

RebiSmart[®]

Instructions for Use

Model: 3.0

RebiSmart[®] autoinjector delivers a pre-set dose of Rebif[®].



EMD
SERONO

Contents

1	Introduction to RebiSmart®	6
	Section 1.1 About the device	8
	Section 1.2 Indications and contraindications.....	9
	Section 1.3 Safety precautions	10
	Section 1.4 Device and supplies	12
2	Getting started	20
	Section 2.1 Charging the device.....	22
	Section 2.2 Enter device settings.....	24
	Section 2.3 Inserting cartridge.....	27

3 Injecting medication with RebiSmart®.....30

Section 3.1 Prepare for injection..... 32

Section 3.2 Attach needle 36

Section 3.3 Administer the injection..... 38

Section 3.4 Detach needle and confirm injection 40

4 Caring for the device.....42

Section 4.1 Storing device and cartridges..... 44

Section 4.2 Taking care of your device 45

Section 4.3 Changing cartridge 46

Section 4.4 Replacing device..... 50

Section 4.5 Travel with device 51

5

Settings.....52

Section 5.1 Menu overview..... 54

Section 5.2 History 55

Section 5.3 Injection settings..... 57

Section 5.4 Device settings..... 62

Section 5.5 Battery status..... 68

6

Troubleshooting.....70

Section 6.1 Interrupted injection 72

Section 6.2 Dropped device..... 74

Section 6.3 Warning and information messages 76

Section 6.4 Frequently asked questions 84

7 Additional information for doctors or nurses.....94

Section 7.1 Complete first time setup wizard 96

Section 7.2 Clinical setup..... 100

8 Technical specifications and appendix.....104

Section 8.1 Technical data 106

Section 8.2 Explanation of symbols..... 108

Section 8.3 Electromagnetic specifications 111

Section 1

Introduction to RebiSmart®



This section introduces you to RebiSmart® and provides important safety information about using RebiSmart® to deliver Rebif® medication.

1.1 About the device	8
1.2 Indications and contraindications	9
1.3 Safety precautions	10
1.4 Device and supplies	12

Section 1.1 About the device

RebiSmart® is an electromechanical autoinjector which delivers a pre-set dose of Rebif® (interferon beta-1a for injection).

- RebiSmart® keeps track of your injections. You can review up to 12 months of injections in the History screen (from the current month and previous 11 months).
- 48 hours are recommended between injections. To prevent from injecting too often, RebiSmart® warns you if a new injection is attempted **less than 48 hours after the previous one**.
- RebiSmart® contains no harmful or toxic materials.

- RebiSmart® will not store or transfer any personal information.
- If you have any questions, talk to your doctor or nurse.
- By turning on the "Data transfer" feature in RebiSmart®, you can view your injection history on a mobile application accessible by you, if it is available in your country.

Data means device injection data and technical log. It does not contain any personal identifiable information. It is anonymous.



Section 1.2 Indications and contraindications

Indications for use:

RebiSmart® is a reusable, electromechanical software-controlled autoinjector intended for subcutaneous (under the skin) injection of Rebif® medication.

RebiSmart® is indicated for use by patients treated with interferon beta-1a (Rebif®). The patient population is comprised predominantly of adults (18+ years) but also adolescents (12-17 years). Intended users of the product also include the patient's caregivers, nurse, doctor and medical support staff.

RebiSmart® facilitates the administration of Rebif®, including self-administration by patients at home. In addition, RebiSmart® supports adherence management by recording the dose history and providing adjustable comfort settings.

Contraindications for use:

You should not use RebiSmart® if you have severe dexterity, visual, upper extremity or cognitive neurological deficits.

Your doctor or nurse will advise if you need support from a caregiver for your injections.

For contraindications related to Rebif® medication, please read the Rebif® Patient Information Leaflet.

Section 1.3 Safety precautions

This section provides general precautions related to using RebiSmart®. Additional warnings and cautions related to specific instructions are highlighted throughout this booklet. If you have any questions after reading this section, do not hesitate to ask your doctor or nurse.



Before you proceed, review these general warning and cautions.

- Carefully read all instructions in this booklet before using RebiSmart® and follow these Instructions for Use while using RebiSmart®. These Instructions for Use provide important safety information about RebiSmart®.
- **DO NOT** discard these Instructions for Use. Keep this booklet in a safe place for future reference.
- You must be trained by a qualified doctor or nurse before using RebiSmart®. If you have not received training, please contact your doctor or nurse.
- RebiSmart® is a personal device for use by only one patient. **DO NOT** share RebiSmart® with anyone else. To avoid risks of injury, including the transmission of infectious bloodborne diseases.



