

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

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.

Your healthcare provider should show you or your caregiver how to prepare the dose of AVONEX and how to inject your AVONEX PEN the right way before AVONEX PEN is used for the first time. Your healthcare provider or nurse should watch you inject the dose of AVONEX the first time AVONEX PEN is used.

Important information: The tip of the cap of the AVONEX PEN 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 PEN, you can store your AVONEX PEN 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.

Preparing the AVONEX PEN:

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

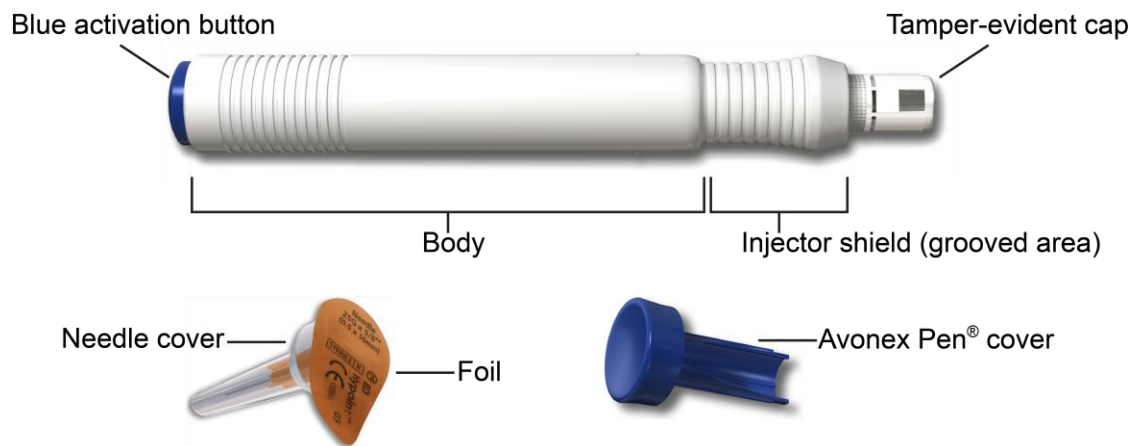
Supplies you will need to give the AVONEX PEN injection:

- 1 AVONEX Administration Dose Pack that contains:
 - 1 AVONEX PEN

- a 25 gauge, 5/8 inch long sterile needle
- 1 AVONEX PEN cover
- 1 alcohol wipe
- 1 gauze pad
- 1 adhesive bandage
- a puncture resistant container for disposal of used AVONEX PEN and needle

Identifying parts of the AVONEX PEN (See Figure A).

Single-Dose Administration Dose Pack Contents – AVONEX PEN, Supplied Needle and AVONEX PEN Cover



(Figure A)

Preparing the AVONEX PEN injection:

Step 1: Hold the AVONEX PEN with the white tamper-evident cap (cap) pointing up (See Figure B).

- Check that the cap is intact and has not been removed. If the cap has been removed or is not tightly attached, **do not** use it. Throw it away and get a new AVONEX PEN. (See **After the AVONEX injection** section at the end of this Instructions for Use.)



Before

(Figure B)

Step 2: With your other hand, grasp the cap and bend it at a 90° angle until the cap snaps off (See Figure C).

- After the cap comes off, you will see the glass tip of the syringe. **Do not** touch the glass tip of the syringe (See Figure D).



(Figure C)

glass syringe tip



After
(glass syringe tip)

(Figure D)

Step 3: Place the AVONEX PEN down on a flat work surface.

Step 4: Pull off the sterile foil from the needle cover (See Figure E).

- Only use the needle that comes with your AVONEX PEN.



(Figure E)

Step 5: Hold the AVONEX PEN with the glass syringe tip pointing up. Press the needle onto the AVONEX PEN glass syringe tip (See Figure F).



Before

(Figure F)

Step 6: Gently turn the needle to the right (clockwise) until it is firmly attached (See Figure G).

- If the needle is not firmly attached, it may leak, and you may not get your full dose of AVONEX.



(Figure G)

- **Do not** remove the plastic cover from the needle (See Figure H).



After
(attached needle)

(Figure H)

Step 7: Hold the body of the AVONEX PEN in 1 hand with the needle and needle cover pointing away from you and other people. **Do not** remove the plastic cover from the needle (See Figure I).



Before

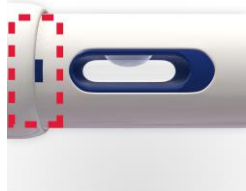
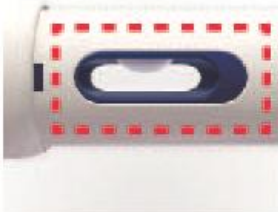
(Figure I)

Step 8: Using your other hand, hold onto the injector shield (grooved area) tightly and quickly pull up on the injector shield until the injector shield covers the needle all the way.

- The plastic needle cover will “pop” off after the injector shield has been fully extended (See Figure J).



