

BETACONNECT™

Instructions for use

Language: English
Version: 2013-10

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Important notes



Warning!

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

Please read these instructions prior to using BETACONNECT™ for the first time. Please keep these instructions in a safe place.

- Keep these Instructions for Use for future reference.
- The BETACONNECT™ reminder function is only intended as a supplement to any memory system that you currently use to remind yourself to take your Betaseron®. You will maintain full responsibility to administer your medication at the appropriate time and to follow the instructions from your Healthcare Professional.
- Use only syringes provided with your Betaseron® with the BETACONNECT™.
- Caution, the syringes are made of glass and can break if dropped or hit too hard.
- The BETACONNECT™ must never be pointed at another person or yourself except in order to inject Betaseron®.
- The BETACONNECT™ is not intended for use on more than one patient (danger of infection).
- The BETACONNECT™ cannot be sterilized.
- The BETACONNECT™ may not be opened or repaired as **no** modification of this equipment is allowed. The batteries are not replaceable.
- This BETACONNECT™ contains re-chargeable batteries. Do not expose to extreme heat or fire. Avoid storage in direct sunlight.
- The BETACONNECT™ is not recommended for the blind or visually impaired without the assistance of a sighted individual trained to use it.
- Keep the BETACONNECT™ and the accessories (e.g. cables) out of reach of children. The cables can lead to possible strangulation.
- The BETACONNECT™ is an electronic device and must be handled with care.
- Do not use the BETACONNECT™ if, during normal use or during recharging, it does not function in accordance with the instructions or if it seems to be damaged.
- Do not use charger and cables other than those provided with the BETACONNECT™ as this may result in increased emission, decreased immunity and reduced electrical safety of the BETACONNECT™.
- For correct function of BETACONNECT™ you must keep the safety release at the front of the BETACONNECT™ clean using a dry/damp cloth or alcohol wipe.
- Only inject into bare skin do not inject through clothes.
- Do not use the BETACONNECT™ in oxygen rich environment.
- Do not use the BETACONNECT™ if:
 - The prefilled syringe cannot be inserted or removed as described.
 - The syringe was not completely emptied during the last attempt to use the BETACONNECT™. Note if the injection has been interrupted, the syringe will not be completely emptied.
 - If unexpected events occur or BETACONNECT™ does not operate as described in this instruction for use.

Chapter 1: First Time Use

1.1. First time use of BETACONNECT™

The folder box contains the following items:

- BETACONNECT™
- Packaging to store your BETACONNECT™
- Charger to charge your BETACONNECT™
- USB cable
- Quick guide
- Instruction for use.

Remove your BETACONNECT™ from its package.

Important: Fully charge the BETACONNECT™ (by plugging the micro USB cable and charger into a power outlet) for approximately 2 hours before using it for the first time. Four green bars indicate the BETACONNECT™ is fully charged.

1.2. Operator Profile and Applied parts

BETACONNECT™ is designed to be used by MS patients (tested with MS patients from 18 years onwards), who have been found capable by MS nurses / health care professionals to operate and perform injections using BETACONNECT™. These patients should be able to perform the reconstitution and preparation of the disposable (user filled) syringe to the proper dose prescribed by their healthcare provider.

Applied parts (parts that come in contact to the skin) are the Safety release, Housing and the Buttons.

1.3. Intended Use

The re-usable electronic autoinjector is intended to help the user by automating subcutaneous injection using a user filled disposable syringe (provided in the Betaseron® package). The BETACONNECT™ is intended for use by an individual as a portable device (normally used at home).