General warning and cautions (continued)

- **DO NOT** change the injection settings on RebiSmart® until you have discussed it with your doctor or nurse.
- Take care not to drop RebiSmart®. RebiSmart® should be handled with care.
- **DO NOT** use RebiSmart® if it is not working properly.
- **DO NOT** attempt to modify, or repair the device, or an incorrect dose might be delivered. Contact your doctor or nurse in case of device malfunction.
- **DO NOT** insert any foreign object into the needle cavity.
- Use Rebif® in accordance with the Patient Information Leaflet.
- **DO NOT** load non-Rebif® cartridges into RebiSmart®. Only use original Rebif® cartridges.
- **DO NOT** use a cartridge if the label is missing or damaged.
- To avoid administration of non-sterile medication:
DO NOT use a Rebif® cartridge if it shows any signs of damage,
DO NOT reuse a cartridge rejected by RebiSmart®
- To avoid risks of injury caused by a broken cartridge, **DO NOT** try to remove broken glass from your RebiSmart®.
- **DO NOT** touch or use the battery charger if it shows signs of damage or is broken.
- Make sure the charging cable does not cause a hazard of tripping or other injury.
- **DO NOT** allow children to play with the charging cable.
- **Report any serious incidents involving your RebiSmart® to the RebiSmart® local representative and your national competent authority for medical devices.**



Section 1.4 Device and supplies

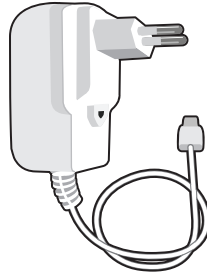
Items provided in device packaging:



1 RebiSmart® autoinjector



1 Battery



1 Battery charger*



1 Storage box



Instructions for Use**

i NOTE: Contact your doctor or nurse for information on the supply of medication cartridges and needles, or if you need replacements for RebiSmart® or any supplies.

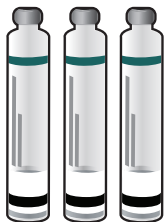
* Number of plug adapters may vary (included for different regions)

** Number of Instructions for Use booklets may vary (included for different languages).

A distributor list is part of device packaging.



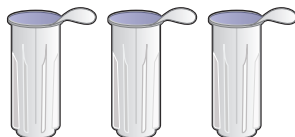
Other supplies needed:



RebiF[®] cartridges



Alcohol wipes



Serofine[®] needles
(29G)



Biohazard (sharps)
container

Not all cartridges, needles, or supplies are approved or available for use in all countries.

The following pages include details about each of the main components:

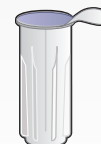
- RebiSmart[®] autoinjector delivers RebiF[®] medication



- RebiF[®] cartridge containing RebiF[®] medication



- Serofine[®] needle (29G) for every injection

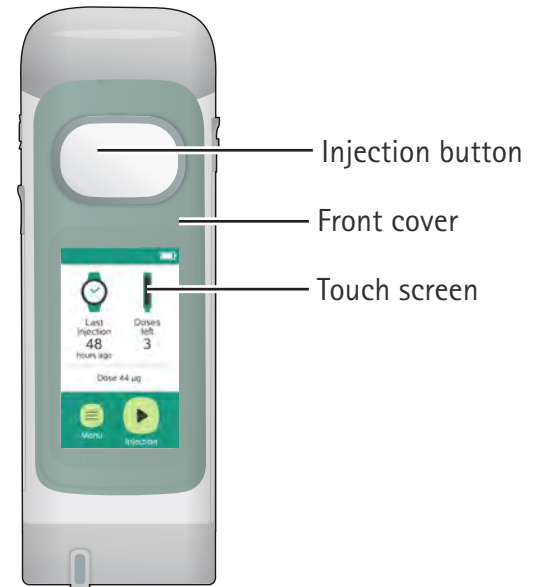


Section 1.4 Device and supplies (continued)

