

Instructions for Use
INTRON® A (In-tron-aye)
(Interferon alfa-2b, recombinant)
Powder for Solution

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 powder for solution
- 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 1 mL to prepare your single dose.
- 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.**
- The vial of mixed INTRON A should be used right away. Do not mix more than 1 vial of INTRON A at a time. If you do not use the vial of 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 INTRON A?"
- After mixing, throw away (discard) the vial of INTRON A after you withdraw one dose of medicine.
- 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?

Before you inject INTRON A, the powder must be mixed with 1 mL (cc) of the sterile water for injection (diluent) from the INTRON A vial package.

1. Find a clean, well-lit, flat work surface.
2. Get one of your INTRON A vial packages. Check the date printed on the carton. Make sure that the expiration date has not passed.

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



Figure A

4. Gently warm the vial of diluent by slowly rolling the vial in the palms of your hands for one minute (See Figure B).

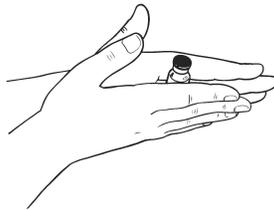


Figure B

5. Remove the protective plastic cap from the tops of both vials (INTRON A powder and the diluent). Clean the rubber stopper on the top of both vials with an alcohol swab (See Figure C).

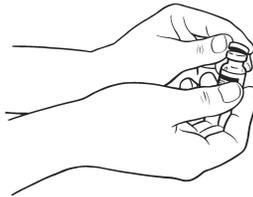


Figure C

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

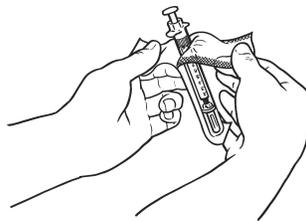


Figure D

7. Remove the needle cover from the syringe. Fill the syringe with air by pulling the plunger back to 1 mL (See Figure E).

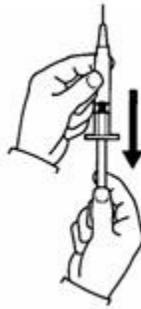


Figure E

8. Hold the diluent vial on your flat work surface. Do not touch the cleaned rubber stopper (See Figure F).

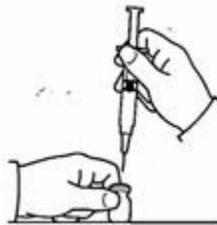


Figure F

9. Push the needle straight down through the middle of the rubber stopper of the diluent vial and slowly inject all the air from the syringe into the air space above the diluent (See Figure G).

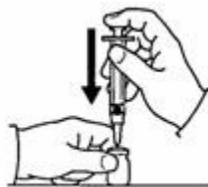


Figure G

10. Keep the needle in the vial. Turn the vial upside down and make sure the tip of the needle is in the diluent.
 - o Important: The sterile water for injection vial contains an excess amount of sterile water (5 mL). **You will only need to withdraw 1 mL to prepare your single dose.**
 - o Slowly pull the plunger back to fill the syringe with diluent to the **1 mL mark** on the side of the syringe (See Figure H).



Figure H

11. With the needle still inserted in the vial, check the syringe for air bubbles (See Figure I).
 - 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 again draw 1 mL of diluent back into the syringe.

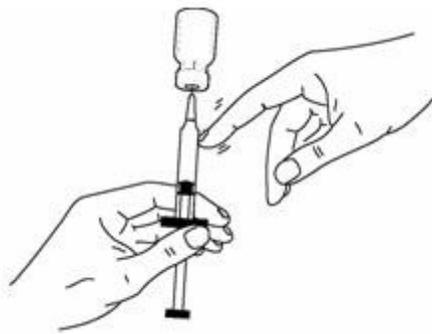


Figure I

12. Remove the needle from the vial. Do not let the syringe touch anything.
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 INTRON A powder vial. Do not touch the cleaned rubber stopper.
 - Place the needle tip, at an angle, against the side of the INTRON A powder vial (See Figure J).



Figure J

- Slowly push the plunger down to inject the diluent into the vial. The stream of liquid should run down the sides of the glass vial.
 - To prevent bubbles from forming, do not aim the stream of diluent directly on the medicine in the bottom of the vial.
 - Do not remove the needle from the vial.
15. Gently swirl the INTRON A vial in a circular motion until the powder is completely dissolved (See Figure K).