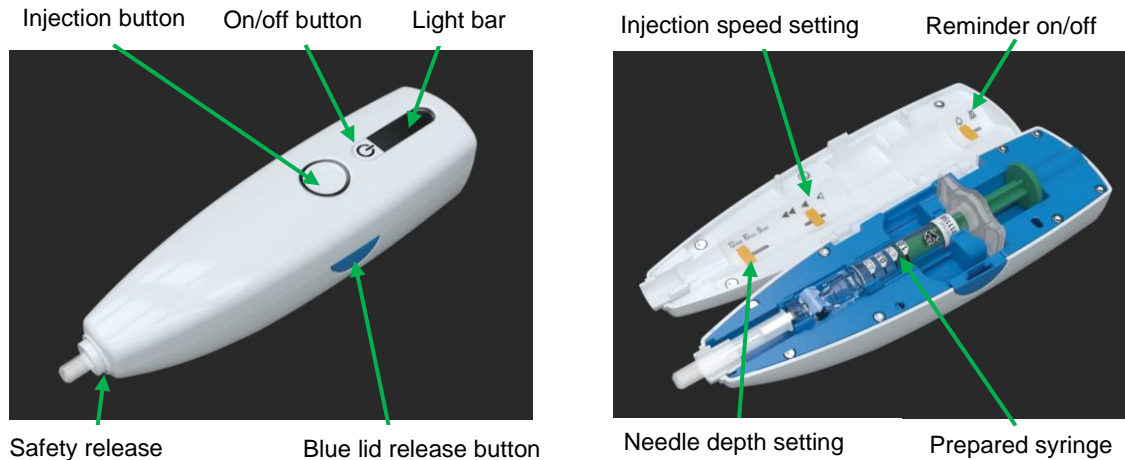
- Application by patient (user) or caregiver.
- Injection sites: abdomen, thigh, buttocks, upper arm (see also the Betaseron® patient information leaflet).
- Short time in contact with skin at injection site every other day.

The BETACONNECT™ is an application aid that allows patients to inject their medication subcutaneously using a user filled disposable syringe.

The BETACONNECT™ provides a visual and acoustic reminder function (notification 48 h after last injection). The visual and acoustic reminder function can be disabled.

Chapter 2: Things you should know about the BETACONNECT™

2.1. Overview



BETACONNECT™ allows needle insertion depths of 8, 10 and 12 mm. Before making any adjustments, please read section "Adjusting the insertion depth".

BETACONNECT™ allows injection speed setting of slow, medium and fast injections. Before making any adjustments please read section "Adjusting the injection speed".

The BETACONNECT™

- Indicates if recharging is necessary.
- Reminds you 48hours after your last injection for one hour to take a new injection, but gives you the option to disable the reminder function.
- Will automatically power down if it is not operated for 20 minutes to save battery power.

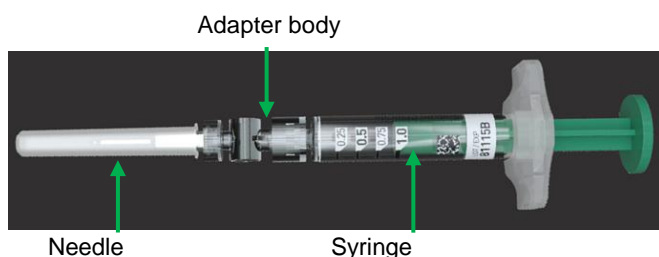
The injection procedure used by the BETACONNECT™ is conducted in **four stages** which are carried out automatically by the BETACONNECT™:

- Phase I** **Inserting the needle** - the syringe is pushed forward so that the needle penetrates the skin.
- Phase II** **Injecting the medication** - the medication is injected subcutaneously (injection speed depends on injection speed setting).
- Phase III** **Dwell time** - the needle briefly remains in the skin to allow the medication to be spread in the subcutaneous skin tissue.
- Phase IV** **Withdrawing the needle** - the syringe and needle are withdrawn after injection. The BETACONNECT™ will sound several short beeps and present a flashing blue light bar visual after the needle was withdrawn.

2.2. Which syringe can be used with the BETACONNECT™? / Injection volumes



Only use syringes (see picture below) provided with your Betaseron®. The syringes have to be reconstituted per the Betaseron® patient information leaflet. Ask your MS nurse / healthcare professional if you need help with this.



BETACONNECT™ is designed to injection volumes between 0.25 to 1.0 ml.

2.3. Charging the BETACONNECT™

Important: The BETACONNECT™ cannot be used for injection while charging. The BETACONNECT™ can be recharged at a temperature from 10°C to 35°C / 50 – 95°F.