RebiSmart® autoinjector

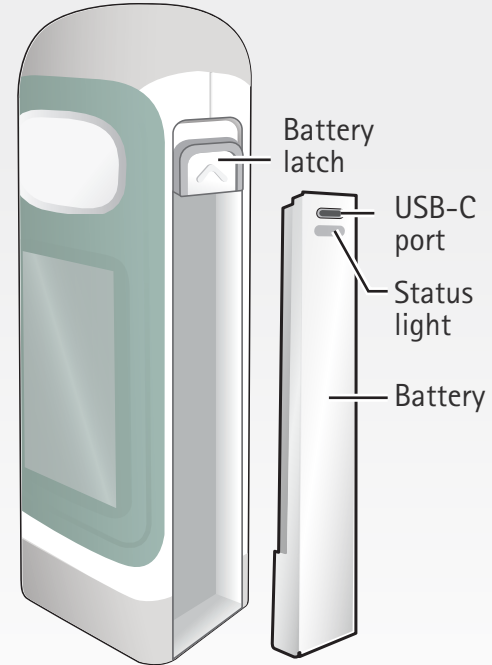
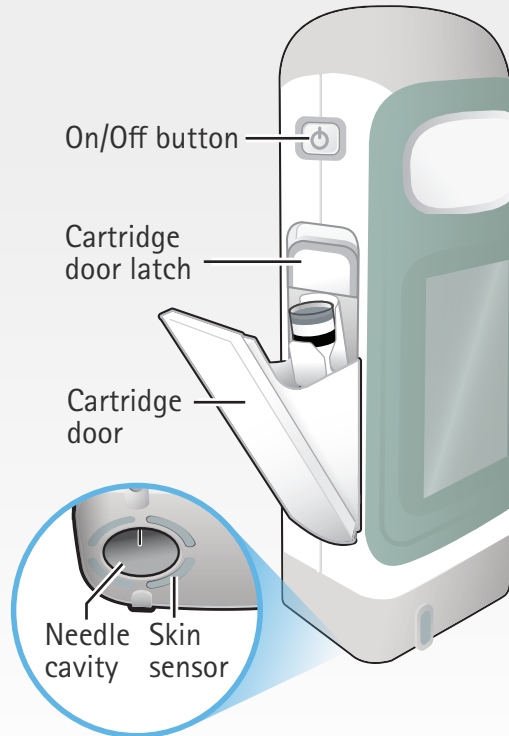
RebiSmart® is an electromechanical device that automatically injects the set dose of medication through single-use needles it inserts and retracts on each injection.

- The skin sensors around the needle cavity detect if the device is positioned correctly onto your skin.
- You can remove the battery to charge it or charge the battery while it is in RebiSmart®.
- Store RebiSmart® in the storage box to keep it clean and avoid contamination from food and dust.





Side views



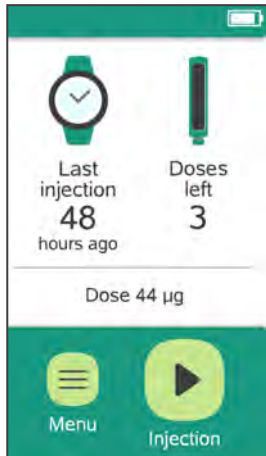
Section 1.4 Device and supplies (continued)

Touch screen

The touch screen provides current information, settings, and instructions on how to administer an injection. You can press buttons, or swipe up and down on lists to navigate the screens and make selections.

You can change the colours of the screen (the screen colours in this booklet might be different then the colours you have chosen).

Buttons on the home screen:



Menu button: provides access to the Injection settings, Clinical setup, Device settings, and History (overview of previous injections) menus



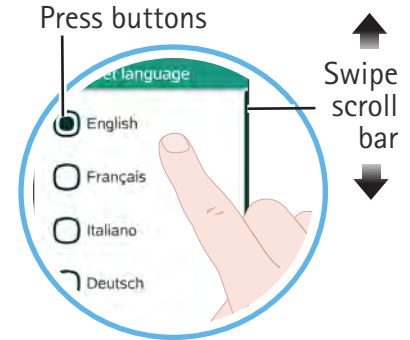
On-screen injection button: begins the guided injection process



Last injection: shows how many hours ago you administered the previous injection



Doses left: shows how many doses are left in the Rebif® cartridge





Rebif[®] cartridges

There are two Rebif[®] cartridge types compatible with RebiSmart[®]:

- 132 µg (microgram, mcg), i.e., 3 doses of 44 µg (concentration: 44 µg/0.5 mL)
- 66 µg, i.e., 3 doses of 22 µg (concentration: 22 µg/0.5 mL)

Carefully check the Rebif[®] medication packaging and cartridge label to ensure that you have the correct medication and cartridge type.

Rebif[®] cartridges have a **28-day expiration** after first use. Discard the cartridge if **28 days have passed since the first injection**.

Detailed medication information and the administration of Rebif[®] is provided in the Rebif[®] Patient Information Leaflet.



132 µg (44 µg/0.5 mL)



66 µg (22 µg/0.5 mL)



WARNING: Make sure to use the correct Rebif[®] cartridge with your RebiSmart[®]. Using the wrong cartridge can cause serious harm.



