



easypod[®]

Instructions For Use

English



MERCK

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Welcome

easypod[®] is an electromechanical auto-injector which administers a pre-set dose of Saizen[®] (somatropin [rDNA origin] for injection).

Please read through these instructions and remember you must have received the appropriate training from a healthcare professional before you use your easypod[®].



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Safety precautions and important information

This section covers important information on how to use your easypod[®].

If you have any questions after reading this section, do not hesitate to ask your healthcare professional.

Carefully read all instructions prior to use and observe all the warnings, cautions and notices in this document.

IMPORTANT:

easypod® must be used exclusively with Saizen® cartridges, in accordance with your prescription. Using the wrong cartridge can cause serious harm. If other cartridges are used in your household make sure that they can not be mixed up with Saizen® cartridges.

easypod® should be used strictly according to this instruction manual and only after proper training from a qualified healthcare professional. Contact your healthcare professional if you have any questions concerning your Saizen® prescription or treatment regimen.

Do not share your easypod® with anyone else, since doing so may result in injury, including the transmission of infectious blood borne diseases.

Children using easypod® must be under adult supervision at all times.

easypod® device description

Do not change the comfort settings on easypod® until you have discussed it with your healthcare professional.

easypod® is an electromechanical auto-injector which automatically administers a pre-set dose of Saizen® (somatropin [rDNA origin]) in cartridges. easypod® can be operated by adults, caregivers of children, and healthcare professionals. **Your easypod® is a personal device for use by only one patient and must not be used by other individuals.**

The 'Teach me' section may be used to review the formal training you have received. Please refer to section 5.7.

Saizen® cartridges

easypod® must be used exclusively with Saizen® cartridges, in accordance with your prescription.

Detailed information on the administration of Saizen® is provided in the Saizen® package Insert.

There are four Saizen® presentations compatible with easypod®.

You must check the expiration date prior to use.

Cartridge content	concentration	cartridge
Saizen® 6 mg	5.83 mg/ml	Solution for injection 
Saizen® 8 mg click.easy®*	5.83 mg/ml	Powder and solvent for solution for injection 
Saizen® 12 mg	8.00 mg/ml	Solution for injection 
Saizen® 20 mg	8.00 mg/ml	Solution for injection 

**may not be available in all countries*

NOTICE:

Do not use Saizen® if it is expired. Refer to Saizen® Patient Information Leaflet for detailed information.

Needles for the easypod® device

easypod® must only be used with Serofine™ single-use, disposable sterile needles. easypod® can use three needle types:

- 0.33 mm × 12 mm (29G × 1/2")
- 0.30 mm × 8 mm (30G × 5/16")
- 0.25 mm × 8 mm (31G × 5/16")

For more information on the size and appropriate choice of needle, ask your healthcare professional.

NOTE:

Not all accessories and associated devices are available for use or approved in all countries.

easypod® is not safe to use with other needles.

Keep needles out of the reach and sight of children. Dispose of used needles safely in an acceptable biohazard (sharps) container.

NOTE:

When a needle is attached, keep the needle and the base of your easypod® pointing down.

Care and handling

easypod® is an electromechanical auto-injector device and should be handled with care.

IMPORTANT:

Do not use easypod® if it is not working properly, do not modify it, and do not attempt to repair it, or an incorrect dose may be delivered. In case of difficulties, refer to the 'Troubleshooting and warning messages' section.

Take care not to drop your easypod® or expose it to shocks. Put the wrist strap securely around your wrist whenever you are handling your easypod® to help avoid accidentally dropping it.



If your easypod® is dropped, check that no broken parts are visible. Then turn it on. If your easypod® displays a **Device failure** warning message, as shown to the left, do not use it, since that indicates a permanent hardware or software failure. Contact your healthcare professional for help.

If following the drop easypod® starts normally, remove and check carefully the cartridge. If there are any signs of damage (such as cracks or cloudiness), remove the cartridge and contact your healthcare professional for help. You may send the defective cartridge back so that it can be examined. If the cartridge breaks inside the device, you should take care not to get hurt by broken glass. If the cartridge is not damaged, put it back in your easypod® and close the cartridge door.

NOTICE:

Do not spill liquid on your easypod®. Never rinse or immerse any part of your easypod® in water.

If your easypod® has been exposed to liquid, it should be wiped with a clean, dry cloth and checked for error messages like the **Device failure** warning shown on the previous page.

Cleaning and maintenance of your easypod®

If necessary, clean your easypod® with a slightly damp cloth just after you have completed your injection, wipe it up and turned it off. Then do not switch on your easypod® for the next 24 hours in order to avoid any malfunction due to the humidity.

When you turn your easypod® back on, check for any error/warning messages. If the device turns on normally, you can then use the device.

When cleaning your easypod®, do not use any chemicals, cleaning solvents, detergents, or alcohol solutions, since this could damage the device.

Your easypod® does not need any special maintenance during its normal working life of 3 years.

Using your easypod® near common household electronic devices should not be a problem.

Your easypod® can be used for up to 3 years after which it must be replaced. Contact your healthcare professional for help. You or your healthcare professional should write down the date you begin using your easypod® in section 6.5 'Replacing your easypod®' of this guide.

Your easypod® contains no harmful or toxic components. The device does not contain any personal information so there are no security or personal protection issues.

NOTE:

- Avoid spilling liquid on your easypod®. Never rinse or immerse any part of easypod® in water or any liquid.
- If your easypod® has been exposed to liquid, wipe it with a clean, dry cloth and check for error messages like the **Device failure** warning shown on page 10.
- Take care not to drop your easypod® or expose it to shocks. easypod® should be handled with care at all times.
- Do not operate easypod® near strong electromagnetic sources like an x-ray machine in a medical facility or a security machine at an airport which may disturb your dose delivery.

IMPORTANT:

Do not use easypod® if it is not working properly and do not attempt to repair it. No modification of this equipment is allowed. In the event of a device failure, a volume of 0.9 ml maximum may be injected. In case of device malfunction, contact your healthcare professional.

Storage of your easypod®



easypod® should be handled with care. Use the wrist strap at all times.

Your easypod® containing a cartridge of Saizen® should be stored according to the Saizen® patient information leaflet.

Store your easypod® arrow up in its closed storage box, particularly when it contains a cartridge of Saizen®. This helps to prevent drops of Saizen® from entering the device and causing malfunctions. Storing your easypod® in this way will also limit exposure to dirt, dust, liquid, and other substances.

