

Instructions for Use
AVOSTARTGRIP[®] Titration Kit
Use with AVONEX[®] (interferon beta-1a) Prefilled Syringe Only

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.

Preparing the AVONEX Prefilled Syringe:

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

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

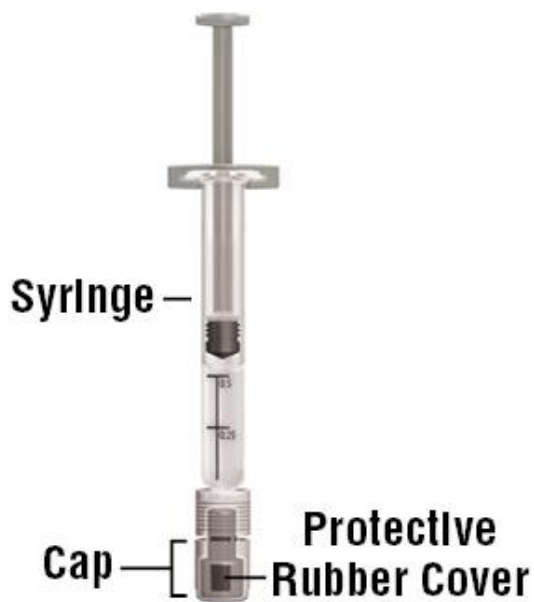
Identifying parts of the AVONEX prefilled syringe (See Figure A):

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

Do not use that syringe. Get a new syringe. Contact MS ACTIVESOURCE at 1-800-456-2255.



(Figure A)

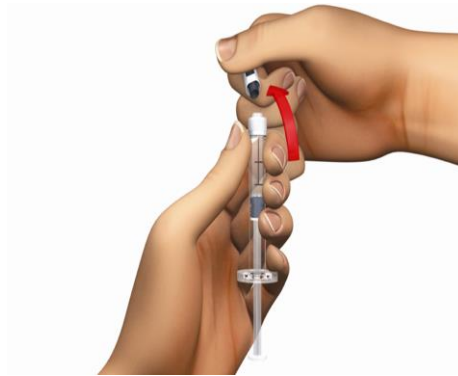
Step 2: With 1 hand, hold the AVONEX prefilled syringe right under the cap and with the cap pointing up (See Figure B).

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

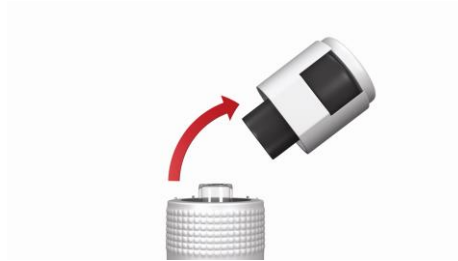


(Figure B)

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).



(Figure C)



(Figure D)

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).



(Figure E)

Step 5: Gently turn the needle forward (clockwise) until it is tight and firmly attached (See Figure F).

- 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.

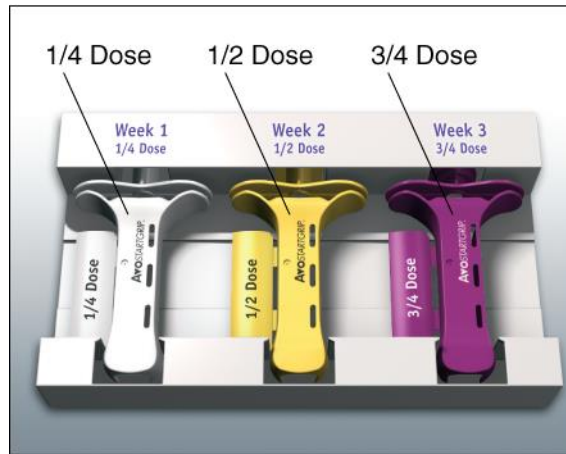


(Figure F)

Using the AVONEX prefilled syringe with the AVOSTARTGRIP titration kit:

- Your AVONEX dose may be titrated over 3 weeks by using AVONEX prefilled syringe with the AVOSTARTGRIP titration kit. The AVOSTARTGRIP is used for giving the week 1, 2, and 3 ($\frac{1}{4}$, $\frac{1}{2}$, $\frac{3}{4}$) injections.
 - **Week 1: $\frac{1}{4}$ dose (white device)**
 - **Week 2: $\frac{1}{2}$ dose (yellow device)**
 - **Week 3: $\frac{3}{4}$ dose (purple device)**
 - **Week 4: a full dose**
- The 3 AVOSTARTGRIP devices are for single-use only with the AVONEX prefilled syringe. **Do not** re-use the AVONEX prefilled syringe and AVOSTARTGRIP devices.
- You must prepare the AVONEX prefilled syringe and needle before you put it into the AVOSTARTGRIP device. **Follow steps 1 to 5 above to prepare the AVONEX prefilled syringe.**

Identifying the parts of AVOSTARTGRIP titration kit (See Figure G):



(Figure G)

- AVOSTARTGRIP has a “collar” on top of the device that will stop the syringe from injecting a full dose (See Figure H). The “collar” makes sure that you do not get the full dose of AVONEX.