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

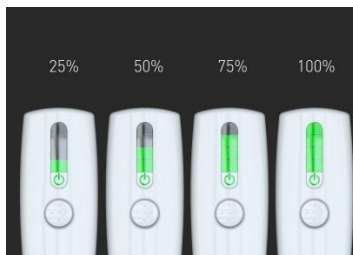


Micro-USB port

To charge the BETACONNECT™, plug the supplied USB charger into your power outlet. Be sure to have the BETACONNECT™ connected to the micro-USB cable & charger.

- *When fully charged, the battery capacity should last for approximately 15 to 20 injections (4-5 weeks).*
- *It is recommended to fully charge your BETACONNECT™.*

Step 2: Charging the BETACONNECT™ and verify charging status



The light bar shows the charging status of the battery level with four green lights.

- *Charging is complete when all four green lights are solid and the BETACONNECT™ turns off.*

2.4. Care, storage and disposal

- Your BETACONNECT™ can be **stored** at a temperature from – 10 to 40°C (14 - 104 °F), 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 mmHg to 795 mmHg).
- Your BETACONNECT™ can be **operated** at a temperature from 5 to 40°C (41 - 104 °F), 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 mmHg to 795 mmHg).
- Always store the BETACONNECT™ with the lid closed and in the BETACONNECT® packaging.
- Protect the BETACONNECT™ from dust, dirt, extreme temperatures or direct sunlight.
- If the BETACONNECT™ is exposed to extreme vibrations, pressure or shock (e.g. dropping or stepping on it) there is a risk of damaging the BETACONNECT™.
- Your BETACONNECT™ is not watertight and should be kept dry. Do not submerge your BETACONNECT™ in liquid.
- Please follow local regulations for disposal of electronic waste. To protect natural resources and to promote material reuse, please separate packaging material from other types of waste and recycle the material through your local recycling system.

2.5. Cleaning

- For correct function of BETACONNECT™ you must keep the safety release clean using a clean damp water cloth or alcohol wipe.
- In case medication is spilled inside the BETACONNECT™, it must be removed using a damp cloth.
- Other parts of the BETACONNECT™ do not normally need to be cleaned; if needed, lightly dampen a cloth with water and wipe the device.
- Do not submerge the BETACONNECT™ in any liquid and do not sterilize the BETACONNECT™.

Chapter 3: Injection Process

3.1. Preparing BETACONNECT™ for injection

Step 1: Turn On BETACONNECT™

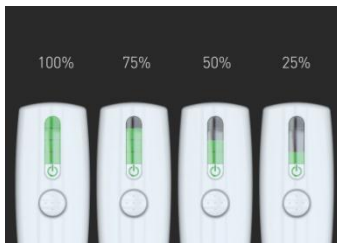


Turn On

Press the on-/off button to start the BETACONNECT™.

- A short beep tells you that the BETACONNECT™ is turned on.
- BETACONNECT™ conducts a self-test each time the BETACONNECT™ is turned on.
- If the on-/off button blinks green continuously or light bar blinks red, see the trouble shooting section on page 14.

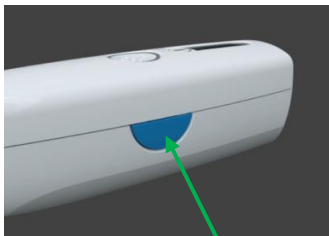
Step 2: Check Battery Status



Check the battery status on the light bar.

- Four green bars indicate the battery is fully charged.
- If there is one green bar flashing in the light bar, there is enough power for one injection but the BETACONNECT™ must be recharged right after.
- A flashing orange bar in the light bar indicates the battery level is too low to perform an injection and the BETACONNECT™ will shut-off. In this case the BETACONNECT™ has to be charged before it can be used.

Step 3: Open the lid



Press to open lid

Fully open the lid by pressing the blue lid release button on the side of the BETACONNECT™.

Step 4: Insert Syringe



Place the syringe into the insertion area in the BETACONNECT™ until it snaps into place. Leave the needle cap on.

- The syringe must be placed in such a way that it matches the printed marking.
- The lid will not close if the syringe is not seated properly.
- Check that the depth and speed settings are correct. For depth and speed setting please read chapter 4 (Adjustments).