NOTE: DO NOT remove cartridge label. Otherwise RebiSmart[®] will reject the cartridge.

Section 1.4 Device and supplies (continued)

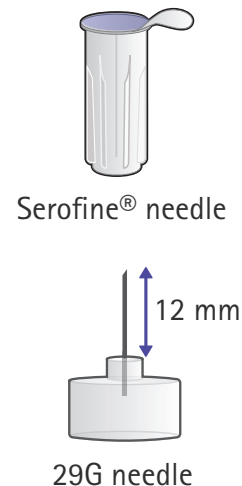
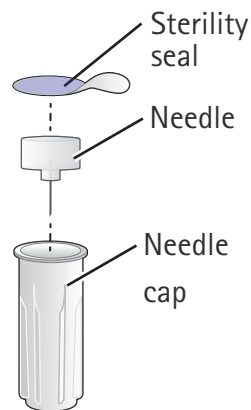
Serofine® needles

There is one Serofine® needle type compatible with RebiSmart®:

- **29G × 1/2"**
(thickness: 0.33 mm × length: 12 mm)

Carefully check the size (or gauge "G") on the needle carton and the sterility seal of each individual needle to ensure if you have the correct needle, prescribed by your doctor or nurse.

Dispose of used needles safely in a biohazard (sharps) container after each injection.



WARNING

- **DO NOT** re-use needles to avoid risks of infection.
- RebiSmart® must be used with **Serofine® single-use, disposable, sterile** needles only.
- Keep needles away from children 3 years old and younger to avoid risks of needle stick injury of third party.



Discard supplies and device

Use a sharps container to dispose of used needles after each injection and to dispose of used cartridges.

Dispose of needles in the sharps container if the expiration date has passed.

Refer to Rebi® Patient Information Leaflet for cartridge disposal. Dispose of cartridges in the sharps container if:

- it is cracked
- the expiration date has passed
- the medication is discolored or contains particles.

When your sharps container is full, dispose of it in accordance with your local community guidelines. If you are not sure about the local disposal guidelines, ask your doctor or nurse.

If you no longer use RebiSmart®, dispose of it in accordance with your local regulation. Contact your doctor or nurse for more information.



⚠ WARNING: DO NOT insert your hands into the biohazard (sharps) container for any reason to avoid needle stick injury.

Section 2

Getting started

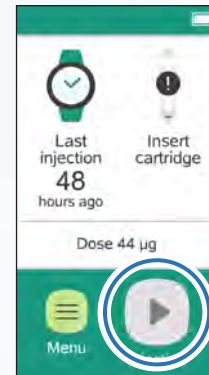


This section provides instructions for setting up the device before administering a first injection.

2.1 Charging the device	22
2.2 Enter device settings	24
2.3 Inserting cartridge	27

Reminders and tips for getting started with RebiSmart®

- You must receive appropriate training from your doctor or nurse before changing any settings and before using RebiSmart®.
- Some device settings can only be changed by a doctor or nurse. If device set up is not complete, the  on-screen injection button will remain disabled. To complete setting up the device for injecting, contact your doctor or nurse.



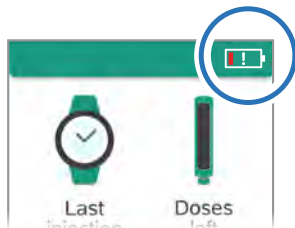
Injection
button
disabled

Section 2.1 Charging the device

Confirm the battery is fully charged before using the device for the first time. If the battery is not charged, use the battery charger supplied with the device. You cannot inject medication when the battery is charging.

Fully charging the battery will take about **2.5 hours**. A fully-charged battery can power the device for **about 30 days**.

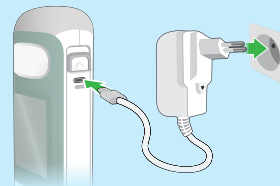
The battery level of the device is displayed at the top of the home screen.



⚠ WARNING: To prevent electric shock, **DO NOT** touch or use the battery charger if it shows signs of damage or is broken.

i NOTE: There are two ways to charge the battery:

Charge the battery while it is in the device.



OR

Remove the battery to charge it. Slide and hold the battery latch up, then slide the battery down to remove.

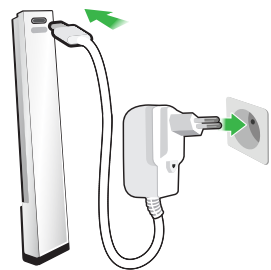


In the latter case, store the device with Rebif® medication according to the Rebif® Patient Information Leaflet.