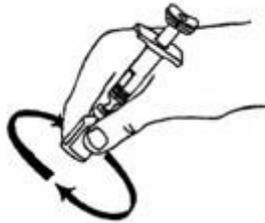


Figure K

- 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 do form, wait until the solution settles and all bubbles rise to the top. Then withdraw your dose from the vial.
16. After the INTRON A completely dissolves, the solution should be clear and colorless to light yellow, without particles. Do not use the mixed solution if you see particles in it, or it is not clear and colorless to light yellow.
17. With the needle in the vial, turn the vial upside down (See Figure L).

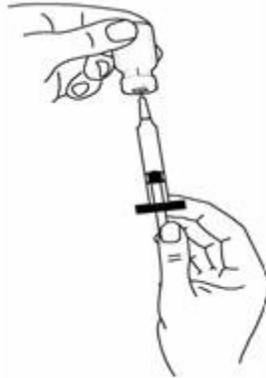


Figure L

- Hold the vial with one hand. Be sure the tip of the needle is in the INTRON A solution. Slowly pull the plunger back to fill the syringe with the exact amount of INTRON A into the syringe that your healthcare provider told you to use.
18. With the needle still inserted in the vial, check the syringe for air bubbles. If you see any air bubbles, gently tap the syringe with your finger until the air bubbles rise to the top of the syringe (See Figure M).

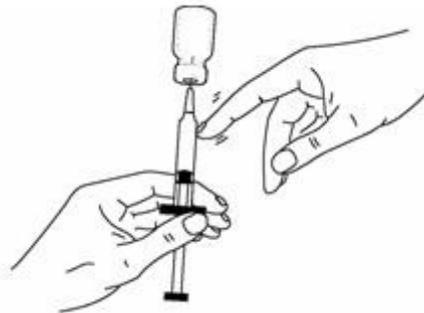


Figure M

19. Slowly push the plunger up to remove the air bubbles. If you push solution back into the vial, slowly pull back on the plunger again to draw the correct amount of INTRON A solution back into the syringe.
20. 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 N):

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



Figure N

For Intramuscular Injection

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

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

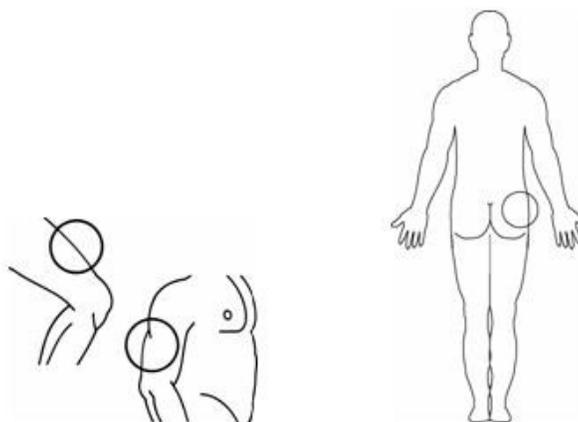


Figure O

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?

21. Clean the injection site with a new alcohol swab. Wait for the skin to dry.
22. Pick up the vial and syringe from your flat work surface. Remove the syringe and needle from the vial.
 - 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.
23. With one hand, pinch a fold of the skin at the cleaned injection site.
24. **For subcutaneous injection (under the skin):**
 - With the other hand, 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 P).



Figure P

25. **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 Q).



Figure Q

26. After the needle is inserted, remove the hand used to pinch the skin and 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 pushing 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 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 25 with a new dose of INTRON A and inject the medicine at a new injection site.

27. 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 the injection site with a bandage.

28. 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,
 - 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 INTRON® A?

- Before mixing, store in the refrigerator between 36°F to 46°F (2°C to 8°C).
- After mixing the INTRON A Powder for Injection, use the solution right away or store the solution in the refrigerator for up to 24 hours between 36°F to 46°F (2°C to 8°C). Allow the solution to come to room temperature before using.
- Do not freeze Intron A.
- Keep away from heat.
- Throw away any medicine left in the vial after you withdraw 1 dose.

Keep INTRON A 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

U.S. License Number 0002

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

Copyright © 1996, 2011, Merck Sharp & Dohme Corp., a subsidiary of **Merck & Co., Inc.**

All rights reserved.

Revised: 02/2016

usifu-mk2958-pwi-5ml-1602r001