

BETACONNECT™ autoinjector

Instructions For Use

Language: English

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Important Information about your BETACONNECT autoinjector:

- Only use prepared BETASERON® (interferon beta-1b) syringes for your injection with the BETACONNECT autoinjector. See the Instructions for Use for BETASERON for how to prepare and measure your dose of BETASERON.
- If this is your first BETASERON injection, it should be given under the supervision of a healthcare provider.
- Before you use the BETACONNECT autoinjector for the first time, make sure you get help with appropriate training on its use from a healthcare provider.

Read these instructions before you use the BETACONNECT autoinjector for the first time. Keep these instructions in a safe place.



Warning!

Whenever you see this symbol it means that safety instructions must be followed.

If you have questions about your BETACONNECT, call BETAPLUS at 1-800-788-1467 to talk with a BETA Nurse.

- **Do not** use the BETACONNECT if:
 - The prefilled syringe cannot be inserted or removed from the BETACONNECT autoinjector according to the instructions.
 - The syringe was not completely emptied during the last time you tried to use BETACONNECT. (If the injection has been stopped, the syringe will not be completely emptied.)
 - Unexpected events happen, or the BETACONNECT does not operate as described in these Instructions for Use.
- Keep BETACONNECT away from heat or fire. Keep it out of direct sunlight.
- Keep BETACONNECT and its accessories, including cables, out of the sight and reach of children. Playing with the cables can lead to strangulation.
- **Do not** use BETACONNECT if, during normal use or during recharging, it does not work as expected or if it appears to be damaged. If this happens, call BETAPLUS at 1-800-788-1467 and speak with a BETA Nurse.
- **Do not** use BETACONNECT in areas with high oxygen levels, such as when supplemental oxygen is in use.
- BETACONNECT is not watertight. Keep it dry. Do not place it in liquid.
- Use your BETACONNECT only with the 30-gauge needles and syringes that come with your BETASERON. Different syringes may not fit or could cause problems with how the BETACONNECT works.
- Remember that the syringes are made of glass and can break if dropped or hit too hard.
- Only inject into bare skin. **Do not** inject through your clothes.
- To avoid risk of infection, **do not** share your BETACONNECT with another person.
- **Do not** point your BETACONNECT at another person or at yourself except when you are ready to inject.
- Seeing or hearing impaired patients should use BETACONNECT only with the help of a caregiver who is trained to use it.
- Use the built-in reminder only as a backup to your main method of tracking injections. Be aware of when a reminder will not happen, such as when injections are interrupted. You still must take BETASERON on schedule, every other day, and follow the instructions from your healthcare provider even if you use the built-in reminder.
- BETACONNECT is an electronic device. Handle it with care.
- **Do not** change or modify this equipment. **Do not** try to open or repair BETACONNECT. The batteries are not replaceable.
- **Do not** wash BETACONNECT in a dishwasher and do not submerge your BETACONNECT in liquid.
- The safety release is located at the tip of BETACONNECT. It is important to keep the safety release clean to make sure your BETACONNECT works the right way. Use a dry or slightly damp cloth or an alcohol wipe.
- If BETACONNECT is exposed to extreme vibration, pressure, or shock (such as being dropped or stepped on), it may be damaged. Check to see that it is working normally.
- BETACONNECT contains rechargeable batteries. Use only the charger and cables that came with BETACONNECT. Other cables may create problems or interfere with other electronic devices.

- Do not use BETACONNECT close to or stacked with other electrical equipment.
- Portable radio frequency (RF) communications equipment, including antennas, can affect medical electrical equipment. Always keep a minimum distance of 12 inches (30 cm) to RF equipment such as mobile phones, and WiFi transceivers when using BETACONNECT. If your BETACONNECT is connected to a computer USB port or is plugged in for charging, it cannot be used for injection. Charge the BETACONNECT at a temperature between 50°F to 95°F (10°C to 35°C).

Chapter 1: Getting to Know Your BETACONNECT autoinjector

1.1. Getting started

The shipment box contains the following items:

- BETACONNECT autoinjector
- Storage case
- Charger
- Micro USB cable (3 feet (1 meter))
- Quick Start Guide
- BETACONNECT autoinjector Instructions for Use (IFU)

Your BETASERON will arrive in a separate shipment from your pharmacy.