The socket-outlet must be easily accessible.

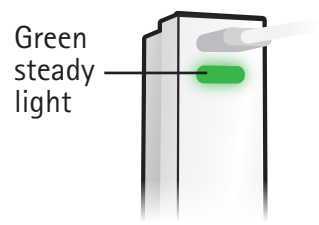


1 Connect battery to power source



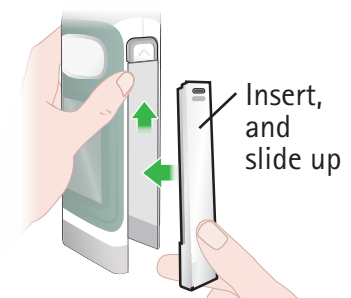
- Plug the battery charger's USB-C plug into the battery port.
- Plug the battery charger into a wall outlet.
- When the status lights flash green, battery is charging.

2 Confirm battery is fully charged



- Check the status light. If light is steady green, battery is fully charged.
- When battery is fully charged, unplug USB cable from battery and power source.

3 Insert battery into device



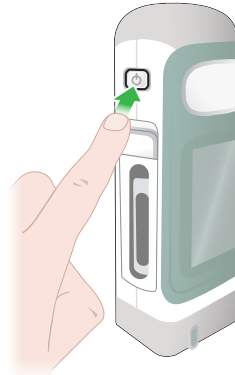
Insert and slide battery back up until it clicks in place.

Now that the battery is charged, you can continue with *"Section 2.2 Enter device settings"*

Section 2.2 Enter device settings

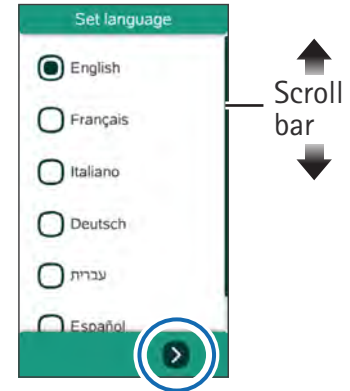
RebiSmart® contains device and injection settings that will need to be set up before you can use the device. These settings can be changed later on as well.

1 Turn on device



Press and hold on/off button until the display switches on. After a few seconds the "Set language" screen appears. Press  to continue.

2 Set language



- Swipe up or down and press checkbox to select language you prefer.
- Press  arrow to continue.

3 Set date and time format



- Press checkbox to select the date and time format you prefer.
- Press  arrow to continue.

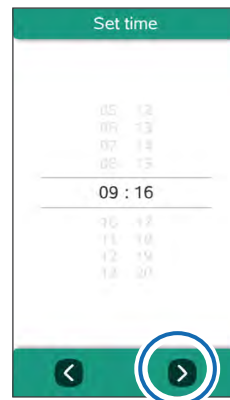
4 Set date



Scroll
bar

- Swipe down or up across screen to go the right month and select current date.
- Press  arrow to continue.

5 Set time



- Swipe down or up to select current time
- Press  to continue.



Section 2.2 Enter device settings (continued)

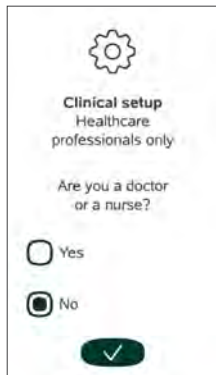
6 Your doctor or nurse must enter clinical settings



Your doctor or nurse must enter the clinical settings that control your dosing and treatment delivery. The  on-screen injection button will remain disabled until the set-up is completed.

If your doctor or nurse is not with you to do it, press "No" when the screen asks, "Are you a doctor or a nurse?"

If you are a doctor or nurse, see *"Section 7.1 Complete first time setup wizard"* for details on entering clinical settings.



 **WARNING: DO NOT** enter clinical settings yourself. Your doctor or nurse must always do this.

 **NOTE:** The PIN code for your RebiSmart® clinical settings is provided to doctors or nurses separately from this Instructions for Use. Clinical settings should only be changed by a doctor or nurse. If the PIN code is lost or forgotten, your doctor or nurse can get another PIN code from the local RebiSmart® representative (refer to the distributor list provided with the device).

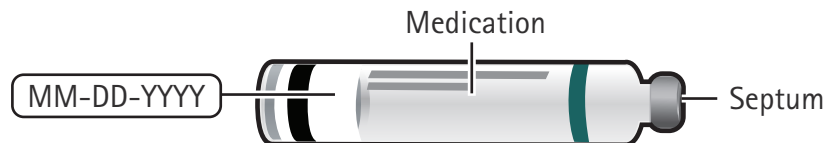
Section 2.3 Inserting cartridge

Before injecting medication (as instructed in Section 3), you must first insert a new Rebif® cartridge. When handling the cartridge, handle with care.

i NOTE

- You can only use the Rebif® cartridges you have been prescribed.
- **DO NOT** remove cartridge label. Otherwise RebiSmart® will reject the cartridge.