IMPORTANT:

It is important that Saizen® is never frozen. Do **not** put Saizen® or easypod® in or near the freezer compartment. Saizen® should **not** be stored at temperatures below 2°C (36°F). **Never inject Saizen® that you know, or suspect, has been frozen.** Use Saizen® in accordance with the Patient Information Leaflet.

Storage box in upright position



This arrow shows the right way up to store easypod®





Getting to know your easypod[®]

This section introduces you to
your easypod[®].

It covers the controls, lights and
sounds and tells you how to care
for your new device.

2.1 easypod® features



Contents of the box:

- 1x easypod® with wrist strap
- 1x storage box
- instructions manual*
- 1x set of batteries
- 1x distributor list

Compatible with:

- needles: Serofine™ 29G, 30G, 31G
- cartridges: Saizen® 6mg, 8mg, 12mg, 20mg

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

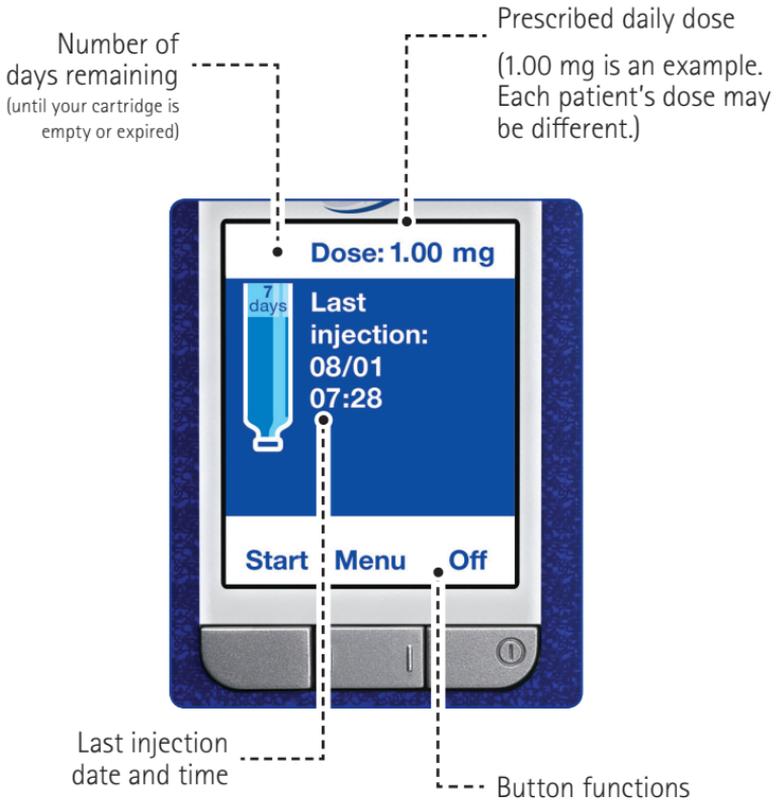
**number of instruction manuals may vary (different languages)*



2.1 easypod® features (continued)



2.2 The information screen



The screen displays instructions and current information.

Your easyPod® uses interactive menus to help you safely set up and use the device.

2.2 The information screen (continued)

You can navigate through these menus, and select various options, by using the three buttons under the screen. The use of these buttons may change according to which screen is displayed. The functions of the buttons are displayed on the screen above each button.

If easypod® is left unused for 30 seconds, the screen display light turns off. Press any button below the display to turn the light back on.

After being idle for 10 minutes, easypod® will automatically turn off. This function cannot be changed.

In these instructions the '>' symbol indicates menu commands in the order they need to be selected. For example **Menu > Device settings** means to open the main menu, then scroll to and select the **Device settings** menu.

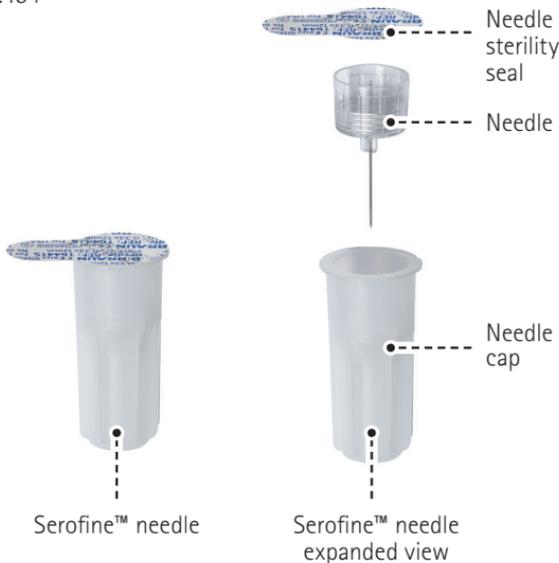


2.3 easypod® accessories and associated devices

2.3.1 easypod® accessories

The following accessories are available:

- Set of easypod® spare facia (customisable accessory for children and teens)
- easypod® storage box
- easypod® travel bag
- 4 AAA Lithium batteries
- Screwdriver (to unscrew the battery cover)
- Pair of pliers (to remove stuck needles)
- Training pad (to practice injections)
- Serofine™ needles 29G × 1/2" (0.33 mm × 12 mm)
- Serofine™ needles 30G × 5/16" (0.30 mm × 8 mm)
- Serofine™ needles 31G × 5/16" (0.25 mm × 8 mm)
- Sharps bin 1 l
- Sharps bin 0.45 l



If you need any replacements for the easypod® device, or one of its accessories, please contact your healthcare professional.

2.3.2 easypod® associated devices

- easypod® connect software
- easypod® connect transmitter

NOTE:

Not all accessories and associated devices are available for use or approved in all countries.

2.4 Lights and sounds

easypod® uses lights and sounds to help guide you while injecting. The sounds are optional, you can turn them off. However, the warning sounds cannot be switched off as they give important safety information.



Green light on
Ready for injection.

1 short beep when placed on skin. **1** 



Green light flashes
Injection in progress.



Green light off
Injection completed.

2 short beeps at end of injection. **2** 



Red light
Warning – injection incomplete or device error.

3 long beeps. **3** 

Sounds

1  1 Beep = Start of process

2  2 Beeps = End of process

3  3 Beeps = Warning or Caution messages:
please read carefully the information on the screen and follow instructions displayed on the screen.