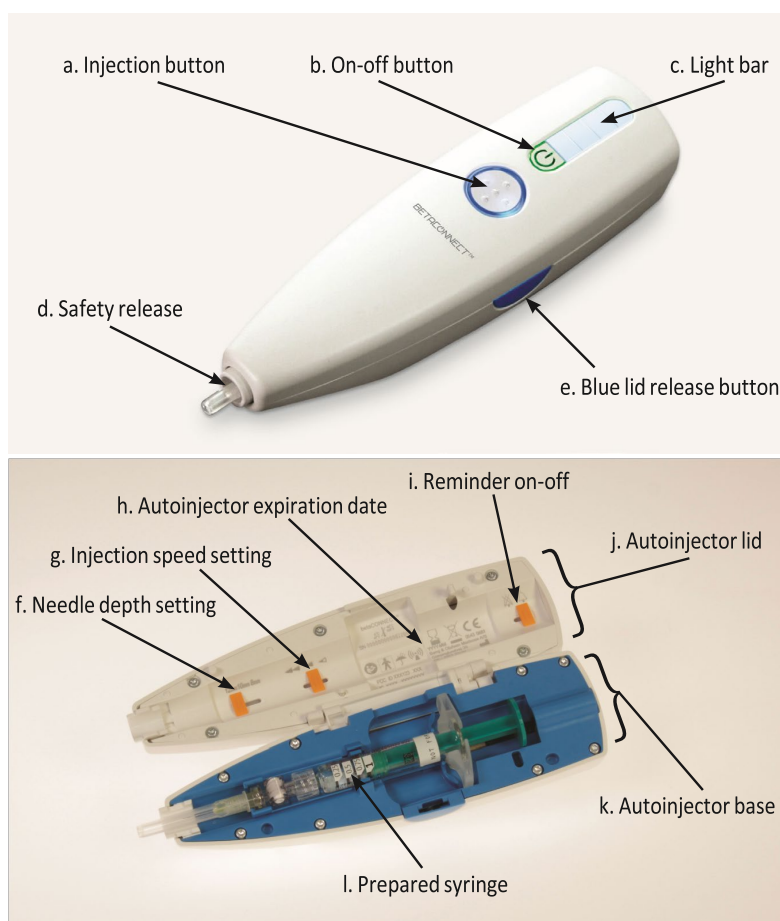
Supplies needed for your BETACONNECT Injection

- BETACONNECT autoinjector
- prepared BETASERON dose in syringe with attached capped needle (See Instructions for Use for BETASERON)
- alcohol prep pad
- puncture resistant sharps container for throwing away used needles and syringes. (See “**Disposing of used needles and syringes**” at the end of these Instructions for Use)

Important: Before you use your BETACONNECT for the first time, you need to charge it fully. Plug the small end of the micro USB cable into your BETACONNECT and the large end into the charger. Plug the charger into a power outlet, and let it charge for about 2 hours. When you see four green bars on the light bar, BETACONNECT is fully charged. If your BETACONNECT is connected to a computer USB port or is plugged in for charging, it cannot be used for injection.

1.2. Features of your BETACONNECT autoinjector

If this is your first BETASERON injection, it should be given under the supervision of a healthcare provider. Use your BETACONNECT to help you take your BETASERON as prescribed. Remember to change your injection sites each time you inject the medicine as shown in the BETASERON Medication Guide. You will need to prepare your required dose with the parts that come with your BETASERON, and place the syringe with your dose in the BETACONNECT autoinjector as shown in the instructions.



- a. Injection button:** A steady blue light indicates that BETA CONNECT is ready to be used for an injection. The injection button flashes blue when the safety release is activated. Press and release the injection button to start the injection. There is no need to keep the button pressed during the injection process.
- b. On-off button:** Use the on-off button to turn BETA CONNECT on and off.
 - If the green light does not stop blinking, it indicates the self-test is not complete.
 - The flashing orange light indicates the battery level is too low to perform an injection.
 - The solid orange light indicates the temperature is too high or too low during charging.
- c. Light bar:** Is an indicator for various functions of the device.
 - Blue light bars show the progress of your injection because the injection procedure does not make a noise.
 - Blue light bar (single) indicates the injection is complete and the needle is withdrawn.
 - Blue light (top of light bar) flashing serves as a reminder that it is time for your injection.
 - Green light bars show level of battery charge.
 - Green light (single bar) flashing indicates there is enough power for one injection but must be recharged after.
 - Red light (top of light bar) flashing indicates an interrupted injection or device malfunction. See Chapter 5 "Troubleshooting".
- d. Safety release:** When you are ready to inject, activate the safety release by gently holding BETA CONNECT against the skin at a 90° angle (straight up and down) and maintain pressure without moving either the BETA CONNECT or yourself. It is important to keep the safety release clean for your BETA CONNECT to work the right way.
- e. Blue lid release button:** Use to open the lid.
- f. Needle depth setting:** BETA CONNECT allows you to adjust needle insertion depths to 12, 10, or 8 mm. (Before making any adjustments, read section 4.1, "Adjusting the injection depth," and talk with your BETA Nurse or healthcare provider.)
- g. Injection speed setting:** BETA CONNECT allows you to set your injection speed at slow, medium, or fast. (Before you make any changes to the speed, read section 4.2, "Adjusting the injection speed.")
- h. Autoinjector expiration date:** BETA CONNECT comes with an expiration date, to show that the device should not be used after the end of the year (YYYY), month (MM), and day (DD), printed as YYYY-MM-DD.