1 Get a new cartridge and inspect



Check that the:

- Packaging and cartridge label have the medication and dosage of Rebif® (132 or 66 µg).
- Cartridge's expiration date has not passed.
- Cartridge is not cracked.
- Cartridge and medication correspond to the description in the Rebif® Patient Information Leaflet (PIL).

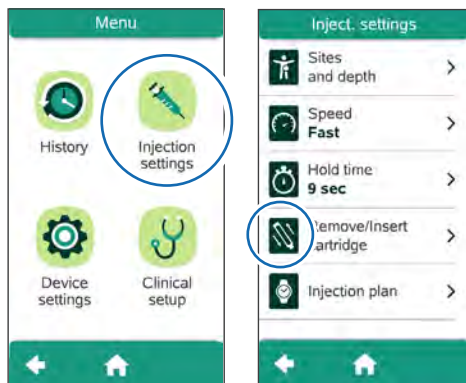
⚠ WARNING

- **DO NOT** use cartridge if it is cracked, if expiration date has passed, or if medication is not clear, contains particles or is not the correct one. Refer to Rebif® PIL for detailed information.
- **DO NOT** touch the cartridge's septum to avoid risks of injection site reactions.



Section 2.3 Inserting cartridge (continued)

2 Unlock cartridge door

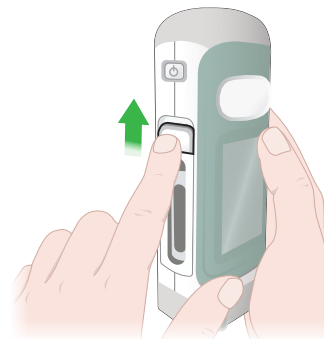


To unlock the cartridge door:

- Open  menu.
- Select  injection settings.
- Select  remove cartridge.

i NOTE: A screen might appear during first use prompting you to insert a cartridge. **DO NOT** force open the cartridge door, this might damage the cartridge door.

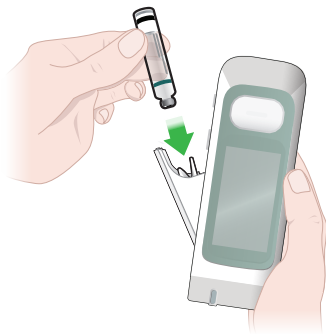
3 Open cartridge door



Slide cartridge door latch up to open door.

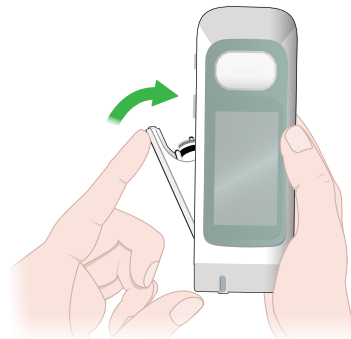
i NOTE: If device contains a cartridge that is not empty, you will need to unlock the cartridge door on the touchscreen first, then replace the cartridge. See "Section 4.3 Changing cartridge".

4 Insert cartridge



Insert cartridge into cartridge holder with metal tip pointing down.

5 Close cartridge door



Push cartridge door to close it.

i NOTE: RebiSmart® may take up to 20 seconds to recognize the cartridge and go back into the menu.



Section 3

Injecting medication with RebiSmart®



This section is a step-by-step guide for injecting medication with RebiSmart®.

3.1 Prepare for injection	32
3.2 Attach needle	36
3.3 Administer the injection	38
3.4 Detach needle and confirm injection	40

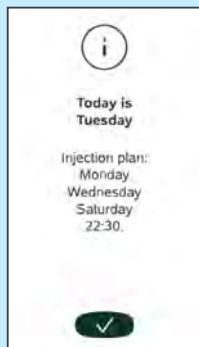
Reminders and tips for injecting with RebiSmart®

CAUTION

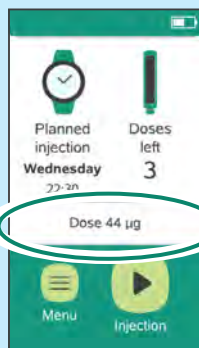
- DO NOT use RebiSmart® if it is not working properly.
 - DO NOT attempt to modify, or repair the device, or an incorrect dose might be delivered. Contact your doctor or nurse in case of device malfunction.
 - DO NOT put the device or medication into the microwave to warm it up.
 - Adolescents must be supervised by a caregiver.
-
- If RebiSmart® is stored in the refrigerator, it might be very cold, you may want to take out the device from the storage box and put it on a stable surface. Wait at least **30 minutes** to let the device and the medication warm up to room temperature.
 - If condensation appears on RebiSmart®, wipe it off with a clean cloth.
 - There is no need to pinch skin at injection site.
 - RebiSmart® will let you know if you try to inject too soon. You can also check the History menu to ensure you are taking your Rebif® injections about 48 hours apart.