2.5 Storing your easypod®

When not in use, always store your easypod® in its closed storage box, arrow pointing up, especially when containing a cartridge of Saizen® cartridges. This helps to avoid drops of Saizen® cartridges entering the device and causing malfunction.

When containing a Saizen® cartridge, easypod® should always be placed in its storage case and stored according to the Saizen® patient information leaflet. Always detach the needle before storing your easypod®.



IMPORTANT:

Do not put Saizen® in or near the freezer compartment.

Saizen® should not be stored at temperatures below 2°C (36°F) as it is important that Saizen® is never frozen.

Never inject Saizen® that you know, or suspect, has been frozen. Use Saizen® in accordance with the Patient Information Leaflet.

If the device is stored in the fridge, store it in the front section of the refrigerator in order to avoid temperatures which are too low.

Saizen® powder and solvent for solution for injection cartridges have a 28-day expiration from the day they are reconstituted (mixed). Saizen® solution for injection cartridges have a 28-day expiration after first use. Cartridges must be used or discarded within this 28 days. Please refer to section 6.2 'Warnings and Cautions'.

If, for any reason your easypod® is not going to be used for more than one month, remove the batteries and store them separately.

2.6 Serofine™ needles

easypod® can use three sizes of Serofine™ single-use, disposable, sterile needles:

- 29G × 1/2" (0.33 mm × 12 mm)
- 30G × 5/16" (0.30 mm × 8 mm)
- 31G × 5/16" (0.25 mm × 8 mm).

The needle size will be chosen in consultation with your healthcare professional who will set the matching **Needle type** setting on your easypod®. The needle type setting can only be changed by your healthcare professional.

Only use the size of Serofine™ needle that has been prescribed for you. The size (or gauge 'G') is clearly written on the needle carton and on the sterility seal of each individual needle.



The 30G and 31G needle can only deliver an injection depth of 4 mm and 6 mm. The 29G needle can deliver an injection depth of 4, 6, 8 and 10 mm.

NOTE:

Not all accessories and associated devices are available for use or approved in all countries.

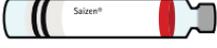
2.7 Saizen® cartridges

easypod® can only be used with Saizen® cartridges.

Always carefully check the packaging and the cartridge label to ensure you have the correct medication and cartridge type.

The cartridges you use must always be in accordance with your prescription.

There are four Saizen® presentations compatible with easypod®:

Cartridge content	concentration	cartridge
Saizen® 6 mg	5.83 mg/ml	Solution for injection 
Saizen® 8 mg click.easy®*	5.83 mg/ml	Powder and solvent for solution for injection 
Saizen® 12 mg	8.00 mg/ml	Solution for injection 
Saizen® 20 mg	8.00 mg/ml	Solution for injection 

**may not be available in all countries*

For Saizen® solution for injection formulation, the cartridge label must not be removed. Check that the label with the information strips is present and undamaged; otherwise the device will reject the cartridge.

For Saizen® powder and solvent formulation (click.easy®), make sure the peel-off label on the cartridge is removed. Check that the 2nd label with the information strips is present and undamaged, otherwise the device will reject the cartridge.

If you have questions or concerns, please contact your healthcare professional.

2.8 Indications-Contraindications-Undesirable effects

Refer to the Saizen® package insert.





Using your easypod[®] for the first time

This section shows you how to get started by installing the batteries, turning on your easypod[®] and inserting a cartridge.

3

3.1 Installing the batteries



Unscrew the battery cover with a screwdriver.

You do not need to fully remove the screw to lift the battery cover.



Hold the battery cover on both sides and slide it off.



Insert the 4 new Lithium AAA batteries, as indicated on the device.

If you need further assistance installing batteries, contact your healthcare professional.

NOTE:

Only use 4 × 1.5 V AAA lithium batteries as they have a higher performance and a longer life. Rechargeable or alkaline batteries are not suitable. The detailed battery specifications can be found in the *Technical Data* section.



Slide the battery cover back onto the easypod[®] device.

After tightening the battery cover screw to fix the battery cover back into place, wait a few minutes before turning on your easypod[®] to allow the device to re-set.



The battery life is approximately one year.

NOTE:

- Risk of fire: battery can explode or leak and cause injury if installed backwards or disassembled.
- Crushed or damaged batteries may result in a fire.
- Damaging a lithium battery may result in an internal short-circuit.
- Keep the primary lithium batteries away from children.
- Use only the same type of primary lithium batteries of the manufacturer Energizer Ultimate AAA (FR03) and do not mix with other types.
- Cover the poles of the lithium batteries by an insulated material at the end of the life time of the batteries before discarding them as per local regulations.
- Do not mix new and old batteries.

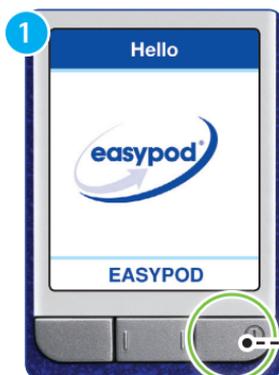
3.2 Before injecting your first dose of Saizen®

Before you begin injecting, easypod® has to be correctly configured with your personal settings.

This process must be carried out by a qualified healthcare professional who will also teach you how to use the device on your own. Refer to 'easypod® settings' in section 5 for guidance.

Once the dosing is set by your healthcare professional, your easypod® is ready for use.

3.3 Starting with your easypod®



Put the wrist strap securely around your wrist whenever you are handling your easypod®.

Turn on your easypod® by pressing and holding the **ON** button until the **Welcome** screen appears, usually after about 5 to 7 seconds.

When you turn on the device for the first time please check whether you need to set up time zone, time and date. Please make sure you start by setting the time zone first. Please refer to section 5.5 '*Device settings*'.

3.4 Inserting a cartridge

Your new easypod® has no Saizen® cartridge inside. Check the new cartridge carefully before inserting it into your easypod®. Check that the dosage of the Saizen® cartridges is the one you were prescribed.

Look at the label on the cartridge to make sure it is not past its expiration date and that it is the correct medication. **Do not insert any other medication's cartridge! – It should just say 'Saizen®' (and not another drug's name) on the label!**

The solution must be clear to slightly opalescent with no particles and without visible signs of deterioration. If the solution contains particles, it should not be injected. For additional information, please refer to your Saizen® package insert.