- i. **Reminder on-off switch:** As a back up to your regular method of tracking injections, use the built-in reminder if you want your BETACONNECT to let you know that it has been 48 hours (2 days) since your last injection. When it is time for your next injection, you should hear a beep and see a flashing light. If you do not want to use the reminder, you can turn it off. See section 4.3, "Setting the injection reminder." Make sure you follow the injection schedule given to you by your healthcare provider.
- j. **Autoinjector lid:** Covers the syringe and base of the auto-injector. You can open the lid by pressing the blue lid release button.
- k. **Autoinjector base:** The base is the part of the autoinjector that holds the prepared BETASERON syringe
- l. **Prepared syringe:** Use only the syringes that come with your BETASERON kit. Remember to refer to the BETASERON® (interferon beta-1b) Medication Guide for instructions on how to prepare your dose and fill the syringe. When you insert a prepared syringe, make sure that it is lined up with the syringe outline in the insertion area.

Signals: The BETACONNECT autoinjector:

- Lets you know when it needs recharging by the on-off button flashing orange. To save battery power, it will automatically power down if not in use for 20 minutes.
- Reminds you when it is time for your next injection with a beep and a blue flashing light at the top of the light bar. (If you do not want to use the reminder, you can turn it off using the toggle switch inside the cover.)

1.3. Only use the syringe and 30-gauge needle that come with your BETASERON



BETACONNECT is designed to inject between 0.25 and 1 mL of reconstituted BETASERON, using the syringe and the 30-gauge needle as part of the Mixject vial adapter that come with your medicine. Prepare your syringe as shown in the BETASERON Instructions for Use and Medication Guide. Call BETAPLUS at 1-800-788-1467 if you need help preparing your injection or have any questions.



Chapter 2: Caring for Your BETACONNECT autoinjector

2.1. Charging your BETACONNECT autoinjector

Important: BETACONNECT must be fully charged before first-time use.

Charge the BETACONNECT at a temperature between 50°F to 95°F (10°C to 35°C). If your BETACONNECT is connected to a computer USB port or is plugged in for charging, it cannot be used for injection.

To charge the BETACONNECT autoinjector, plug the provided micro USB cable into the charger and into your BETACONNECT. Plug the charger into a power outlet, and let it charge for about 2 hours.

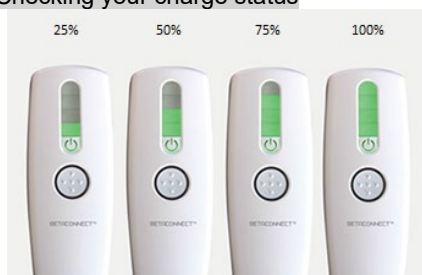
Step 1: Connect the supplied micro-USB cable and charger.



- A full charge will help make sure that BETACONNECT is ready when you are. However, it is recommended to charge your BETACONNECT only when it indicates "Battery Low" (25%).
- When fully charged, the battery capacity should last for at least 15 injections in normal use.

Recommendation: Do not turn on the BETACONNECT until you are ready for your injection. This will save battery power.

Step 2: Checking your charge status



- Charging is complete when **all 4 green bars** of the light bar are solid.
- When you disconnect BETACONNECT from the charger or power source BETACONNECT will turn off.

2.2. Cleaning your BETACONNECT autoinjector

- Always store BETACONNECT with the lid closed and in its plastic storage case to help protect it from dust, dirt, extreme temperatures, or direct sunlight.
- It is important to keep the safety release clean for your BETACONNECT to work the right way. Use a dry or slightly damp cloth or an alcohol wipe.
- If medicine is spilled inside BETACONNECT, remove it right away using a damp cloth, as the liquid could cause damage to the BETACONNECT.
- Other parts of BETACONNECT do not normally need to be cleaned. If needed, lightly dampen a cloth with water and wipe the device.
- Never place BETACONNECT in any liquid. **Do not** try to clean it in a dishwasher.

Chapter 3: Injecting With Your BETACONNECT autoinjector

Important: Before you use your BETACONNECT for the first time, you need to charge it fully; 4 green bars in the light bar mean your BETACONNECT is fully charged.

