

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

Version: August 2019
Manufacturer: EMD Serono, Inc.
Rockland, MA 02730 U.S. Lic. 1773
MS LifeLines: 1-877-447-3243



EMD Serono, Inc. is an
affiliate of Merck KGaA,
Darmstadt, Germany



Instructions For Use



Exclusively for use with



Welcome


This guide contains information on how to use Rebif® Rebidose®, a pre-assembled, single-use autoinjector that administers one dose of Rebif® (interferon beta-1a) for the treatment of relapsing forms of multiple sclerosis.

Please read these instructions carefully before you start using the Rebif® Rebidose® and remember, you must have received the appropriate training before injecting.

If at any time, you have questions or concerns, please contact your health care provider or call MS LifeLines at 1-877-447-3243.

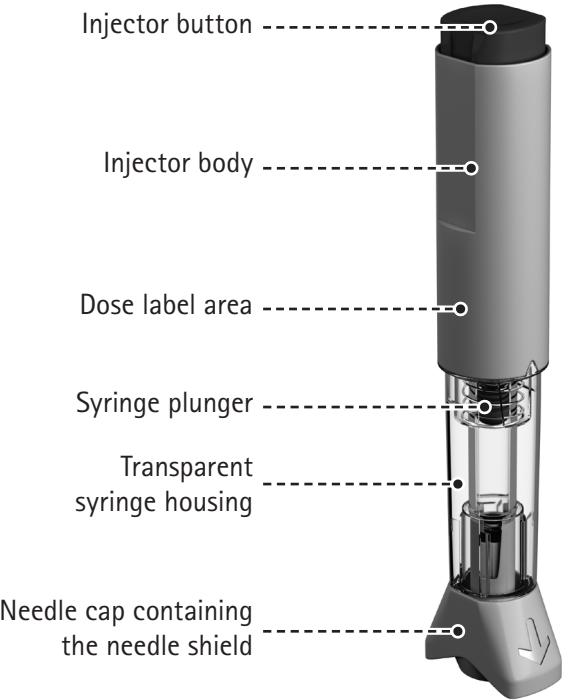
Rx Only

Contents

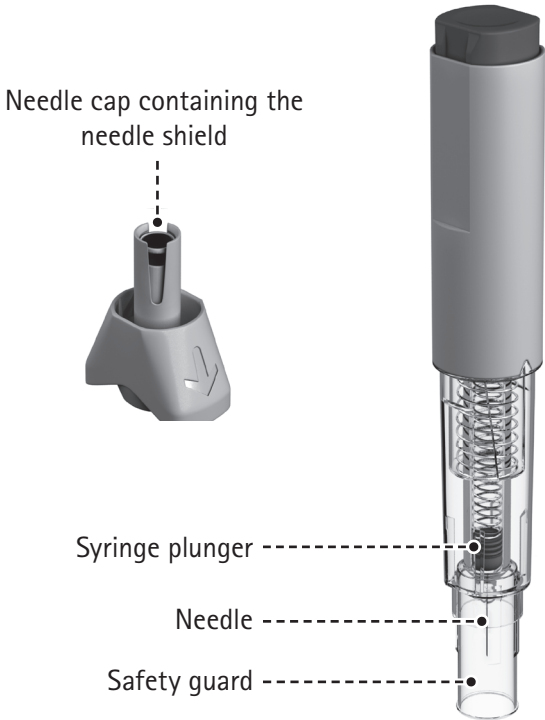
Rebif® Rebidose® features.....	4
 Warnings.....	6
Important Information	8
How Supplied.....	10
Titration.....	12
Choosing an injection site.....	13
Step 1: Prepare for your injection	14
Examine syringe and expiration date.....	15
Step 2: Administer your injection	18
Step 3: Finish your injection	20
Disposal	22
Storage	25
Travel.....	26
Notes.....	27

Rebif® Rebidose® features

Before injection:



After injection:



⚠ Warnings

- Always use the injection technique advised by your health care provider and contact them with any questions you might have.
 - Always keep the Rebidose® autoinjector out of the reach of children.
 - **Do not** share the Rebidose® with anyone. Doing so may result in injury, including the transmission of infectious blood-borne diseases. Adhere to strict safety and antiseptic precautions at all times.
 - **Do not** insert your fingers into the opening of the safety guard.
 - **Do not** try to re-use a Rebidose® single-use autoinjector that has already been used.
 - Adhere to proper disposal procedures to avoid a needle stick injury.
-