IMPORTANT:

Saizen® powder and solvent for solution for injection cartridges have a 28-day expiration from the day they are reconstituted (mixed). Saizen® solution for injection cartridges have a 28-day expiration after first use. Cartridges must be used or discarded within those 28 days.

The device will track the number of remaining doses and the expiry date of the cartridge.

To insert a cartridge:



Press the **Start** button.

The device will read **Remove and change cartridge.**

Open the cartridge door by sliding the cartridge door button upwards.

The display will read **Insert cartridge.**



Place a new cartridge into the cartridge holder, making sure the metal tip is pointing down.



Push the cartridge door closed until it clicks shut. It will beep once when ready. You can start the injection by pressing **Start**.



The device will prompt you to insert a new needle.

Wrong cartridge inserted or not recognized

There are three scenarios when inserting a new cartridge:

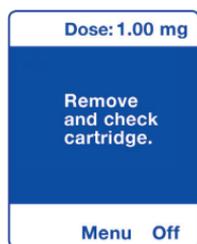
1. The cartridge has been accepted and the device will display the **Insert new needle** message.
2. The cartridge label has been damaged and the device will display the **Remove and check cartridge** message.
3. The cartridge is not the correct one and the device will display the **Wrong cartridge** warning.

1. The cartridge has been accepted:



The device will display **Insert new needle**. Insert a new needle and follow screen instructions to start your injection.

2. The cartridge label has been damaged or removed:



The device will display the **Remove and check cartridge** message.

Remove the cartridge and carefully check its label. Make sure it has the correct medication (Saizen®) and is for the correct dose.

If so, make sure the information strips on the cartridge label are not damaged. Replace the cartridge.

If accepted, the device will display **Insert new needle**.

If the cartridge is still not recognized, the device will display the **Wrong cartridge** warning.

3. The cartridge is not the correct one



This warning message indicates that the wrong cartridge has been inserted.

Press **OK**.

Remove the cartridge and check your cartridge is the correct medication (Saizen®).

Insert a new cartridge.

If accepted, the device will display **Insert new needle**. If rejected, the device will show the **Wrong cartridge** warning.

3.4 Inserting a cartridge (continued)

IMPORTANT:

Inspect each new Saizen® cartridge carefully according to the Saizen® Patient Information Leaflet. If you have **ANY** doubt that it is the correct medication, do not use this cartridge. Contact your healthcare professional.

Your easypod® is set up to use only Saizen® cartridge type. The cartridge type setting can only be changed by your healthcare professional. Using any other cartridges can cause serious harm.





Injecting with easypod[®]

This section is a step-by-step guide for administering an injection with your easypod[®].

4

4.1 Getting ready

Before you begin, put all the items listed below within easy reach on a stable and clean surface, such as a table:

- Your easypod® containing a Saizen® cartridge
- Serofine™ needle (29G, 30G or 31G, whichever has been prescribed for you)
- Alcohol wipes/swabs or cotton balls and rubbing alcohol
- Small adhesive bandage strip (if needed)
- A biohazard (sharps) container

NOTE:

When children are injecting, an adult must supervise at all times throughout the process.

Wash your hands thoroughly with soap and water.

If your easypod® has just been removed from the refrigerator it will be very cold. You may want to remove the device from the storage case to warm and wait 5 minutes before turning it on. This will help the batteries to work properly.

As per your healthcare professional recommendations, choose your injection site.

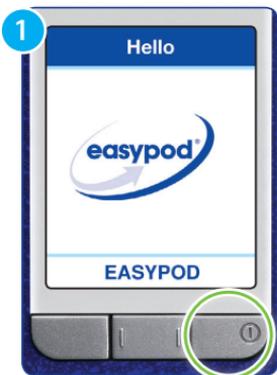
NOTE:

Prepare the chosen injection site according to the instructions given by your healthcare professional.

You will find a **Teach me** guide in the Menu that can assist you with the injection process. This is not a substitute for training. See section 5.7 'Teach me' for details.



4.2 Turning on your easypod®



Put the strap around your wrist. Turn on the device by pressing and holding the **ON** button until either the 'hourglass' screen or the welcome screen appears, usually after about 5 to 7 seconds.

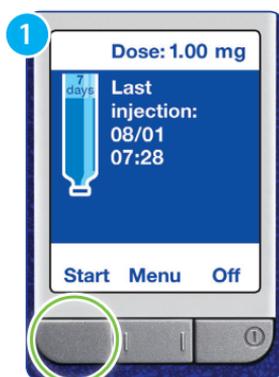


After a few more seconds the welcome screen is automatically replaced by the information screen.

NOTE:

1.00 mg is an example of a prescribed daily dose. The dose displayed will differ from patient to patient.

4.3 Starting your injection



Press the **Start** button. easypod® will check the cartridge.

NOTE:

If your device has just been removed from the refrigerator it will be very cold. A **Device is too cold** warning will be displayed if the device temperature is below 4°C / 39°F. You may want to remove the device from the storage case to warm and wait 5 minutes before turning it on. This will help the batteries to work properly.



If the cartridge is OK the **Insert new needle** message will appear on the screen.

If the remaining content in the Saizen® cartridge only partially covers the daily dose, please refer to section 4.6 '*Partial dose injection procedure*'.

4.4 Attaching the Serofine™ needle



IMPORTANT:

Always handle needles carefully to avoid needle stick injury.

Do not use the needle if the sterility seal is damaged or detached to avoid risks of infection.



Check the needle type (gauge) corresponds to your Serofine™ needle. Take a new needle and remove the sterility seal. Make sure that the sterility seal is fully removed before use.



When device screen displays **Insert new needle**, push the needle cap, containing the needle, straight into the needle cavity until it clicks into place. Let go of the needle cap during the needle attachment.

easypod® beeps once. **1**  (unless muted)

When the needle is attached, easypod® beeps twice. **2**  (unless muted)



When device screen displays **Remove empty cap**, remove it by pushing it sideways until it detaches and can be withdrawn. Do not pull it straight down as this action may damage your easypod®.



NOTE:

Keep the empty needle cap for removing the needle after injection.

4.5 Administering your injection



Prepare the injection site as directed by your healthcare professional.

easypod® shows a **Place on skin. Press injection button** message.

Hold your easypod® vertically against your skin.

Do not pinch your skin at the injection site before, during, or after the injection.