3.1. Preparing your BETACONNECT autoinjector

Step 1: Turn your BETACONNECT on



Before turning BETACONNECT on, make sure BETACONNECT is within operating temperature. If stored below 41°F (5°C), wait at least 4 hours before turning BETACONNECT on.

Remove the fully charged BETACONNECT from its plastic storage case. Press the on-off button:

- A short beep will tell you that BETACONNECT is turned on. Wait for the power-on self-test to finish (it takes only a few seconds). When BETACONNECT is ready, the injection button will glow blue and the green light bar will show your charge status.
- If after the BETACONNECT is turned on the on-off button does not stop blinking or the light bar blinks red, see Chapter 5, "Troubleshooting."

Step 2: Check your charge



Check the charge status on the light bar:

- 4 green solid bars indicate that the battery is fully charged.
- If only 1 green bar is flashing, there is enough power to give one complete injection, but the BETACONNECT must be recharged afterwards, before the next injection.
- A flashing orange on-off button means that the battery level is too low to perform an injection. BETACONNECT will shut off, and you will need to charge it before you can inject.



Step 3: Open the lid



Press the blue lid release button on the side of the BETACONNECT, and fully open the lid.

Important: Remember to refer to the BETASERON (interferon beta-1b) Instructions for Use and Medication Guide for instructions on how to prepare your dose in the syringe.

Step 4: Insert the syringe into your BETACONNECT



When you have prepared a dose in the provided syringe, leave the needle cap on. Gently fit the syringe into the molded syringe outline in the BETACONNECT autoinjector base until it snaps into place.

- The syringe must be lined up with the syringe outline to fit correctly.
- The lid will not close if the syringe is not seated properly.
- Check that your depth and speed settings are correct for your best injection conditions. (For depth and speed setting see Chapter 4, "Making Adjustments.")

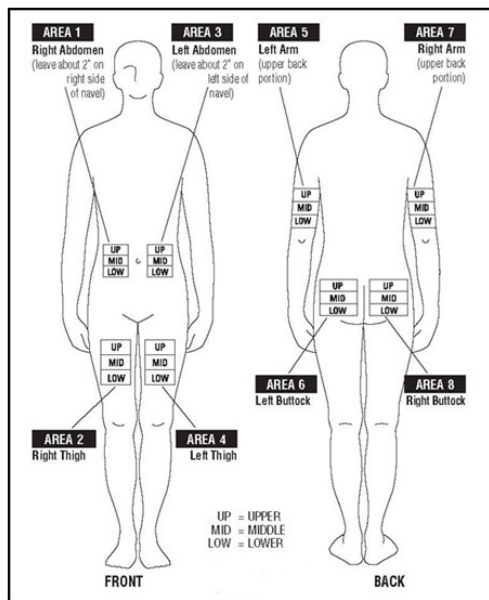
Step 5: Close the lid and check the injection button



Close the lid. You will hear a click when it shuts.

- When the injection button shows a steady blue light this means that BETACONNECT is now ready to be used for an injection.
- The lid must be fully closed to administer an injection.

3.2. Injection steps



- BETASERON is injected under the skin and into the fat layer between the skin and the muscles (subcutaneous tissue).
- The best areas for injection are where the skin is loose and soft and away from the joints, nerves, and bones such as the stomach (abdomen), upper arm, thigh or buttock.
- **Do not** use the area near your navel or waistline. If you are very thin, use only the thigh or outer surface of the arm for injection.
- Choose a different site each time you give yourself an injection. **Do not** inject in the same area for 2 injections in a row.
- **Do not** inject BETASERON in a site where the skin is red, bruised, infected, or scabbed, has broken open, or has lumps, bumps, or pain.
- Tell your healthcare provider if you find skin conditions like the ones mentioned here or any other unusual -looking areas where you have been given injections.

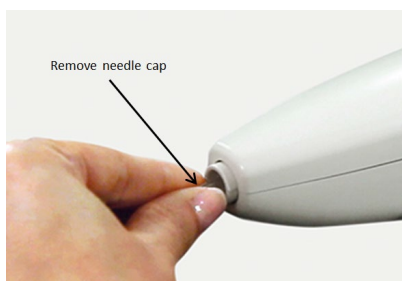
The BETACONNECT cannot work the right way if an injection is attempted in areas that are hardened. Hardened areas change the force needed for injection and the medicine may not be able to spread.

Step 1: Clean the injection site



Clean the injection site with an alcohol prep pad using a circular motion. Start at the injection site and move outward. Let the skin area air dry.