(Figure H)

Attaching the AVOSTARTGRIP device:

Step 6: Choose the right AVOSTARTGRIP titration device for your weekly dose.

- **Week 1 Injection:** Choose the **white** device to give $\frac{1}{4}$ dose (See Figure I).



(Figure I)

- **Week 2 Injection:** Choose the **yellow** device to give $\frac{1}{2}$ dose (See Figure J).



(Figure J)

- **Week 3 Injection:** Choose the **purple** device to give $\frac{3}{4}$ dose (See Figure K).



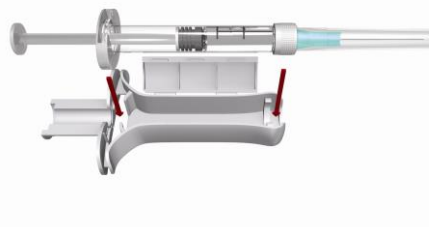
(Figure K)

Step 7: Put the right AVOSTARTGRIP device on a flat surface with the door open (See Figure L).

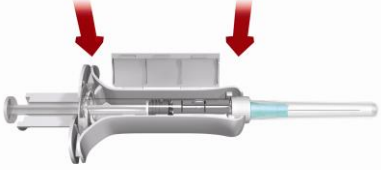



(Figure L)

Step 8: Line up the AVONEX prefilled syringe over the AVOSTARTGRIP device with the plunger pointing to the left and the needle pointing to the right (See Figure M).

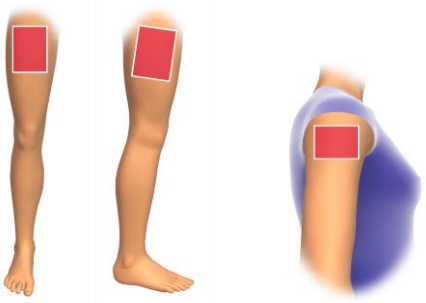
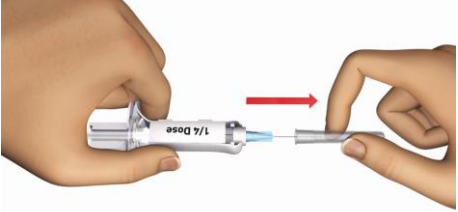





(Figure M)

<p>Step 9: Push the AVONEX prefilled syringe down into the AVOSTARTGRIP device until both ends “snap” into place (See Figure N).</p>	 <p>(Figure N)</p>
<p>Step 10: Using two fingers, push the door down until it closes over the AVONEX prefilled syringe (See Figure O).</p> <ul style="list-style-type: none"> You will hear a “snap” when the door is closed the right way. Do not open door after it is closed. 	 <p>(Figure O)</p>
<p>Step 11: Check to make sure that the AVONEX prefilled syringe is in the AVOSTARTGRIP device the right way and that the door is tightly closed.</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 P and Q).
- 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.

<p>Step 12: Choose an injection site and wipe the skin with an alcohol wipe (See Figures P and Q). 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 P) (Figure Q)</p>
<p>Step 13: Pull the protective cover straight off the needle (See Figure R). Do not twist the cover off.</p>	 <p>(Figure R)</p>
<p>Step 14: 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° angle, through the skin and into the muscle (See Figure S). Once the needle is in, let go of the skin.</p>	 <p>(Figure S)</p>
<p>Step 15: Make sure that you push the plunger all the way down until it touches the collar (See Figure T).</p>	 <p>(Figure T)</p>
<p>Step 16: Pull the needle out of the skin (See Figure U). 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 gauze and apply an adhesive bandage. 	 <p>(Figure U)</p>

After the AVONEX injection:

Do not recap the needle. Recapping the needle can lead to a needle stick injury.

- Throw away the used AVONEX prefilled syringes, AVOSTARTGRIP devices, and needles in a sharps container or some type of hard plastic or metal container with a screw cap such as a detergent bottle or coffee can. Check with your healthcare provider about the right way to throw away the container. There may be local or state laws about how to throw away used AVONEX prefilled syringes, AVOSTARTGRIP devices, and needles. **Do not** throw away used AVONEX prefilled syringes, AVOSTARTGRIP devices, and needles in household trash or recycling bins.
- 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, AVOSTARTGRIP device, and needle for each injection. **Do not** re-use your AVONEX prefilled syringe, AVOSTARTGRIP device, or needles.
- **Do not** share your AVONEX prefilled syringe, AVOSTARTGRIP device, or needles.
- Keep the AVONEX prefilled syringe, AVOSTARTGRIP device, and needles out of the reach of children.
- You can use the table below to keep track of your weekly injections.

Week	Dose	Use Titration Device	Date/Time
Week 1	¼ Dose	White	
Week 2	½ Dose	Yellow	
Week 3	¾ Dose	Purple	
Week 4	Full Dose	None	

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised 09/2016

Manufactured for:

Biogen Inc.

250 Binney Street

Cambridge, MA 02142 USA

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1-800-456-2255

I11073-05