When your easypod® is properly positioned against your skin, the injection button light turns green and easypod® beeps once. **1**  (unless muted)



Press the injection button to begin injecting.

NOTE:

If you do not perform the injection immediately, your easypod® will beep once every 30 seconds for 3 minutes.

After 10 minutes it will turn off automatically, this will re-set the device and you will have to start the injection process again.



During your injection, the green injection button light flashes and the **Injection in progress** message is displayed.

Keep easypod® steady and in constant contact with your skin throughout the injection. There is no need to keep pushing the injection button.



When the injection is complete the green injection button light turns off and your easypod® beeps twice.  (unless muted)

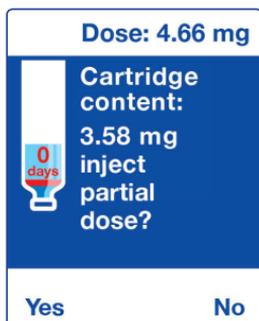


Gently lift your easypod® away from your skin.

Press **OK** to confirm your injection has been completed satisfactorily.

4.6 Partial dose injection procedure

easypod® keeps track of the amount of medication remaining in the current cartridge. When the dose adjustment function is off, the partial dose injection screens below appear. You may want to discuss dose adjustments settings with your healthcare professional to reduce medication wastage or number of injections.



If the remaining content of Saizen® cartridge only partially covers the daily dose, your easypod® will display the **Inject partial dose?** message.

You can press **No** and change the cartridge to inject a full daily dose.

or

Press **Yes**, inject the remaining medication and record this partial dose as the daily dose or make two injections which amount to the full daily dose. The first injection uses the medication remaining in the current cartridge.

Follow the screen instructions to detach the needle and remove the cartridge.

Then insert a new cartridge and attach a new needle in order to complete your injection.

easypod® calculates the correct partial dose to complete the full dose.

Select **No** at the end of the first injection if you do not wish to continue with the second part of the injection (but only a partial dose will have been injected).

4.7 Interrupted injection

Dose: 1.50 mg	
	Partial dose: 0.8 mg
	Missing: 0.7 mg
	Continue injection?
	Yes No

If you remove your easypod® from your skin before the injection is complete, easypod® will stop administering Saizen® cartridges. The needle will automatically retract, the injection button will turn red and easypod® will beep three times. 

A **Partial dose** message will be displayed on the screen.

Select **Yes** if you wish to continue with the remaining dose to complete the injection.

Select **No** if you do not wish to continue with the second part of the injection (but only a partial dose will have been injected).

If you wish to complete the injection, follow the screen instructions to detach the used needle.

Then attach a new needle. It will be then possible to proceed with the remaining dose injection.

Before using your easypod® for the first time, you may want to discuss recommendations for continuing interrupted injections with your healthcare professional.

4.8 Detaching the Serofine™ needle



Make sure you use an empty needle cap. The device screen will display the following steps. Push the cap straight into the needle cavity until it clicks into place. easypod® beeps once. The screen will display the following steps, in addition to the beep(s). **1**  (unless muted)

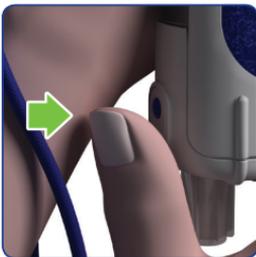


Let go of the needle cap.



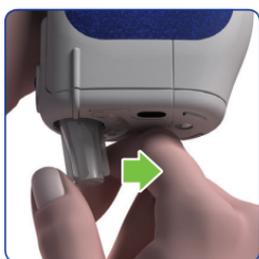
Press and hold the needle release button until your easypod® beeps twice. **2**  (unless muted)

The needle is now detached and inside the needle cap.





When the device screen displays **Remove cap**, remove it by pushing it sideways until it detaches and can be withdrawn.



NOTE:

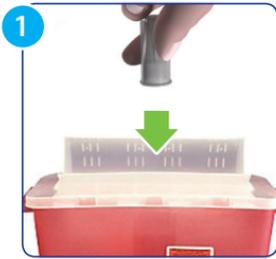
- Do not pull it straight down as this action may damage your easypod®.
- If the needle release button is released too quickly the needle may detach incorrectly and a warning message will appear.

In this case, carefully replace the needle cap and try again. If difficulties persist, refer to the *'Troubleshooting and warning messages'* section.



Please refer to the Saizen® patient information leaflet for storage conditions.

4.9 Finishing your injection



Dispose of the used needle safely in an acceptable biohazard (sharps) container.

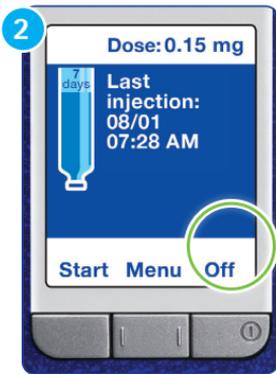
IMPORTANT:

Improper disposal may result in needle stick injury.

Never re-use needles.

Dispose your biohazards (sharps) container according to local regulations.

Check that the date of your injection is displayed on the screen.



Press and hold the **Off** button until your easypod[®] has turned off and the information screen has closed, usually after about 3 to 5 seconds.

NOTE:

Remember to store your easypod[®] in its storage box with the arrow pointing up when it contains a cartridge of Saizen[®] according to the Saizen[®] patient information leaflet. Storing your easypod[®] in this way helps avoid drops of Saizen[®] from entering the device and causing malfunctions, and will also limit exposure to dirt, dust, liquid, and other substances.

4.10 Changing a cartridge when empty



If, when you press the **Start** button, the cartridge is empty or has insufficient content for one injection, your easypod® will display **Cartridge empty. Change cartridge** and the cartridge content will be **0** and shown in red.

A new cartridge must be inserted. Check that the needle has been removed.

If your easypod® is set up to inject a partial dose when the cartridge is nearly empty, you will follow a different procedure. Refer to section 4.6 '*Partial dose injection procedure*'. Ask your healthcare professional about this.



Open the cartridge door by sliding the cartridge door button upwards.

If the cartridge door opens but the cartridge remains in the device, try closing and re-opening the door.

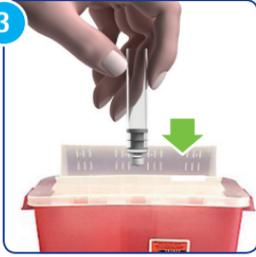
NOTE:

If the cartridge is not empty, the door will not open. To remove a cartridge before it is empty, see section 5.4 '*Removing a cartridge before it is empty*'.