Step 5: Illumination of injection button



Injection button

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

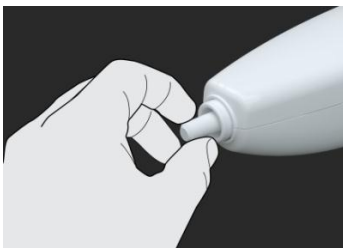
- *The injection button is illuminated with a steady blue light. This means that the BETACONNECT™ is now ready to be used for an injection.*
- *The lid must be fully closed to administer an injection.*

3.2. Injection procedure

Step 6: Clean the injection site

Clean the chosen injection area with an alcohol swab.

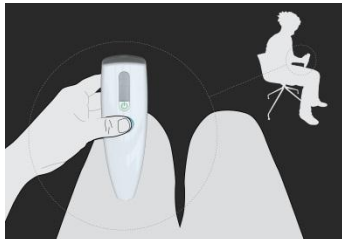
Step 7: Remove needle cap



Remove the needle cap by pulling it off at the front of the BETACONNECT™. Do not twist when removing the needle cap.

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

Step 8: Place the BETACONNECT™ against the injection site

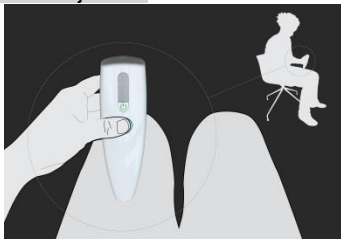


Gently hold the BETACONNECT™ at a 90° angle against the skin to activate the safety release.

- *The injection button illuminates with a flashing blue light when the safety is released.*
- *Make sure you hold the BETACONNECT™ against your skin for the entire injection.*

Important: Make sure not to accidentally touch the front of the BETACONNECT™ when there is a syringe in it because you may accidentally start the injection by pressing the injection button.

Step 9: 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 9: Verify Injection Status



Four blue reducing illuminated lights show the injection status.

Do not interrupt the injection. The injection cycle will be interrupted by:

- (Preliminary) Removing the BETACONNECT™ from the injection site.
- Pressing the on/off button.

Important: The injection procedure is quiet; therefore, the light bar will give you the injection status.

Always hold the BETACONNECT™ perpendicular, at a right angle, against your injection site during the entire

Step 9: Completeness of Injection

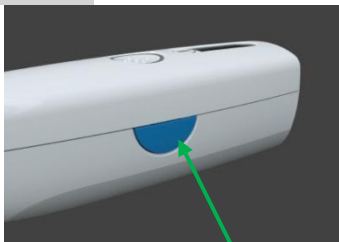


Do not remove the BETACONNECT™ from the injection site until the BETACONNECT® has indicated that the injection is complete.

- *Withdrawing the needle - the syringe and needle are withdrawn after the injection.*
- *Upon injection completion, the BETACONNECT™ will have two short beeps and a flashing blue light bar.*
- *The BETACONNECT™ will automatically power down after the injection is completed.*

3.3. Removing the used syringe and needle

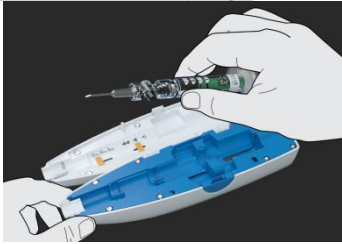
Step 10: Open the lid



Push to open lid

Fully open the lid by pressing the blue lid release button on the side of the BETACONNECT™.

Step 11: 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*

Important: Be careful not to get injured by the needle when you remove the empty syringe.

Do not put the needle cap back on the syringe

Always dispose of your empty syringe immediately after you completed your injection into an appropriate sharps container.

Chapter 4: Adjustments

Important: Check the settings prior to each injection to ensure you are injecting at the right injection depth and injection speed recommended by your MS nurse /healthcare professional.

4.1. Adjusting the injection depth

Step 1: Open the lid fully



Insertion depth slider

The setting allows injection depths of 8 mm, 10 mm and 12 mm by moving the injection depth slider.