After
(extended)

<ul style="list-style-type: none"> When the injector shield is extended the right way, you will see a small blue rectangular area next to the oval medicine display window (See Figure K). 	<p>(Figure J)</p>  <p>Safety Lock (visible)</p> <p>(Figure K)</p>
<p>Step 9: Check the oval medicine display window and make sure the AVONEX is clear and colorless (See Figure L).</p> <p>You might see air bubbles in the oval medicine display window. This is normal and will not affect your dose.</p> <ul style="list-style-type: none"> Do not use AVONEX PEN if the liquid is colored, cloudy, or contains any lumps or particles. Throw away the AVONEX PEN in an FDA-cleared sharps container and get a new one, then repeat steps 1 to 9. (See After the AVONEX injection section at the end of this Instructions for Use .) 	 <p>Oval Medicine Display Window</p> <p>(Figure L)</p>

Giving the AVONEX injection:

- Your healthcare provider should show you or your caregiver how to prepare the dose of AVONEX and how to inject your AVONEX PEN the right way before AVONEX PEN is used for the first time. Your healthcare provider or nurse should watch you inject the dose of AVONEX the first time AVONEX PEN is used.
- Inject your AVONEX PEN exactly as your healthcare provider has shown you.
- AVONEX PEN is injected into the muscle (intramuscularly).
- AVONEX PEN should be injected into the upper, outer thigh (See Figure M).
- Change (rotate) 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.
- Do not** push down on the injector shield and the blue activation button at the same time until you are ready to give your injection.

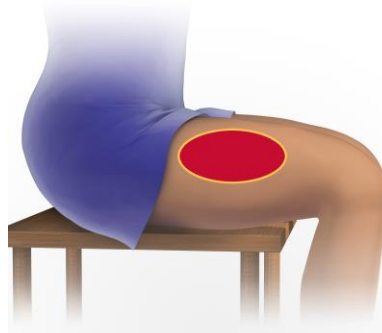
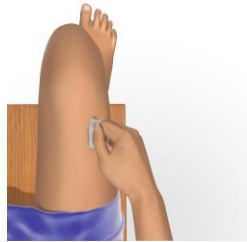
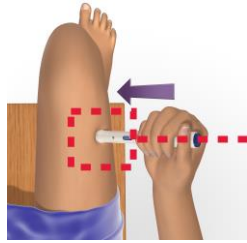

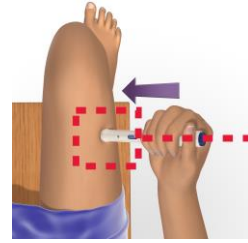


Figure M

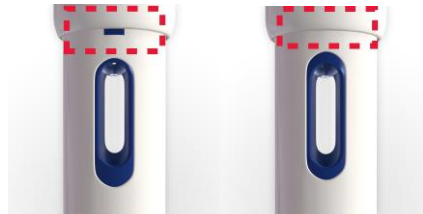
<p>Step 10: Choose an injection site and wipe the skin with an alcohol wipe (See Figure N). Let the injection site dry before injecting the dose.</p> <ul style="list-style-type: none"> • Do not touch this area again before giving the injection. 	 <p>(Figure N)</p>
<p>Step 11: Place the AVONEX PEN on the injection site (See Figure O).</p>	 <p>(Figure O)</p>
<p>Step 12: Hold the body of the AVONEX PEN at a 90° angle to the injection site, and make sure you can see the window (See Figure P).</p>	 <p>(Figure P)</p>

Step 13: Keeping your fingers away from the blue activation button, firmly push the body of the AVONEX PEN down against the thigh to release the safety lock (See Figure Q). **Do not** lift the AVONEX PEN off the injection site.

- Check to make sure the safety lock has been released. You will know the safety lock is released when the small blue rectangular area above the oval medicine display window is gone (See Figure R).



(Figure Q)

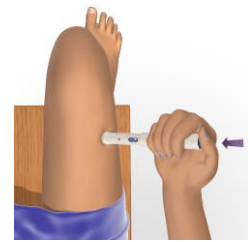


Safety Lock (visible) Safety Lock (released)

(Figure R)

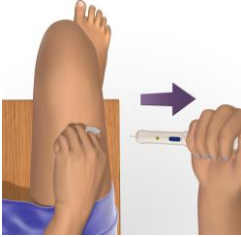



Step 14: Continue to firmly maintain pressure and push down on the AVONEX PEN against the injection site, then push down on the blue activation button with your thumb (See Figure S). Keep the AVONEX PEN pushed down against the injection site and slowly count to 10.

- **You will hear a “click” when the injection starts.** If you **do not** hear a “click”, your injection was not given the right way.
 - If this happens, make sure that the injector shield is extended, the safety lock is completely released, and that you are firmly maintaining pressure and pushing down against the injection site. Press the blue activation button with your thumb again. If you still **do not** hear a “click”, call Biogen at 1-800-456-2255.



(Figure S)



<p>Step 15: After you count to 10, pull the AVONEX PEN straight out of the skin (See Figure T). Use the gauze pad to apply pressure to the injection site 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 T)</p>
<p>Step 16: Check the circular display window on the AVONEX PEN to make sure that it is yellow. This is to be sure that you have been given your full dose (See Figure U).</p> <ul style="list-style-type: none"> If you did not receive your full dose of AVONEX, throw away the AVONEX PEN in a FDA-cleared sharps disposal container and call your healthcare provider. Do not re-use the AVONEX PEN. 	 <p>Circular Display Window</p> <p>(Figure U)</p>
<p>Step 17: Do not hold the AVONEX PEN cover with your hands. Place the AVONEX PEN cover on a flat work surface. Line up the exposed needle with the hole of the AVONEX PEN cover, and insert directly into the opening (See Figure V).</p>	 <p>(Figure V)</p>
<p>Step 18: Firmly press the AVONEX PEN down until you hear a “click” to seal the needle (See Figure W). You may need to hold both hands around the AVONEX PEN body to snap the AVONEX PEN cover into place.</p>	 <p>(Figure W)</p>

After the AVONEX injection:

Throw Away your AVONEX:

- Put your used needles and PENS 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 PEN

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