Step 2: Remove the needle cap



Remove the needle cap by pulling it off at the front of the BETACONNECT. **Do not** twist the needle cap when removing it, as twisting could loosen the needle connection and cause leaking.

In case the safety release is accidentally activated (temporarily pushed in) during this operation, the battery status light bars will switch off. The BETACONNECT will still work the right way.

Important: Be careful not to accidentally press the injection button while removing the needle cap.

Step 3: Place the BETACONNECT autoinjector against the injection site



Gently hold the BETACONNECT against the skin at a 90° angle (straight up and down) to activate the safety release.

- The injection button flashes blue when the safety release is activated.
- If movement happens, the safety release may deactivate and will need to re-activate. Make sure you hold the BETACONNECT against your skin for the entire injection.

Important: When BETACONNECT is in “ready” or “inject” mode with a syringe inside, take special care not to accidentally press the injection button before you are sure you are ready to start the injection.

Step 4: Start the injection



Press and release the injection button to start the injection.

- There is no need to keep the button pressed during the injection process.
- The light bar will have a blue light indicator.
- Keep pressure on the BETACONNECT device. Moving the device or injection area will deactivate the safety release, causing the BETACONNECT to not start, or interrupt, the injection.

Step 5: Check the injection status



The lit blue bar goes down in stages as the injection progresses.

Do not interrupt the injection.

The injection cycle will be interrupted if you:

- Press the on-off button before the injection is complete.
- Remove or slightly move your BETACONNECT from the injection site before the injection is complete.

Important: If the injection is stopped before your injection is complete, you will see a blinking red light on the top of the light bar.

Check to make sure you received your full dose. If you did not receive your full dose, call your BETA Nurse or healthcare provider. In case of an interrupted injection, the 48-hour reminder function is not activated, even if the reminder function switch is enabled. See Section 4.3.

It is important to make sure that you received your complete dose.



Important: The injection procedure does not make a noise. Use the blue bars of the light bar to check the injection status.

Always hold BETACONNECT straight up and down. Keep it pressed against your injection site for as long as the injection lasts.

Step 6: When the injection is finished



BETACONNECT will sound 2 short beeps and show a blue, flashing bar after the injection is complete and the needle is withdrawn.

Do not remove BETACONNECT from the injection site until the injection is complete.

- BETACONNECT will automatically power down once the injection is complete.

3.3. Removing the used syringe and needle

Step 1: Open the lid



Press the blue lid release button on the side of the BETACONNECT, and fully open the lid.

Step 2: Remove the used syringe



Remove the syringe by gently lifting it straight out of the BETACONNECT.

- Hold the BETACONNECT with your other hand while removing the syringe.
- Check the syringe to be sure the entire dose was delivered. If entire dose was not delivered, call your BETA Nurse or healthcare provider.

Important: Take care to avoid the needle when you remove the empty syringe. It could injure you or others.

Do not put the needle cap back on the syringe.

Always dispose of your empty syringe promptly, using an appropriate sharps container.

Step 3: Disposing of Used Needles and Syringes

Put your used BETASERON syringe and needle in a FDA-cleared sharps disposal container right away after use.

- **Do not throw away (dispose of) your used syringes and needles in your household trash.**
- 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 stable during use
 - leak-resistant
 - 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 dispose of used syringes. For more information about the 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.

Keep the disposal container out of the reach of children.

Chapter 4: Making Setting Adjustments

4.1. Adjusting the injection depth

Important: Talk with your BETA Nurse or healthcare provider before you change your injection settings.

Reminder: A replacement BETACONNECT may need to be adjusted to the best settings for you. Depth setting can be used to get the best injection depth for a user and may be different based on the user and injection location.

Step 1: Open the lid fully

Press the blue lid release button to open the lid.



You can set injection depths of 12, 10, or 8 mm by moving the injection depth slider.

When you receive BETACONNECT, it is set to the injection depth of 12 mm. Ask your healthcare provider if you should use a different depth before changing.

Step 2: Set the depth slider to the desired setting



To adjust the injection depth:

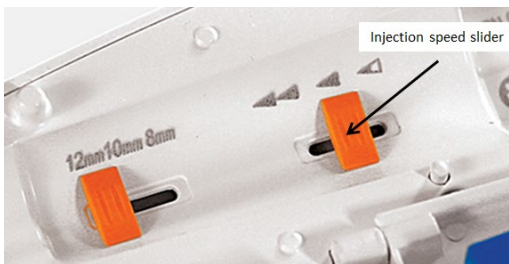
- 12 mm: Move the slider to the 12-mm setting.
- 10 mm: Move the slider to the 10-mm setting.
- 8 mm: Move the slider to the 8-mm setting.