Remove the empty cartridge.

3



IMPORTANT:

A used cartridge is a biohazard and must be disposed of correctly.

Dispose of the empty cartridge safely in an acceptable biohazard (sharps) container. Biohazards (sharps) container shall be disposed of according to local regulations.

Check the new cartridge to ensure it is your prescribed Saizen® cartridge dose and the expiration date has not passed. The solution must be clear to slightly opalescent with no particles and without visible signs of deterioration. If the solution contains particles, it should not be injected. For additional information, please refer to the Saizen® patient information leaflet. If the cartridge breaks inside the device, you should take care not to get hurt by broken glass.

IMPORTANT:

Saizen® powder and solvent for solution for injection cartridges have a 28-day expiration from the day they are reconstituted (mixed). Saizen® solution for injection cartridges have a 28-day expiration after first use. Cartridges must be used or discarded within this 28 days. For more details, refer to Saizen® Patient Information Leaflet.

4.10 Changing a cartridge when empty (continued)



Place the correct Saizen® cartridge into the cartridge holder, making sure the metal tip is pointing down.



Push the cartridge door closed until it clicks shut. Your easypod® will beep once when ready. 1 

easypod® is ready for use again.





easypod[®] settings

Before using your easypod[®] there are a number of settings which can be changed.

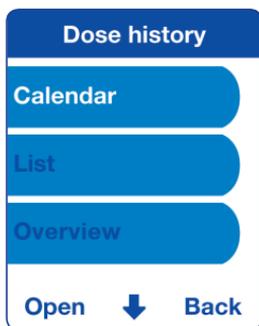
This process is explained in the following pages.

5.1 easypod® menu

When pressing the **Menu** button after switching on your easypod®, different settings appear:

- Dose history
- Battery status
- Comfort settings
- Remove cartridge
- Device settings
- Clinical settings
- Teach me
- Data transfer

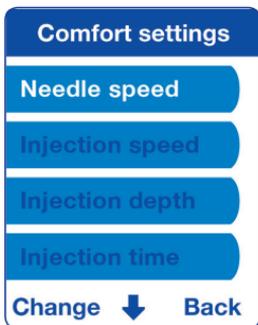
Clinical settings are only dedicated to healthcare professionals and are described in section 7.2.



There are three **Dose history** views:

- Calendar**
- List**
- Overview**

You cannot change the **Dose history**, you can only view it.



There are four **Comfort settings**:

Needle speed
Injection speed
Injection depth
Injection time

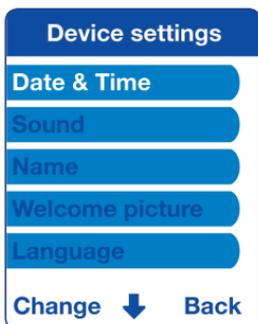
NOTE:

It is recommended not to change the settings listed above unless directed to do so by your healthcare professional.

Medical advice is required to make these changes.

The default settings are:

needle speed: medium
injection speed: medium
injection depth: 6 mm
injection time: 5 s



There are five **Device settings**:

Date & Time
Sound
Name
Welcome picture
Language

You can change the **Device settings** listed above as desired.

5.2 Dose history

Monitoring your dose history

NOTE:

You must set the correct date and time on your device to enable this feature to work properly.

easyPod® records the date and time of every injection, enabling you to easily monitor your dose history. This recording display can be turned off using the **Dose log** setting, but only by a healthcare professional with the appropriate PIN code (see 'Additional information for healthcare professionals' in section 7).

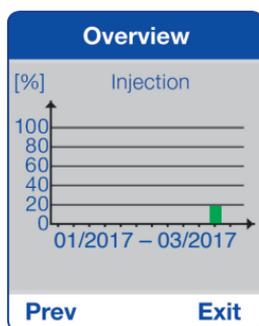
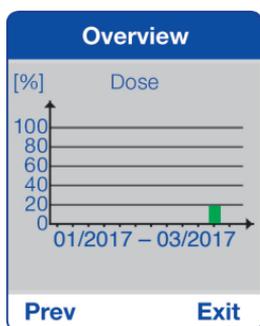
You can view your dose history at any time in a **Dose calendar**, **Dose list** or **Overview** format:

1. Choose **Menu > Dose History**. And press **Open** to select.
2. Use the **↓** button to scroll to one of the three options; select **Calendar**, **List** or **Overview** to view the dose history in different layouts.

Selecting **Overview** shows two graphical displays options.

Selecting **Dose** shows a graph of the doses administered.

Selecting **Injections** shows a graph of the injections administered. Use the **Prev** and **Next** buttons to scroll through pages of data.



The dose history displays use the following colour codes:

Colors	Description
Red	Injection missed
Green	Injection completed
Orange	Interrupted injection; only a partial dose delivered
Black (Dose list)	Cartridge changed
Blue (Dose calendar)	Days in the future

Dose list		
281116	23:59	
291116	23:59	
301116	23:59	
011216	12:14	0.50 mg
011216	12:32	8.49 mg
021216	13:17	0.50 mg
031216	13:21	0.50 mg
041216	13:21	0.50 mg
051216	13:21	0.50 mg

Prev Exit

Dose calendar		
December 2016		
	1	2 3 4
5	6 7 8 9	10 11
12	13 14 15 16	17 18
19	20 21 22 23	24 25
26	27 28 29 30	31

Prev Next Exit

These graphs enable you to check whether you are always receiving the full dose from the Saizen® cartridge and that the right number of injections are being made, as prescribed by your healthcare professional and set on your easyPod®.

NOTE:

Do not use this data for diagnostic purposes.

5.3 Battery status

You can check the status of your easypod® batteries at any time:

Choose **Menu** and use the ↓ button to scroll to > **Battery status**, press **Open** to select.

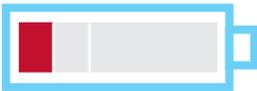
The Battery status indicator will be displayed.



Three green bars indicate a full battery.



Two orange bars indicate a partly used battery.



One red bar indicates the battery is nearly empty.

The battery life is approximately one year.

When the device displays the **Low battery** or **Replace battery** warning, refer to section 6.2 '*Warnings and Cautions*'.