⚠ Warnings

- Check the expiration date on the Rebidose® autoinjector label and its carton. If the medication has expired, **Do not** use it.
 - Examine the contents of the syringe carefully through the transparent housing. The liquid should be clear or slightly yellow. Inspect for cracks or breakage in the syringe or other parts. **Do not** use Rebidose® if it is cracked or broken or if the liquid is cloudy, discolored or contains particles.
 - If the Rebidose® has been dropped more than 3 feet, or if it looks damaged for any reason, **Do not** use it. Instead, dispose of it in an acceptable biohazard (sharps) container and use a new Rebidose® autoinjector.
 - Contact your health care provider about any damaged Rebidose® autoinjector.
-

Important Information

- Store your Rebidose® autoinjectors in a refrigerator until ready for use.
- If you or someone around you is injured by the needle, contact your health care provider immediately and dispose of the Rebidose® in an acceptable biohazard (sharps) container.
- Injecting Rebif® the medicine in the Rebidose® autoinjector may cause skin reactions including soreness, redness, pain, bruising, or swelling. Tell your health care provider about any skin reactions that become swollen, painful, or look infected and do not heal within a few days.

- Use a different site each time you inject. **Do not** inject Rebif® where your skin is irritated, reddened, bruised, infected or abnormal in any way.
- The Rebidose® autoinjector contains a glass syringe. In very rare cases, the syringe may break during the injection. If this happens, immediately dispose of any broken glass and the damaged Rebidose® autoinjector in the biohazard (sharps) container, taking necessary precautions to avoid injury. Contact your health care provider or MS LifeLines at 1-877-447-3243 immediately.

How Supplied

Rebidose® is available in 3 dose sizes. Check that the dose of Rebif® is the one prescribed for you by looking at the Rebidose® carton and at the dose label on the Rebidose® autoinjector.

Rebidose® autoinjectors are supplied in these 3 packaging presentations:

- Titration Pack
 - 6 Rebif® 8.8 mcg Rebidose® autoinjectors with a lime green injector button.
 - 6 Rebif® 22 mcg Rebidose® autoinjectors with a yellow injector button.
- 12 Rebif® 22 mcg Rebidose® autoinjectors with a yellow injector button.
- 12 Rebif® 44 mcg Rebidose® autoinjectors with a teal green injector button.



Titration

At the beginning of Rebif® treatment, your health care provider may prescribe a titration phase to gradually increase to the intended dosage.

The Rebif® Titration Pack contains six 8.8 mcg Rebidose® autoinjectors with a lime green injector button and six 22 mcg Rebidose® autoinjectors with a yellow injector button.

The titration period lasts 4 weeks and during this time, you will administer 12 injections:

- **Weeks 1 and 2:** Use one 8.8 mcg autoinjector three times a week, at least 48 hours apart.
- **Weeks 3 and 4:** Use one 22 mcg autoinjector three times a week, at least 48 hours apart.

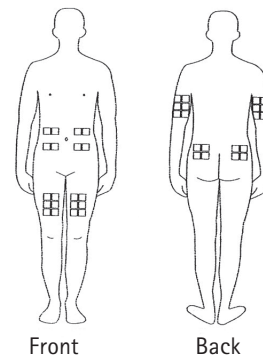
Your health care provider may provide a different dose and schedule.

Choosing an injection site

The best sites for giving a subcutaneous injection are those areas with a layer of fat between the skin and muscle. These include the thigh, the outer surface of the upper arm, the stomach and the buttocks.

Do not use the area near your waistline or within 2 inches of your navel.

Only choose one site for injection. Use a different site each time you inject.



⚠ Caution

Do not inject Rebif® where your skin is irritated, reddened, bruised, infected or abnormal in any way.

Step 1: Prepare for your injection

1.1) Before you begin, you may find injecting more comfortable if you allow time for the Rebif® to warm up to room temperature before injecting. Therefore, it is recommended that you remove the Rebidose® autoinjector from the refrigerator at least 30 minutes prior to use.

Caution

Do not heat or microwave a Rebidose® autoinjector.

1.2) Put all of the items listed below within easy reach on a table or other stable surface:

- 1 Rebidose® autoinjector containing Rebif®
- Alcohol wipes/swabs or cotton balls and rubbing alcohol
- Small adhesive bandage strip (if needed)
- A biohazard (sharps) container (see Disposal section on page 22)

1.3) Wash your hands thoroughly with antibacterial soap.

1.4) Open the tray over a table or soft surface by peeling back the plastic covering and remove 1 Rebidose® autoinjector. **Do not** remove the needle cap until you are ready to inject because the autoinjector could roll off the table and become unsterile.

1.5) Check the expiration date on the Rebidose® autoinjector label and its carton. If the medication has expired, **do not** use it.