4.2. Adjusting the injection speed

Important: Talk with your BETA Nurse or healthcare provider before you change your injection settings.

Setting the injection speed allows you to adjust and select the best medicine delivery speed for you.

Step 1: Open the lid fully



Press the blue lid release button to open the lid.

The setting allows for a slow, medium, or fast injection.

When you receive BETACONNECT, it is set to the medium injection speed. Ask your healthcare provider if you should use a different injection setting before changing.

Step 2: Set the injection speed slider to the desired setting



To adjust the injection speed:

- Fast: Move slider to ◀◀ symbol.
- Medium: Move slider to ◀ symbol.
- Slow: Move slider to ▶ symbol.

4.3. Setting the injection reminder for back up use only

Step 1: Open the lid fully



Press the blue lid release button to open the lid.

The BETACONNECT will alert you when 48 hours (2 days) have passed since your last fully completed injection. The reminder automatically resets after each fully completed injection.

When it is time for your next injection, you should hear a beep and see a blue flashing light. The light will flash for 1 hour, and the beep will sound 1 time every 15 minutes for 1 hour.


The reminder is turned on (enabled) when you receive BETACONNECT. If you do not want to use it, you will need to turn it off using the switch shown at left.


- Use the built-in reminder only as a backup. You still must take BETASERON on schedule, every other day, and follow the instructions from your healthcare provider even if you use the built-in reminder.
- **In case an injection is interrupted, the 48-hour reminder function is not activated. The reminder will not re-activate until after a fully completed injection.**

Step 2: Set the reminder function



To set the reminder:

On, move the slider to 

Off, move the slider to 

Step 3: When the reminder goes off



Your BETACONNECT will begin to beep and the top of the blue light bar will flash to remind you when it is time to inject (as long as previous injection was completely given without being interrupted).



- The flashing light reminder lasts for 1 hour.
- The beep occurs every 15 minutes for 1 hour.
- You can mute the beep and still have the flashing light reminder by pressing the injection button or opening the lid.
- To cancel both the beep and the flashing light reminder, press the on-off button.

Chapter 5: Troubleshooting

If you need assistance setting up, using, or maintaining your BETACONNECT autoinjector, talk with your BETA Nurse or healthcare provider, or call BETAPLUS at 1-800-788-1467 anytime.

Problem	Cause	Solution
Unable to turn the BETACONNECT autoinjector on by pressing the on-off button	1. On-off button was not pressed long enough.	1. Firmly press the on-off button for more than 2 seconds.
	2. Battery is not charged.	2. Recharge the BETACONNECT autoinjector.
	3. Battery or electronic failure.	3. Contact your BETA Nurse for a replacement.
It is past the expiration date on your BETACONNECT autoinjector	4. BETACONNECT has expired.	4. Please contact your BETA nurse / healthcare professional for a replacement.
BETACONNECT autoinjector turns off automatically	1. BETACONNECT autoinjector will automatically turn off after 20 minutes of inactivity.	1. Press the on-off button to turn on.



Problem	Cause	Solution
	2. BETACONNECT autoinjector will power off if the battery level is too low.	2. Recharge your BETACONNECT autoinjector if the battery indicator (on/off button) flashes orange when you turn your device on.
Unable to use the BETACONNECT autoinjector while it is being charged	1. The BETACONNECT autoinjector will not operate while it is being charged.	1. Fully charge the BETACONNECT autoinjector and remove the charger before use.
Unable to use the BETACONNECT autoinjector while it is connected to a USB port	1. The BETACONNECT autoinjector will not operate while it is connected to a USB port.	1. Disconnect the BETACONNECT autoinjector from the USB port.
Unable to open the lid	1. The lid cannot be opened during the injection process.	1. Wait until the injection process is completed.
	2. The lid or the blue lid release button does not function.	2. Turn on BETACONNECT. After BETACONNECT has completed the self-test, open the lid. Please contact your BETA nurse / healthcare professional for a replacement, in case the lid cannot be opened after initiating the self-test.
Unable to inject while the safety release is activated	1. The safety release does not function.	1. Ask your BETA Nurse or healthcare provider for a replacement.
Unable to charge the BETACONNECT autoinjector	1. The wrong micro-USB cable or charger is used.	1. Make sure you only use the charger and cables that come with your BETACONNECT autoinjector.
	2. The micro-USB connection is worn out.	2. Ask your BETA Nurse or healthcare provider for a replacement.
Unable to insert the syringe into the BETACONNECT autoinjector	1. The wrong syringe type is used.	1. Use only the syringes that come with your BETASERON.
	2. The syringe is not placed into the insertion area correctly.	2. Make sure that the syringe is lined up with the syringe outline in the insertion area.
	3. The syringe is not prepared correctly.	3. Refer to the instructions in the BETASERON Medication Guide, and prepare a new syringe if necessary.
	4. The plunger is pulled past the 1 mL mark.	4. Adjust the plunger to the 1 mL mark, or the dose prescribed to you by your healthcare provider.
The green light on the on-off button does not stop blinking after the BETACONNECT	1. The self-test is not completed.	1. Make sure the safety release in the front of the BETACONNECT autoinjector is not pressed.


