

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 for use in the BETACONNECT autoinjector.**
- **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 the right way to use it 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 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.
- 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. 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.
- The safety release is located at the tip of BETACONNECT. It is important to keep the safety release clean. 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.
- 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
- Quick Start Guide
- BETACONNECT autoinjector Instructions For Use (IFU)

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

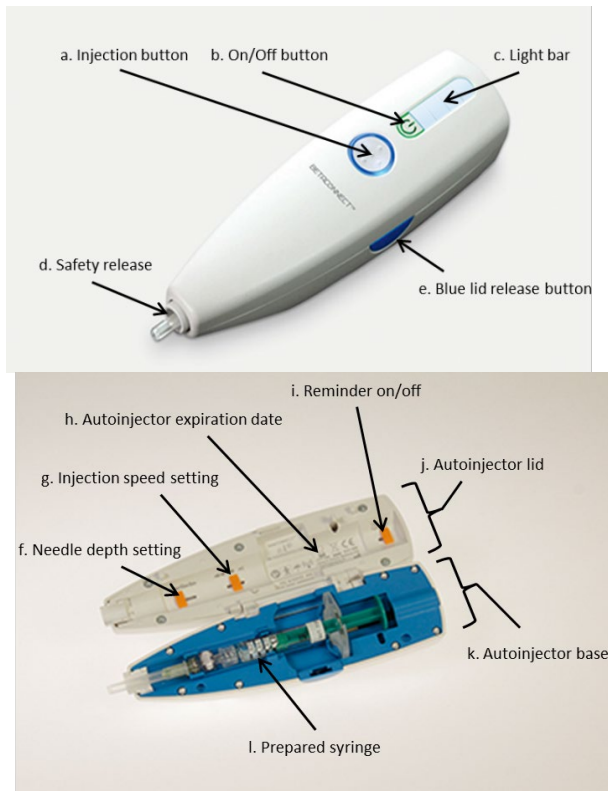
Supplies needed for your BETACONNECT Injection

- BETACONNECT autoinjector
- prepared BETASERON syringe with attached capped needle (See Instructions for Use for BETASERON Prefilled Syringe)
- 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, BETACONNECT is fully charged.

1.2. Features of your BETACONNECT autoinjector

Check with your healthcare provider before using your BETACONNECT for the first time. 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 the syringe that comes with your BETASERON, and place it in the BETACONNECT autoinjector as shown in the instructions.



- a. **Injection button:** Press and release the injection button to start the injection. The injection button flashes blue when the safety is released. There is no need to keep the button pressed during the injection process.
- b. **On/off button:** Use the on/off button to turn BETACONNECT on and off. If the on/off button blinks green continuously, or the light bar blinks red, see chapter 5, "Troubleshooting."
- c. **Light bar:** Because the injection procedure is quiet, the light bar shows the progress of your injection. BETACONNECT will also sound 2 short beeps and show a blue, flashing bar once the injection is complete and the needle is withdrawn.
- d. **Safety release:** When you are ready to inject, activate the safety release by gently holding BETACONNECT against the skin at a 90° angle (straight up and down). It is important to keep the safety release clean.
- e. **Blue lid release button:** Use to open the lid.
- f. **Needle depth setting:** BETACONNECT 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:** BETACONNECT 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:** BETACONNECT 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:** 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:** 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. Remember to refer to the BETASERON® (interferon beta-1b) Medication Guide for instructions on how to prepare your syringe. When you insert a prepared syringe, make sure that it is lined up with the syringe outline in the insertion area.

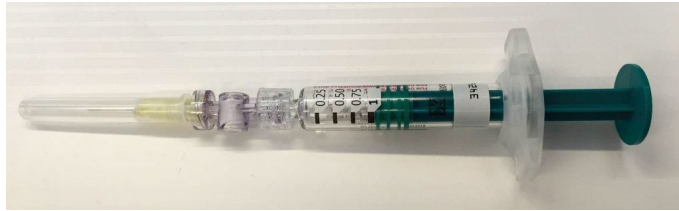
Signals: The BETACONNECT autoinjector:

- Lets you know when it needs recharging. 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 flashing light. (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 that come with your medicine. Prepare your syringe as shown in the BETASERON 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.

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



To charge the BETACONNECT autoinjector, plug the 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.

A full charge will help make sure that BETACONNECT is ready when you are. A full charge should last for between 15 to 20 injections, or for 4 to 5 weeks.

Step 2: Checking your charge status



- Charging is complete when **all 4 green bars** are solid.
- When you disconnect BETACONNECT™ from the charger 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. 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.
- 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 mean your BETACONNECT is fully charged.