By default, BETACONNECT™ is set to the standard injection depth of 12 mm. Discuss with your healthcare provider if a different depth should be used prior to changing the depth setting.

Step 2: Set the depth slider to the desired setting



Adjustment:

12 mm: Move the slider below the 12mm setting

10 mm: Move the slider below the 10mm setting

8 mm: Move the slider below the 8mm setting.

4.2. Adjusting the injection speed

Step 1: Open the lid fully



Injection speed slider

The setting allows slow, medium and fast injections.

By default, BETACONNECT™ is set to the medium injection speed. Discuss with your healthcare provider if a different injection speed should be used prior to changing the injection speed setting.

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



Adjustment:

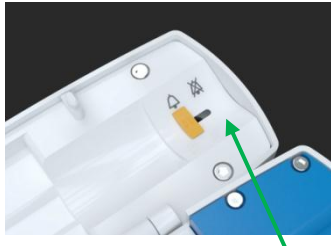
Fast: Move slider below ◀◀ symbol.

Medium: Move slider below ◀ symbol.

Slow: Move slider below ◀◀ symbol.

4.3. Setting the reminder function

Step 1: Open the lid fully



Reminder enabled

If the reminder function is activated, the BETACONNECT™ will remind you 48 hours after your last injection to take a new injection.

This reminder function is reset after each injection and the 48 hours will start counting again.

By default, the reminder function of the BETACONNECT™ is enabled.

Step 2: Set the reminder function to the desired setting



Adjustment:



: Reminder function enabled



: Reminder function disabled

Step 3: Reminder feature



Reminder signal



The reminder is an intermitting beep and a blue flashing light at the top of the light bar.

- *The flashing light reminder lasts for one hour.*
- *The beep occurs every 15 minutes for one 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 flashing light reminder, press the on/off button.*

Chapter 5: Trouble shooting

If assistance is needed during setting up, using, or maintaining the BETACONNECT™ contact your MS nurse / healthcare professional.











Problem	Cause	Solution
It is not possible to turn on the BETACONNECT™ 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™.
	3. Battery or electronic failure.	3. Please contact your MS nurse / healthcare professional for a replacement.
BETACONNECT™ turns automatically off.	1. BETACONNECT™ will automatically turn off after 20 minutes of inactivity.	1. Press the on-/off-button to turn on.
	2. BETACONNECT™ will power off if the battery level is too low.	2. Recharge the BETACONNECT™ if the battery indicator is flashing orange when you turn on the BETACONNECT™.
It is not possible to use the BETACONNECT™ while being charged	1. The BETACONNECT™ will not operate when it is being charged.	3. Charge the BETACONNECT™ and remove charger before use.
It is not possible 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 opening button does not function.	2. Please contact your MS nurse / healthcare professional for a replacement.
It is not possible to inject by activating the safety release	1. The safety release does not function.	1. Please contact your MS nurse / healthcare professional for a replacement.
It is not possible to charge the BETACONNECT™	1. The wrong USB cable or charger is used.	1. Make sure that the charger and cables provided with the BETACONNECT™ are used.
	2. The USB connection is worn out.	2. Please contact your MS nurse / healthcare professional for a replacement.
It is not possible to insert the syringe into the BETACONNECT™	1. The wrong syringe type is used.	1. Only use syringes provided with your Betaseron® with the BETACONNECT™.
	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 correctly.
The green light on the on-/off button does not stop blinking after the BETACONNECT™ was turned on.	1. The self-test is not completed.	1. Make sure the safety release in the front of the BETACONNECT™ is not pressed.
		2. Make sure the lid is closed.
		3. Make sure no buttons are depressed.