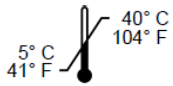








Problem	Cause	Solution
autoinjector was turned on 		2. Open the lid and close the lid. Make sure the lid is fully closed.
		3. Make sure no buttons are pressed down.
		4. Hold the on-off button to shut down BETACONNECT autoinjector, and turn it on again. If the problem is not solved, contact your BETA Nurse or healthcare provider.
A red blinking light is shown at the top of the light bar on BETACONNECT autoinjector  Notice: A red blinking light does not indicate battery failure.	1. The injection procedure was interrupted as designed, due to safety release activation interruption or due to higher than normal force needed for giving the injection.	1. If the injection was interrupted, check to see if the entire dose was injected. If it was not, talk with your BETA Nurse or healthcare provider.
	2. A malfunction was detected during self-test when BETACONNECT was turned on.	2. Hold the on-off button down to shut down BETACONNECT autoinjector and turn it on again. If the red blinking light is still there, talk with your BETA Nurse or healthcare provider.
An orange light (on/off button) is shown on the BETACONNECT autoinjector during charging	1. The temperature is too low or too high for charging.	1. The BETACONNECT can be recharged at a temperature from 50°F to 95°F (10°C to 35°C).
Needle is not retracted.	1. EMC (electromagnetic compatibility) interference or malfunction.	1. Contact your BETA nurse / healthcare professional for a replacement. Be careful not to get injured by the needle.



Chapter 6: Technical Specifications

6.1. Symbols

The following symbols are used on your BETACONNECT autoinjector and its packaging.

	It is important that you read these instructions before you use the BETACONNECT autoinjector.
	The symbol (use-by-date) comes with an expiration date to show that the device should not be used after the end of the year (YYYY), month (MM), and day (DD), printed as YYYY-MM-DD. Ask your BETA Nurse or Healthcare provider for a replacement.

	Keep your BETACONNECT autoinjector dry.
	The BETACONNECT autoinjector can be operated at a temperature from 41°F to 104°F (5°C to 40°C), at a humidity level of 15% to 93% relative humidity, not condensing, and an atmospheric pressure range of 700 hPa to 1,060 hPa (525 mm Hg to 795 mm Hg).
	The BETACONNECT can be stored at a temperature from 14°F to 104°F (-10°C to 40°C) at a humidity level of 20% to 93% relative humidity, not condensing, and an atmospheric pressure range of 700 hPa to 1,060 hPa (525 mm Hg to 795 mm Hg).
	<p>The BETACONNECT autoinjector contains electrical and electronic components, and must not be disposed of using standard garbage collection. Talk to local authorities about regulations on disposal of electrical and electronic equipment.</p> <p>Follow local regulations for disposal of electronic waste. To protect natural resources and to promote material reuse, separate packaging material from other types of waste, and recycle the material through your local recycling system.</p>
	The BETACONNECT autoinjector is a type BF device, and provides protection against electrical shock and electrical current leakage.
	Manufacturer
	The unique serial number of this BETACONNECT autoinjector.
	The BETACONNECT autoinjector complies with the requirements of The Medical Device Directive (MDD 93/42/EEC), the Radio and Telecommunications Terminal Equipment Directive (R&TTE 1999/5/EC), and the RoHS (Restriction of Hazardous Substances) directive (2011/65/EU).
	<p>The BETACONNECT autoinjector radiates nonionizing electromagnetic signals.</p> <p>Bluetooth 4.0 @2.4GHz using a customized encrypted protocol.</p> <p>Bluetooth transmission power less than 1mW.</p>
	This device complies with part 15 of the FCC Rules. Operation is subject to the following 2 conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IC: 3775E-BETAC1	<p>The BETACONNECT autoinjector is IC-authorized under the listed grantee code showing compliance to Canadian regulations regarding unlicensed transmissions.</p> <p>This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following 2 conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.</p>
 R 202-SMB067 T D 13-0036 202	<p>Japanese Radio Law and Japanese Telecommunications Business Law Compliance.</p> <p>This device is granted pursuant to the Japanese Radio Law (電波法) and the Japanese Telecommunications Business Law (電気通信事業法).</p> <p>This device should not be modified (otherwise the granted designation number will become invalid).</p>
 (01) 05713495000015 (10) B00050475 (17) 200501 (21) 17055000009999	<p>The Unique Device Identifier (UDI) that appears on the carton is shown by a barcode and human readable format:</p> <p>(01): Device Identifier (10): Batch Number (17): Expiry date in YYMMDD format (21): Serial number</p>

EMC compliance levels

BETACONNECT has been tested for electromagnetic disturbances according to international standards for a home healthcare environment. The table below list the compliance levels for BETACONNECT.

