombinant)

Solution for Injection

Be sure that you read, understand and follow these instructions before injecting INTRON A. Your healthcare provider should show you how to prepare, measure and inject INTRON A 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 INTRON A. For each injection, you will need the following supplies:

- 1 vial of INTRON A solution
- 1 single-use disposable syringe and needle
- 1 cotton ball or gauze
- 2 alcohol swabs
- 1 sharps disposal container for throwing away (dispose of) your 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:

- Never re-use disposable syringes and needles.
- Make sure you have the right syringe and needle to use with INTRON A.
 Your healthcare provider should tell you what syringes and needles to use to inject INTRON A.

How should I prepare a dose of INTRON® A?

- 1 Find a well lit, clean, flat working surface.
- 2. Before removing INTRON A from the carton, look at the expiration date printed on the carton. Make sure that the expiration date has not passed. Do not use if the expiration date has passed.
- 3. Wash your hands well with soap and warm water (See Figure A). Keep your work area, your hands and injection site clean to decrease the risk of infection.



Figure A

4. Remove 1 vial of INTRON A solution from the carton (See Figure B).



Figure B

- 5. Look at the vial of INTRON A. The solution should be clear and colorless, without particles. Do not use the vial of INTRON A if the medicine is cloudy, has particles or is not clear and colorless.
- 6. Remove the protective plastic cap from the top of the INTRON A vial. Clean the rubber stopper on the top of the INTRON A vial with an alcohol swab (See Figure C).



Figure C

7. Gently warm the INTRON A solution by slowly rolling the vial in the palms of your hands for about one minute (See Figure D). Do not shake the vial.



Figure D

8. Open the package of the syringe you are using (See Figure E) and if it does not have a needle attached, then attach a new needle to the syringe.

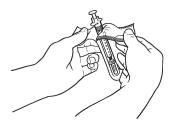


Figure E

9. Remove the protective cap from the needle of the syringe. Fill the syringe with air by pulling back on the plunger to the mark on the syringe that matches the dose prescribed by your healthcare provider (See Figure F).

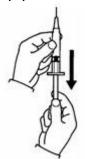


Figure F

10. Hold the vial of INTRON A Solution for Injection on your flat working surface (See Figure G). Do not touch the cleaned rubber stopper.

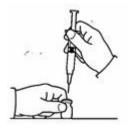


Figure G

11. Push the needle straight down through the middle of the rubber stopper of the vial containing the INTRON A solution (See Figure H). Slowly inject all the air from the syringe into the air space above the solution.

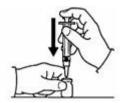


Figure H

- 12. Keep the needle in the vial. Turn the vial upside down (See Figure I).
 - Make sure the tip of the needle is in the INTRON A solution.
 - Slowly pull the plunger back to fill the syringe with INTRON A solution to the dose (mL or cc) prescribed by your healthcare provider.



Figure I

- 13. With the needle still in the vial, check the syringe for air bubbles (See Figure J).
 - o 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 solution back into the vial, slowly pull back on the plunger to draw the dose (mL or cc) prescribed by your healthcare provider.

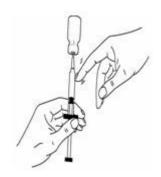


Figure J

14. Do not remove the needle from the vial. Lay the vial and syringe on its side on your flat work surface until you are ready to inject the INTRON A solution.

How should I choose a site for injection?

Based on your treatment, your healthcare provider will tell you if you should inject a dose of INTRON® A under the skin (subcutaneous injection) or into the muscle (intramuscular injection). If it is too difficult for you to inject, ask someone who has been trained to give injections to help you.

For Subcutaneous Injection

The best sites for injection are areas on your body with a layer of fat between skin and muscle such as (See Figure K):

- the front of your middle thighs
- the outer area of your upper arms
- the abdomen, except around your belly button (navel)

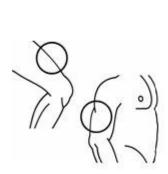


Figure K

For Intramuscular Injection

The best sites for injection into your muscle are (See Figure L):

- the front of your middle thighs
- your upper arms
- the upper outer areas of your buttocks



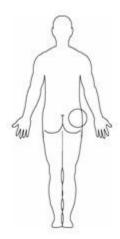


Figure L

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

- 15. Clean the injection site with a new alcohol swab. Wait for the area to dry.
- 16. Pick up the vial and syringe from your flat work surface. Remove the syringe and needle from the vial.
 - o Hold the syringe in the hand that you will use to inject INTRON A.
 - Do not touch the needle or allow it to touch the work surface.
- 17. With your other hand, pinch a fold of the skin at the cleaned injection site.

For subcutaneous injection (under the skin):

o Hold the syringe (like a pencil) at a **45-degree angle** to the skin. With a quick "dart-like" motion, push the needle into the skin (See Figure M).



Figure M

For intramuscular injection (into the muscle):

Hold the syringe (like a pencil) at a **90-degree angle** to the skin.
 With a quick "dart-like" motion, push the needle into the muscle (See Figure N).



Figure N

- 18. After the needle is inserted, remove the hand used to pinch the skin. Use it to hold the syringe barrel.
 - Pull the plunger back 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 INTRON[®] A.
 - Withdraw the needle and dispose of the syringe and needle in the sharps disposal container. See "How should I dispose of used syringes, needles and vials?" at the end of this Instructions for Use
 - o If there is bleeding, cover the injection site with a bandage.
 - o Then, repeat steps 1 through 18 with a new dose of INTRON A and inject the medicine at a new injection site.
- 19. 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.
 - o If there is bleeding, cover the injection site with a bandage.
- 20. Dispose of 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 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:
 - made of a heavy-duty plastic,
 - 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 INTRON® A?

- Store in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not freeze Intron A.
- Allow the INTRON A Solution for Injection to come to room temperature before using. INTRON A Solution in Multidose vials for Injection may be used to give more than 1 injection of medicine.
- Throw away any unused INTRON A Solution for Injection remaining in the vial after 1 month
- Keep away from heat.
- Keep INTRON A and all medicines out of the reach of children.

Manufactured by:

Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.,** Whitehouse Station, NJ 08889, USA U.S. License Number 0002

For patent information: www.merck.com/product/patent/home.html

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