5.4 Removing a cartridge before it is empty

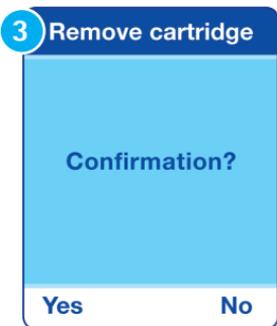
You may need to remove a cartridge while not empty because of travelling or rejection of partial injection, etc.



Press the **Menu** button to select the main menu.



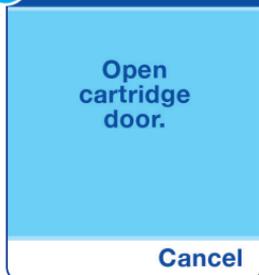
Scroll down to **Remove cartridge** and press the **Open** button to select.



Your easypod® asks you to confirm this choice.
Press **Yes** to confirm.

5.4 Removing a cartridge before it is empty (continued)

4 Remove cartridge



Wait until your easypod® displays the **Open cartridge door** message and beeps twice.  (unless muted)



Slide the cartridge door button up to open it and remove the cartridge.

If the cartridge door does not open fully, close it again and repeat the step above, ensuring that you slide the cartridge door button up to the top.

If there is a problem with the cartridge, dispose of it safely in an acceptable biohazard (sharps) container.

If no problem is detected, the cartridge can be used again.

5.5 Device settings

Date and time

Please set up timezone first, as it may change the date and time afterwards.

NOTE:

Adjustments for daylight saving time must be made manually. Date and time and any daylight saving time adjustments must be set or corrected when you receive your device.

By default, your device will be pre-set in the international format.

Setting the time zone

To ensure that easypod® correctly records your dose history, you must set your current time zone:

1. Choose **Menu > Device settings > Date & Time > Timezone** and press **Change** to select.
2. Use the **↓** button to scroll to your current time zone. The menu shows values based on Greenwich Mean Time (GMT).
3. Press **OK** to set your time zone.

Setting the date and time

To set the date and time:

1. Choose **Menu > Device settings > Date & Time**.
2. Use the **↓** button to select **Date** or **Time** and press **Change** to select.
3. Use the **↑** button to display the required value.
4. Press **OK** to confirm your choice and move to the next setting.
5. Repeat this procedure until the date and time have been correctly set.
6. Choose **Back > Exit** to return to the information screen.

Setting the date and time format

easypod® offers three choices of date and time layout:

- dd/mm/yy (per default)
- mm/dd/yy am/pm
- yy/mm/dd 24h

You can change the way easypod® displays date and time information to suit your preference:

1. Choose **Menu** > **Device settings** > **Date & Time** > **Format** and press **Change** to select.
2. Use the **↓** button to scroll to your preferred format.
3. Press **OK** to confirm.
4. When you have finished making changes, choose **Back** > **Exit** to return to the information screen.

Setting sounds

Sound is a useful aid for injection, but it can be turned off if preferred. However, when your injection site is in an area you cannot see, it is recommended that you leave the sound on.

The three warning beeps which alert you to an error or an incomplete injection are always on, as they give important safety information.

When your easypod® is new the sound setting is activated. To switch it off, please follow these steps:

1. Choose **Menu** > **Device settings** > **Sound** and press **Change** to select.
2. Use the **↓** button to scroll to **Off**.
3. Press **OK** to turn sound off.
4. Choose **Back** > **Exit** to return to the information screen.

Setting name

You can change the name that appears on the welcome screen of your easypod®:

1. Choose **Menu** > **Device settings** > **Name**.
2. Use the **↑** button to step through the alphabet until you see the letter you need.
3. Press **OK** to select and move the cursor forward.
4. Repeat step 2 and 3 until you have selected your chosen name.
5. When finished, press **OK** until you return to the **Device settings** menu.
6. Choose **Back** > **Exit** to return to the information screen.

Welcome picture

You can change the picture that appears on the welcome screen of your easypod®:

1. Choose **Menu** > **Device settings** > **Welcome picture**; the currently selected welcome picture appears.
2. Use the **↓** button to scroll through the pictures available.
3. When the image you have chosen appears, press **OK** to confirm and return to the **Device settings** menu.
4. Choose **Back** > **Exit** to return to the information screen.

Setting language

When you receive your easypod®, the language is set to English. To change the language:

1. Choose **Menu > Device settings > Language** and press **Change** to select.
2. Use the **↓** button to step through the languages available until your desired language is highlighted.
3. Press **OK** to confirm your choice.
4. Choose **Back > Exit** to return to the information screen.

NOTE:

If your easypod® is set to a language you do not understand by mistake, it can be difficult to navigate back to the Language setting.

Re-setting to English

Your easypod® can be re-set to use English by using the following procedure:

1. Use the right hand button to return to the information screen.
2. Hold down the right hand button until easypod® switches off.
3. Hold down **both** the middle and the right hand buttons together. Continue to hold them down until easypod® starts up, usually after about 7 seconds.
4. The **Reset to English?** message appears.
5. Press **Yes** to confirm. Your easypod® will start up with the language re-set to English.

5.6 Comfort settings

If the injection is painful or there are some Saizen® drops on your skin, you may contact your healthcare professional for advice on adapting the **Comfort settings**.

Setting the needle speed

NOTE:

The **Needle speed** setting should only be changed after discussion and guidance from your healthcare professional.

The **Needle speed** is the speed of the needle insertion during the injection. It can be set to one of three values: **Slow**, **Medium** and **Fast**. To set the **Needle speed**:

1. Choose **Menu** > **Comfort settings** > **Needle speed** and press **Change** to select.
2. Use the ↓ button to scroll to the needle speed you wish to set.
3. Press **OK** to confirm your choice.
4. Choose **Back** > **Exit** to return to the information screen.

Setting the injection speed

NOTE:

The **Injection speed** setting should only be changed after discussion and guidance from your healthcare professional.

The **Injection speed** is the rate at which medication is delivered during the injection. It can be set to one of three values: **Slow**, **Medium** and **Fast**.

However, the **Fast** speed is only available for the 29G & 30G needles. If your easy pod® is set to use a 31G needle (see '*Setting the needle type*' section), then only the **Slow** and **Medium** options will be displayed on the menu. To set the **Injection speed**:

1. Choose **Menu** > **Comfort settings** > **Injection speed** and press **Change** to select.
2. Use the ↓ button to scroll to the injection speed you wish to set.