Electromagnetic compatibility (EMC) Compliance levels	Basic EMC standard
EMC – Radiated RF Emission / Conducted RF Emission: RF emissions CISPR 11 : Group 1 RF emissions CISPR 11 : Class B Radiated Emission: 30 MHz-1 GHz Conducted emission: 150kHz-30MHz	IEC 60601-1-2:2014 CISPR 11:2019+A1:2010
EMC - RF Field radiated immunity – Electrical field: 10 V/m 80 MHz to 2.7 GHz, 1 kHz 80% AM	IEC 60601-1-2: 2014 IEC 61000-4-3
EMC: Conducted Disturbances Immunity, induced by RF fields: Conducted immunity disturbance by RF fields 3 V _{rms} 150 kHz to 80 MHz (6V _{rms} in ISM and amateur radio bands)	IEC 60601-1-2: 2014 IEC 61000-4-6
EMC - Power Frequency Magnetic Field, Immunity: 30 A/m	IEC 60601-1-2: 2014 IEC 61000-4-8
EMC - Fast transients and bursts Immunity: Fast transients and bursts ±2 kV ac mains Surge ±1 kV Line-to-Line ac mains	IEC 60601-1-2: 2014 IEC 61000-4-4 IEC 61000-4-5
EMC – Voltage dips and interruptions: 0% U _T ; 250/300 cycle 0% U _T ; 0,5 cycle, At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U _T ; 1 cycle, 70% U _T ; 25/30 cycles Single phase: at 0°	IEC 60601-1-2: 2014 IEC 61000-4-11

Electromagnetic compatibility (EMC)	Basic EMC standard
Compliance levels	
EMC - RF Field Immunity to Proximity fields from Wireless communication equipment, Immunity at 0,3m separation: a) 27 V/m at 380-390 MHz b) 28 V/m at 430-470 MHz c) 9 V/m at 704-787 MHz d) 28 V/m at 800-960 MHz e) 28 V/m at 1700-1990 MHz f) 28 V/m at 2400-2570 MHz g) 9 V/m at 5100-5800 MHz	IEC 60601-1-2: 2014 IEC 61000-4-3
ESD Immunity: ±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	IEC 60601-1-2: 2014 IEC 61000-4-2

Notice: Essential Performance for this instrument is defined by the manufacturer as:

- This instrument does not have an Essential Performance. Absence or loss of Essential Performance cannot lead to any unacceptable immediate risk.

Expiration (use-by-date) and disclaimer

After the use-by-date, your BETACONNECT autoinjector has to be replaced. Ask your BETA Nurse or healthcare provider for a new BETACONNECT autoinjector. The use-by-date can be located inside the lid indicated by year (YYYY), month (MM), and day (DD), printed as YYYY-MM-DD. **Do not** use your BETACONNECT autoinjector after the expiration date.

The BETACONNECT reminder function is only intended as a supplement to any memory system that you currently use to remind you to take your BETASERON. This does not relieve you from your responsibility to take your BETASERON as directed by the Instructions for Use. The correct application of BETASERON according to the Instructions for Use shall remain your sole responsibility.

BETACONNECT stores information about the time and date of injections, injection speed and volume, needle depth, and information about the use of the device in an internal memory for the total number of injections which are expected within the maximum lifetime of three years.

If you have any questions about BETASERON, contact your BETA Nurse at **1-800-788-1467**, or read the Medication Guide and full Prescribing Information for BETASERON (interferon beta-1b).

Talk with your BETA Nurse or healthcare provider:

- If you have any questions about your BETACONNECT
- If you do not need it anymore and want to dispose of it
- If your BETACONNECT does not work the right way or if unexpected events happen.

Manufactured by:
 Medicom Innovation Partner a/s
 Gimsinglundvej 20
 DK-7600 Struer
 Denmark

Manufactured for:



Bayer HealthCare
 Bayer HealthCare Pharmaceuticals Inc.
 Whippany, NJ 07981

U.S. License 1778

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

5/2024