Section 3.1 Prepare for injection

NOTE



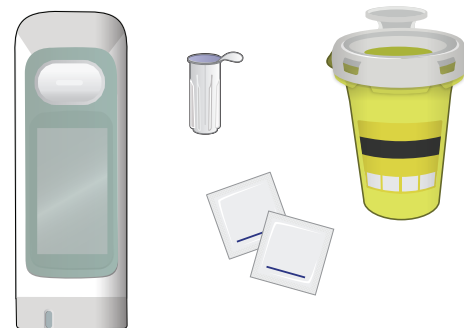
If an injection plan is set up, a notice appears to tell you if it is the right time to inject (RebiSmart® will not provide a sound or LED reminder).



Depending on which dose mode is active, RebiSmart® will present:

- "Dose" for the standard dose.
- "Dose reduction" when dose reduction mode is ON.
- "Titration" when titration mode is ON.

1 Gather supplies



Place all items listed below on a stable surface (e.g., a table) within easy reach:

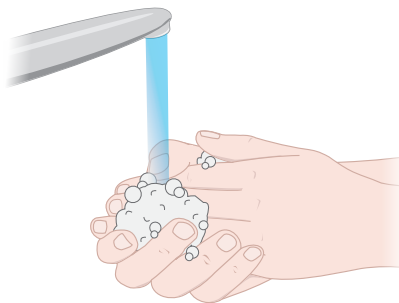
- RebiSmart® containing a cartridge (132 or 66 µg)
- Serofine® needle (29G)
- Alcohol wipes
- Sharps container

2 Check device



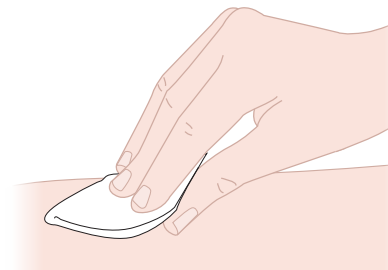
Before each injection, check the device. Make sure the cartridge and medication correspond to the Rebif® Patient Information Leaflet (PIL), and there are no signs of damage.

3 Wash hands



Wash your hands well with soap and water and dry them with a clean towel.

4 Prepare injection site

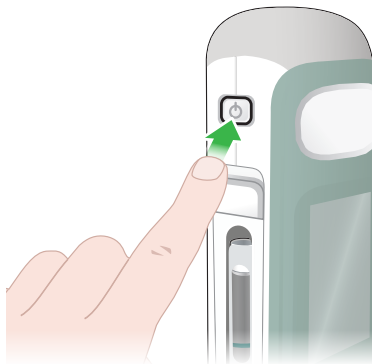


Select and prepare your injection site. Injection site should be based on the Rebif® PIL and discussed with you doctor or nurse.



Section 3.1 Prepare for injection (continued)

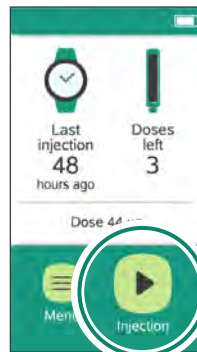
5 Turn on device



Press and hold on/off button until the display switches on.

After a few seconds the home screen will appear.

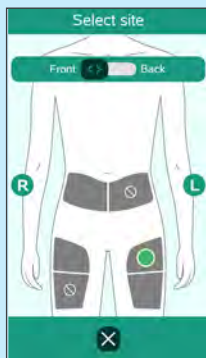
6 Press injection



Press  on-screen injection button to start the injection process. RebiSmart® will guide you step-by-step to administer an injection.

i NOTE: If you have set up the rotation guide feature, RebiSmart® will display the possible injection sites for your injection after pressing  on-screen injection button (refer to *Section 5.3 Injection settings* to set up the rotation guide).

Select an injection site:



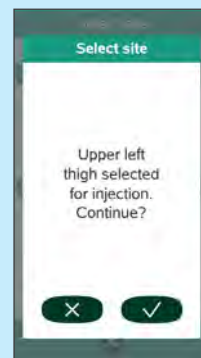
 Green circle means you can select that injection site.