3.1 Preparing your BETACONNECT autoinjector

Step 1: Turn your 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 the on/off button blinks green continuously, 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 for an injection, but the BETACONNECT must be recharged afterwards.
- A flashing 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) Medication Guide for instructions on how to prepare your syringe.

Step 4: Insert the syringe into your BETACONNECT



When you have prepared a 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.
- The lid will not close if the syringe is not seated properly.
- Check that your depth and speed settings are correct. (For depth and speed setting see chapter 4, "Making Adjustments.")

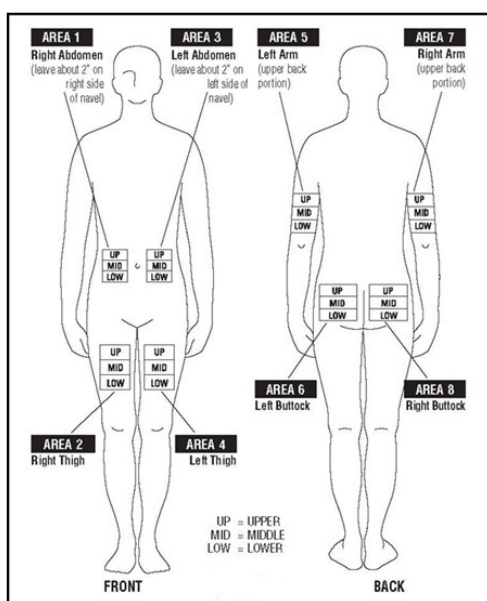
Step 5: Close the lid and check the injection button



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.

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.

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 is released.
- 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.

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.

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 your BETACONNECT from the injection site before the injection is complete.



If the injection is stopped before your injection is complete you will see a blinking red light. Check to make sure you received your full dose. If you did not receive your full dose, call your BETA Nurse or healthcare provider.

Important: The injection procedure is quiet. Use 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 BETACONNECT with your other hand while removing the syringe. Check the syringe to be sure the entire dose was delivered.

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.

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.

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

Step 1: Open the lid all the way



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 injection. The reminder automatically resets after each 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.

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.


- 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.
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.
	2. BETACONNECT autoinjector will power off if the battery level is too low.	2. Recharge your BETACONNECT autoinjector if the battery indicator flashes orange when you turn your device on.




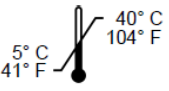


Problem	Cause	Solution	
Unable to use the BETACONNECT autoinjector while it is being charged	1. The BETACONNECT autoinjector will not operate while it is being charged.	1. Fully charge the BETACONNECT autoinjector and remove the charger before use.	
Unable to use the BETACONNECT autoinjector while it 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. Ask your BETA Nurse or healthcare provider for a replacement.	
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 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 autoinjector was turned on		1. The self-test is not completed.	1. Make sure the safety release in the front of the BETACONNECT autoinjector is not pressed.
		2. Open the lid and close the lid. Make sure the lid is fully closed.	2. Open the lid and close the lid. Make sure the lid is fully closed.
		3. Make sure no buttons are pressed down.	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.	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 on the BETACONNECT autoinjector	1. The injection procedure was interrupted.	1. If the injection was interrupted, check to see that the entire dose was injected. If it was not, talk with your BETA Nurse or healthcare provider.	







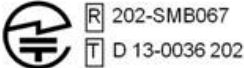
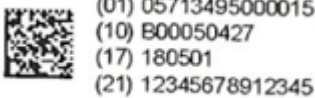
Problem	Cause	Solution
	2. A malfunction was detected.	2. Hold the on/off button down to shut down BETACONNECT autoinjector and turn it on again. If the red blinking light is still there, talk with your BETA Nurse or healthcare provider.
An orange light is shown on the BETACONNECT autoinjector during 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).

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 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).
	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. 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.</p>
	<p>Manufacturer</p>
	<p>The unique serial number of this BETACONNECT autoinjector.</p>
 0543 0681	<p>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>
	<p>The BETACONNECT autoinjector radiates nonionizing electromagnetic signals.</p>
 FCC ID: 2AAGY-BETAC1	<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.</p>
<p>IC: 3775E-BETAC1</p>	<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>
	<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>
	<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>

Expiration and disclaimer

After the expiration date, your BETACONNECT autoinjector has to be replaced. Ask your BETA Nurse or healthcare provider for a new BETACONNECT autoinjector. The expiration 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.

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.

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

9/2022