

INSTRUCTIONS FOR USE
AVONEX® (a-vuh-necks)
(interferon beta-1a)
injection for intramuscular use
single-dose prefilled syringe

Read the Instructions for Use before you start using AVONEX and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Important information: The tip of the cap of the AVONEX prefilled syringe is made of natural rubber latex. Tell your healthcare provider if you are allergic to rubber or latex.

How should I store AVONEX?

- Store AVONEX in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze AVONEX. **Do not** use AVONEX that has been frozen.
- If you cannot refrigerate your AVONEX prefilled syringes, you can store your AVONEX prefilled syringes at room temperature up to 77°F (25°C) for up to 7 days.
- **Do not** store AVONEX above 77°F (25°C). **Do not use** AVONEX that is stored at temperatures higher than 77°F (25°C).
- Throw AVONEX away in an FDA-cleared sharps disposal container if it has not been stored as stated above. (See **After the AVONEX injection** section at the end of this Instructions for Use.)
- Keep AVONEX in the original carton to protect it from light.

Supplies you will need for the AVONEX injection:

- 1 AVONEX Administration Dose Pack that contains:
 - 1 AVONEX prefilled syringe
 - 23 gauge, 1¼ inch long sterile needle
- 1 alcohol wipe
- 1 gauze pad
- 1 adhesive bandage
- a puncture resistant container for disposal of used syringes and needles

Preparing the dose of AVONEX:

- Find a well-lit, clean, flat work surface like a table and collect all the supplies you will need to give yourself or receive an injection.
- Take 1 AVONEX Administration Dose Pack out of the refrigerator about 30 minutes before you plan on injecting the AVONEX dose to allow it to reach room temperature. **Do not** use external heat sources such as hot water to warm the AVONEX prefilled syringe.

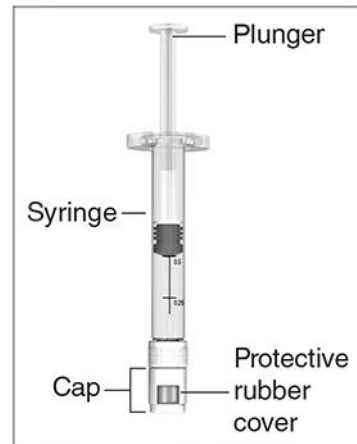
- Check the expiration date printed on AVONEX prefilled syringe, AVONEX Administration Dose Pack, and the outer carton. **Do not** use AVONEX prefilled syringe past the expiration date.
- Wash your hands with soap and water.

Identifying parts of the AVONEX prefilled syringe (See Figure A):

Preparing the AVONEX injection:

Step 1: Hold the AVONEX prefilled syringe with the cap pointing down and with the 0.5 mL mark at eye level (See Figure A).

- Check the syringe:
 - The syringe should not have any cracks or damage.
 - Check that the cap is intact and has not been removed.
 - The amount of liquid in the syringe should be at or very close to the 0.5 mL mark.
 - AVONEX should look clear, colorless, and should not have any particles in it.
- **Do not** use the AVONEX prefilled syringe if:
 - the syringe is cracked or damaged
 - the solution is cloudy, colored, or has lumps or particles in it
 - the cap has been removed or is not tightly attached or
 - there is not enough liquid in the syringe
If you cannot use that syringe, you will need to get a new syringe. Contact Biogen at 1-800-456-2255.




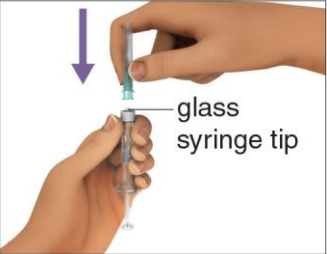



(Figure A)

Step 2: With 1 hand, hold the AVONEX prefilled syringe right under the cap and with the cap pointing up (See Figure B).

- Make sure you are holding the AVONEX prefilled syringe by the ridged part, directly under the cap.