1.6) Examine the contents of the syringe carefully through the transparent housing. The liquid should be clear or slightly yellow.

1.7) Inspect for cracks or breakage in the syringe or other parts. **Do not** use Rebidose® if it is cracked or broken or if the liquid is cloudy, discolored or contains particles.

Step 1: Prepare for your injection (continued)

1.8) Use an alcohol wipe to clean the injection site. Let your skin dry to prevent stinging during injection.

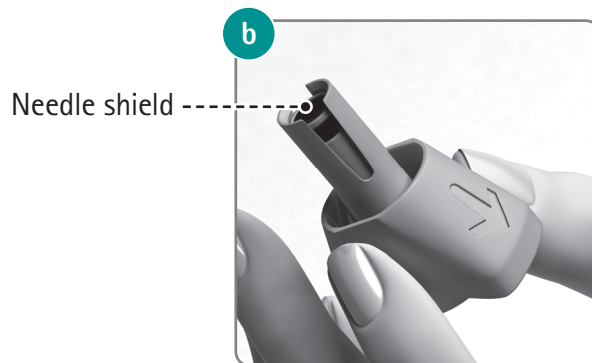
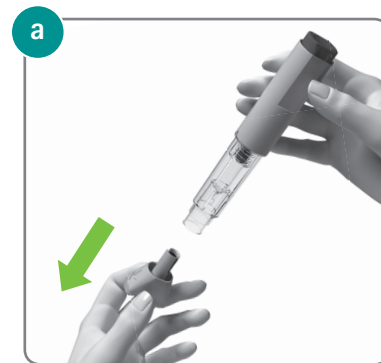
1.9) Hold the Rebidose® by the injector body (fig **a**) and pull off the needle cap.

1.10) Look inside the needle cap to make sure you see a black needle shield inside the cap (fig **b**).

1.11) Dispose of the needle cap and proceed to the injection step without delay.

⚠ Warning

If the Rebidose® has been dropped more than 3 feet, or if it looks damaged for any reason, **do not** use it. Instead, dispose of it in an acceptable biohazard (sharps) container and use a new Rebidose® autoinjector.



Step 2: Administer your injection

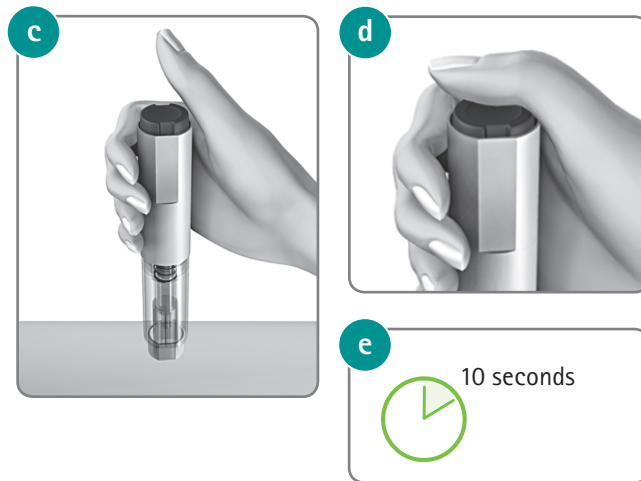
2.1) Hold the Rebidose® autoinjector in your palm with your thumb above the injector button.

2.2) Place the Rebidose® upright with the needle end flat against your skin at a 90° angle. Push the Rebidose® against your skin until you feel resistance; this action unlocks the injector button (fig **c**).

2.3) Keep the Rebidose® pressed firmly against the skin and use your thumb to push the injector button (fig **d**). You will hear a click, which means the injection has begun.

2.4) Keep the Rebidose® pressed firmly against your skin for at least 10 seconds while the medication is dispensed (fig **e**).

If you have any problems, contact MS LifeLines at 1-877-447-3243.



Caution

If the injection does not start, release the injector button and make sure that the Rebidose® is still pressed firmly against your skin. Then push firmly on the injector button, listening for the click that indicates the start of the injection.