 'Do not' circle means do not select that injection site because it was used recently.



Select an injection site and it will highlight and add a dot.

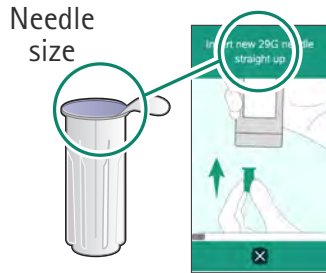
You can press  to view the Front or Back.



Press  to confirm your choice.

Section 3.2 Attach needle

1 Get a new needle



- Get a new Serofine® needle.
- Check that needle size (gauge "G") on the needle cap's sterility seal is the same as the needle size on RebiSmart® screen (29G).
- Check that the needle's expiration date has not passed.

2 Remove seal

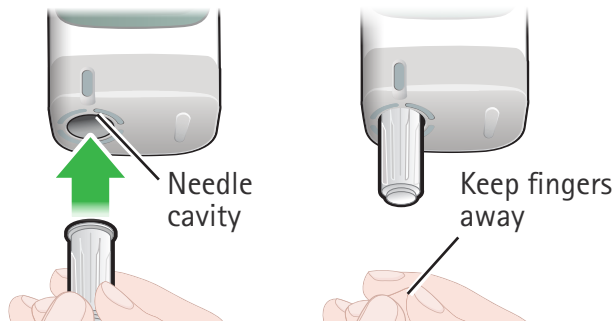


Pull flap and fully remove sterility seal.

WARNING

- Handle needles carefully to avoid injury.
- To avoid risks of injury or infection, **DO NOT** use needle if sterility seal is damaged or detached, the needle is expired or the needle gauge is wrong.

3 Insert needle, let go

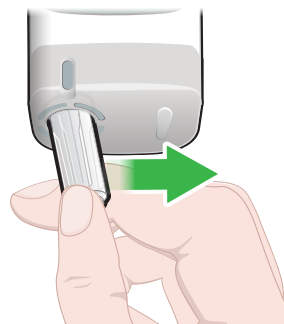


When RebiSmart® screen tells you "Insert new needle":

- Push needle cap with needle straight into the needle cavity until it clicks.
- Let go of the cap while the needle attaches.

⚠ WARNING: NEVER insert fingers into the needle cavity to avoid needle stick injury.

4 Remove cap



When RebiSmart® screen tells to, push the needle cap sideways to remove it.

DO NOT inspect the needle cavity when the device is ready for injection.

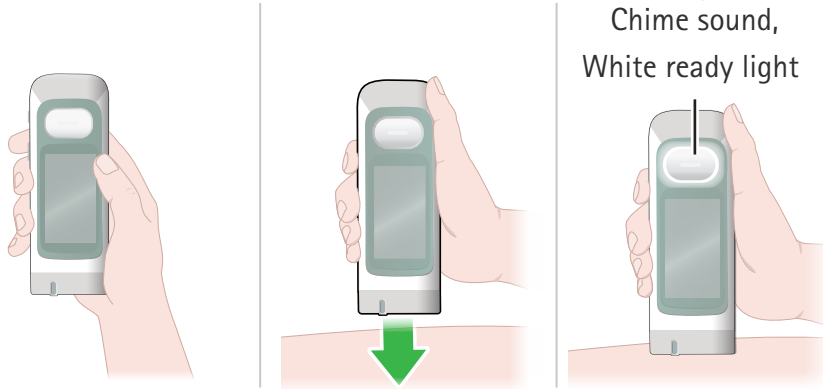
⚠ WARNING

- **DO NOT** pull needle cap straight down. This might damage RebiSmart®.
- Save the needle cap to safely remove and dispose the needle after injecting.



Section 3.3 Administer the injection

1 Hold device against skin



Your doctor or nurse will show you how to inject:

- Hold RebiSmart® as straight as possible firmly against injection site, so the skin sensor fully touches your skin (there is no need to pinch the skin at the injection site).
- When RebiSmart® is in correct position and ready to inject, RebiSmart® plays a chime sound and the injection button light will turn white.

i NOTE: If you **DO NOT** inject right away RebiSmart® will give you instructions to:

- After 60 seconds – continue or cancel injection
- After 10 minutes – insert an empty needle cap to unload the expired needle. A new needle will have to be used to continue with the injection.
- After 30 minutes – the device will shut down and the cartridge will be rejected. When turned on, the device will ask you to replace the needle and cartridge.