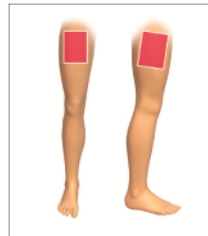
<p>Step 3: With the other hand, grasp the cap and bend it at a 90° angle until the cap snaps off (See Figure C and Figure D).</p>	<p>(Figure B)</p>  <p>(Figure C)</p>  <p>(Figure D)</p>
<p>Step 4: Open the sterile needle package and take out the covered needle. Hold the AVONEX prefilled syringe with the glass syringe tip pointing up. Press the needle on the AVONEX prefilled syringe glass tip (See Figure E).</p>	 <p>Needle cover</p>  <p>glass syringe tip</p> <p>(Figure E)</p>
<p>Step 5: Gently turn the needle to the right (clockwise) until it is tight and firmly attached (See Figure F).</p> <ul style="list-style-type: none"> • If the needle is not firmly attached, it may leak and you may not get your full dose of AVONEX. • Do not remove the plastic cover from the needle. 	 <p>(Figure F)</p>

Giving the AVONEX injection:

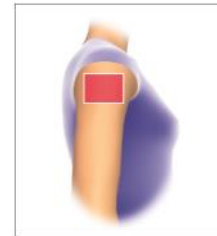
- Your healthcare provider should show you or a caregiver how to prepare and inject the dose of AVONEX before AVONEX prefilled syringe is used for the first time. Your healthcare provider or nurse should watch you inject the dose of AVONEX the first time AVONEX prefilled syringe is used.
- Inject your AVONEX exactly as your healthcare provider has shown you.
- AVONEX is injected into the muscle (intramuscularly).
- AVONEX should be injected into the thigh or upper arm (See Figures G and H).
- Change (rotate) your injection sites for each dose. **Do not** use the same injection site for each injection.
- **Do not** inject into an area of the body where the skin is irritated, reddened, bruised, infected or scarred in any way.

Step 6: Choose an injection site and wipe the skin with an alcohol wipe (See Figures G and H). Let the injection site dry before injecting the dose.

- **Do not** touch this area again before giving the injection.

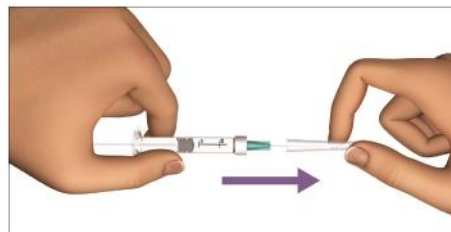


(Figure G)



(Figure H)

Step 7: Pull the protective cover straight off the needle (See Figure I). **Do not** twist the cover off.

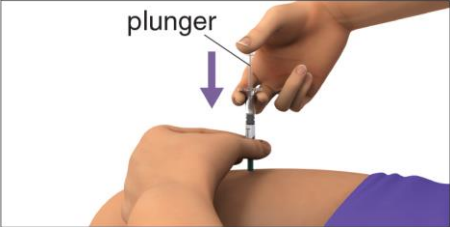



(Figure I)

Step 8: With 1 hand, stretch the skin out around the injection site. With the other hand, hold the syringe like a pencil. Use a quick dart-like motion and insert the needle at a 90 degree angle, through the skin and into the muscle (See Figure J). After the needle is in, let go of the skin.



(Figure J)

<p>Step 9: Slowly push the plunger down until the syringe is empty (See Figure K).</p>	 <p>(Figure K)</p>
<p>Step 10: Pull the needle out of the skin (See Figure L). Press down on the injection site with the gauze pad for a few seconds or rub gently in a circular motion.</p> <ul style="list-style-type: none"> If you see blood after you press the injection site for a few seconds, wipe it off with the gauze pad and apply an adhesive bandage. 	 <p>(Figure L)</p>

After the AVONEX injection:

- **Do not** recap the needle. Recapping the needle can lead to a needle stick injury.
- Put your used needles and syringes in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have an 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 needles and syringes. 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.

Check Your Injection Site:

- After 2 hours, check the injection site for redness, swelling or tenderness. If you have a skin reaction and it does not clear up in a few days, contact your healthcare provider.

General information about the safe and effective use of AVONEX

- Always use a new AVONEX prefilled syringe and needle for each injection. **Do not** re-use your AVONEX prefilled syringe or needles.
- **Do not** share your AVONEX prefilled syringe or needles.
- Keep the AVONEX prefilled syringe and needles 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:

Biogen Inc.

Cambridge, MA 02142 USA

U.S. License # 1697

1-800-456-2255

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