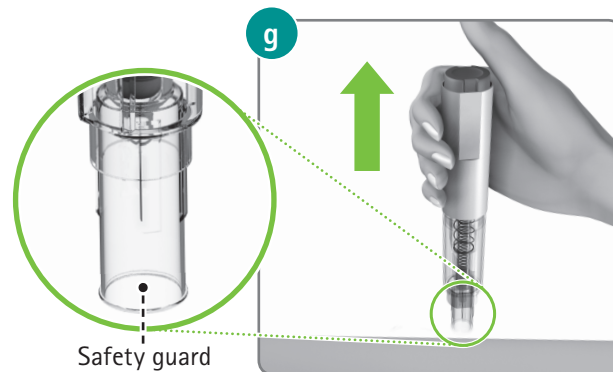
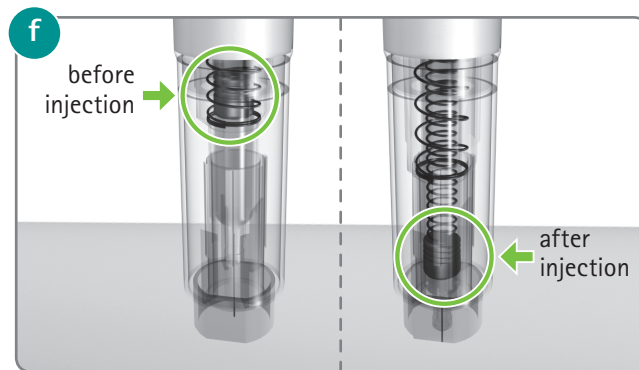
Step 3: Finish your injection

3.1) Before lifting the Rebidose® from your skin, make sure that the syringe plunger has moved to the bottom and that the entire dose has been injected (fig **f**).

3.2) Lift the Rebidose® from the injection site. The safety guard slides down and locks into place to protect you from the needle (fig **g**). If any liquid is left in the syringe or if you have any other problems, contact your health care provider or MS Lifelines at 1-877-447-3243.

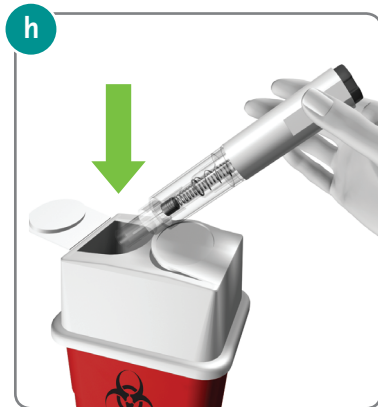
Do not try to put the needle cap on the used Rebidose® autoinjector. It is no longer needed.

3.3) If desired, use a small adhesive bandage to cover the injection site.



Disposal

1) Put your used Rebidose® autoinjectors in a FDA-cleared sharps disposal container right away after use (fig **h**). Do not throw them away (dispose of) in your household trash.



2) 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;

- 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.

3) When your sharps disposal container is almost full, you will need to follow your community guidelines for the correct way to dispose of it. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>

4) 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.

Disposal (continued)

Caution

Always keep the biohazard (sharps) container out of the sight and reach of children.

Warning

- **Do not** insert your fingers into the opening of the safety guard.
 - **Do not** try to re-use a Rebidose® single-use autoinjector that has already been used.
 - Adhere to proper disposal procedures to avoid a needle stick injury.
-

Storage

- Each Rebidose® autoinjector contains a single dose of Rebif®.
- Store Rebidose® autoinjectors in the refrigerator between 36°F and 46°F (2°C to 8°C). **Do not freeze**. If a refrigerator is not available, Rebidose® may be stored between 36°F and 77°F (2°C to 25°C) for up to 30 days away from heat and light.
- **Do not** put them in or near the freezer compartment. **Do not** inject Rebif® that you know or suspect has been frozen.
- Keep the Rebidose® in its packaging and only open one when you need it. Refer to the Rebif® drug package insert and medication guide for specific storage guidelines.

Travel

- When you travel, take 3 Rebidose® autoinjectors with you for each week of your trip. Take some extra in case you are away for longer than expected.
- Remember to pack an empty biohazard (sharps) container for proper disposal.
- When traveling by air, always carry Rebidose® autoinjectors in your hand luggage because the aircraft luggage compartment can be very cold and the Rebif® could freeze.
- It is safe to pass Rebidose® autoinjectors through x-ray machines, but you may need a note from your health care provider to allow you to carry them aboard an airplane.
- Prior to traveling, always check with your airline and your health care provider about bringing injectable medication with you.

Notes

You may find it helpful to record information about your 3 weekly injections (Inj.) to discuss with your health care provider.

Week 1	Inj. Site	Date& Time	Site Reaction	
Inj. 1			Yes	No
Inj. 2			Yes	No
Inj. 3			Yes	No
Week 2	Inj. Site	Date& Time	Site Reaction	
Inj. 1			Yes	No
Inj. 2			Yes	No
Inj. 3			Yes	No
Week 3	Inj. Site	Date& Time	Site Reaction	
Inj. 1			Yes	No
Inj. 2			Yes	No
Inj. 3			Yes	No
Week 4	Inj. Site	Date& Time	Site Reaction	
Inj. 1			Yes	No
Inj. 2			Yes	No
Inj. 3			Yes	No