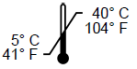
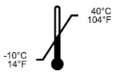
Problem	Cause	Solution
		<p>4. Hold on-/off button to shut down BETACONNECT™ and turn it on again.</p> <p>If the problem is not solved contact your MS nurse / healthcare professional.</p>
<p>A red blinking light is shown on the BETACONNECT™.</p> 	<p>1. The injection procedure was interrupted.</p> <p>2. A malfunction was detected.</p>	<p>1. In case the injection was interrupted ensure the entire dose is injected. Consult your MS nurse / healthcare professional if the entire dose was not received.</p> <p>2. Hold the on-/off button down to shut down BETACONNECT™ and turn it on again.</p> <p>If the problem is not solved contact your MS nurse / healthcare professional.</p>
<p>An orange light is shown on the BETACONNECT™ during charging.</p>	<p>1. The temperature is too low or too high.</p>	<p>1. The BETACONNECT™ can be recharged at a temperature from 10°C to 35°C / 50 – 95°F.</p>

Chapter 6: Technical Specifications

6.1. Labeling

On your BETACONNECT™/packaging the following symbols are used:

	It is important that you read this instruction before you use the BETACONNECT™.
	The symbol is accompanied by an expiry date to indicate that the device should not be used after the end of the indicated year (YYYY) and month (MM) printed as YYYY-MM.
	Keep the BETACONNECT™ dry.
	The product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives/authorities for disposal of electrical and electronic equipment. When disposing of electrical and electronic equipment by use of the collection systems available in your country, you protect the environment, human health and contribute to the prudent and rational use of natural resources.
	The BETACONNECT™ is a type BF device and provides protection against electrical shock and electrical current leakage.
	Manufacturer
	The unique serial number of this BETACONNECT™
	The BETACONNECT™ 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), the EMC Directive (2004/108/EC) and the RoHS (Restriction of Hazardous Substances) directive (2011/65/EU).
	The BETACONNECT™ radiates non ionizing electromagnetic signals.
	This device complies with part 15 of the FCC Rules. Operation is subject to the following two 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.
	The BETACONNECT™ is IC-authorized under the listed grantee code showing

IC: 3775E-BETAC1	compliance to Canadian regulations regarding Unlicensed Transmissions.
	The BETACONNECT™ is authorized under the listed grantee code showing compliance to the Japanese regulation regarding Low Power Communication System/ Wireless Lan System.
	The BETACONNECT™ can be operated at a temperature from 5 to 40°C / 41 - 104 °F.
	The BETACONNECT™ can be stored at a temperature from – 10 to 40°C / 14 - 104 °F.

6.2. Technical Specification

Type:	BETACONNECT™, class IIa medical device in Europe or class II medical device in the USA
Life time	3 years after manufacturing date
Serial Number (SN)	Please refer to the inside of the lid of your BETACONNECT™
Size:	165 x 52 x 42 mm (approximately 6.496 x 2.047 x 1.654 Inch)
Weight:	Approx. 185 g / 6.4 oz.
Light Display:	Light-emitting diode (LED)
Power Supply	1 rechargeable internal Li-Ion battery.
Electromagnetic Compatibility	The BETACONNECT™ meets the requirements of EN 60601-1-2 Like most electronic devices, using the BETACONNECT® in the immediate vicinity of mobile phones or microwave appliances may result in impaired functioning. Use and store BETACONNECT™ outside such an environment. Mobile phones should, depending on their transmitting power, be kept at a distance of at least 1 m / 3.28 ft.) from the BETACONNECT™ while it is in use.
Radio transmitting hardware	Bluetooth 4.0 using a customized encrypted protocol. Class B digital device Bluetooth and USB communication can only be established using dedicated software, contact your MS nurse / healthcare professional.

Expiry and disclaimer

After the expiry date your BETACONNECT™ has to be replaced. Contact your MS nurse / healthcare professional to receive a new BETACONNECT™. The expiry date can be located inside the lid indicated by year (YYYY) and month (MM) printed as YYYY-MM.

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 Patient Information Leaflet. The correct application of Betaseron® according to such instructions shall remain your sole responsibility.

Bang & Olufsen Medicom shall have no liability for incidental or consequential damages. Some states may not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

Last page

If you have any **questions** relating to your Betaseron[®] **medication**, please contact the manufacturer or refer to the information leaflet provided with the medication.

Please contact our local representative or your MS nurse / healthcare professional, if you **have any questions** on the BETACONNECT[™] if you do not need it anymore, if you want to dispose of it or in case of **malfunctions**.

We reserve the right to modify technical specifications and the documentation.

Manufactured by
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Model BETACONNECT[™]