3. Press **OK** to confirm your choice.
4. Choose **Back** > **Exit** to return to the information screen.

Setting the injection depth

NOTE:

The **Injection depth** setting should only be changed after discussion and guidance from your healthcare professional.

The **Injection depth** is the depth the needle penetrates the skin during injection. It can be set to one of four values: 4 mm, 6 mm, 8 mm, or 10 mm.

However, the **8 mm** and **10 mm** options are only available for the 29G needle. If your easypod® is set to use either the 30G or 31G needle (see 'Setting the needle type' section), then only the **4 mm** and **6 mm** options will be displayed on the menu. To set the **Injection depth**:

1. Choose **Menu** > **Comfort settings** > **Injection depth** and press **Change** to select.
2. Use the **↓** button to scroll to the injection depth you wish to set.
3. Press **OK** to confirm your choice.
4. Choose **Back** > **Exit** to return to the information screen.

Setting the injection time

NOTE:

The **Injection time** setting should only be changed after discussion and guidance from your healthcare professional.

The **Injection time** is the time the needle remains in the skin after medication has been administered. The needle is automatically retracted after this time, which can only be between 3 – 30 seconds (the default is 5 seconds).

To set the **Injection time**:

1. Choose **Menu > Comfort settings > Injection time** and press **Change** to select.
2. Use the **↑** button to scroll to the injection time you wish to set.
3. Press **OK** to select and move the cursor forward.
4. Repeat step 2 and 3 until you have selected your chosen time.
5. Press **OK** to confirm your choice.
6. Choose **Back > Exit** to return to the information screen.

5.7 Teach me

Your easypod® has a built-in pictorial guide to the basic steps for inserting a cartridge and administering an injection.



NOTE:

This **Teach me** guide can assist you with the injection process, but, it is not a substitute for training.

To view the **Teach me** guide:

1. Choose **Menu** > **Teach me** and press **Open** to confirm.
2. The first screen of the **Teach me** guide will be displayed. Use the **Next** button to step through the sequence of pictures.
3. When you have finished press the **Menu** button to return to the main menu.

Examples of on-screen images:



5.8 Data transfer

You may have agreed with your healthcare professional to transfer your injection data with the help of the easypod® connect transmitter to a secure internet based database to allow your healthcare professional to monitor the treatment with Saizen®.

Before transferring your injection data for the first time, you must have signed a consent form with your healthcare professional.



If you have a transmitter, details of how to use this device will be explained by your healthcare professional and can be found in the 'easypod® connect transmitter Instructions For Use'.

1. Connect your transmitter and prepare it for data transmission as described in the 'easypod® connect transmitter Instructions For Use'.
2. On your easypod®, choose **Menu > Data transfer** and press **Open** to confirm. The **Place in transmitter** message will be displayed.
3. Press **Yes**. The **Infrared connection** message will be displayed while easypod® connects to the transmitter. You may also see the hour glass timer.
4. Place your easypod® in the transmitter with the screen facing you.
5. When a connection has been successfully made, data transfer will begin. Your easypod® displays the **Transfer to database** message while the transfer takes place.
6. When completed your easypod® displays the **Data transfer completed** message.
7. Remove your easypod® from the transmitter and choose **Back > Exit** to return to the information screen.

Your easypod® has a reminder function to help users to remember to make weekly data transmissions. This reminder can be switched on or off by your healthcare professional, see the 'Connection' chapter in section 7.2.





Troubleshooting and warning messages

This section gives you help and advice on overcoming problems with your easypod[®] and the injection procedure.

There are also answers to some frequently asked questions.

For anything you cannot find here, please contact your healthcare professional.

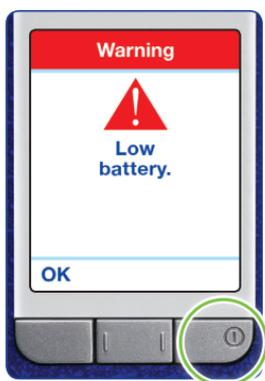
6.1 Replacing the battery

A **Low battery** warning indicates that the battery level is running low. The batteries must be changed within 24 hours.

A **Replace battery** warning indicates that the battery has run out. You will not be able to continue until the batteries are changed.

NOTE:

easyPod® uses 4 × AAA Lithium batteries. Only Lithium batteries should be used as they have a high capacity and will not run out unexpectedly. Rechargeable or alkaline batteries cannot be used. Be careful to correctly orientate the batteries as shown in the battery container. 4 × AAA Lithium batteries will normally last around one year.



Turn off the device.





NOTE:

- Remove batteries if the device is not used for at least one month.
- Risk of fire: batteries can explode or leak and cause injury if installed backwards, disassembled, or charged incorrectly.
- Crushed or damaged batteries may result in a fire.
- Damaging a lithium battery may result in an internal short circuit.
- Keep the primary lithium batteries away from children.
- Use only the same type of Energizer Ultimate AAA (FR03) primary lithium batteries from the manufacturer and do not mix with other types.
- Cover the poles of the lithium batteries with an insulated material at the end of the battery life time before discarding them as per local regulations.
- Refer to section 3.1 *'Installing the batteries'*.

6.2 Warnings and Cautions

This section gives an overview of all warning and caution messages that may be displayed on your easypod®.

Should a warning or caution message appear, carefully read the text and follow the displayed instructions.

If you have questions or concerns, please contact your healthcare professional.



This warning indicates that easypod® has detected that the cartridge has been in the device for longer than the in-use expiration date. The cartridge **must** be changed.

Press **OK**, open the cartridge door and remove the expired cartridge.

Dispose of it safely in an acceptable biohazard (sharps) container.

IMPORTANT:

A used cartridge is a biohazard and **must** be disposed of correctly according to local regulations.



This warning indicates that the cartridge door is incorrectly closed.

Check that the cartridge door is properly closed.



This warning indicates that the cartridge is empty or that it does not contain enough Saizen® for your next injection.

Press **OK** and follow the procedure from the 'Changing a cartridge when empty' section.



This warning indicates that an error occurred with the cartridge.

Open the cartridge door and remove the cartridge. Check that the cartridge is not empty.

Push the cartridge gently into the cartridge container to ensure that it is correctly positioned in your easy pod® and close the cartridge door.

Press **OK**.

If the issue continues, please contact your healthcare professional.



This warning indicates that an error occurred during the needle attachment or detachment sequence.

Directly below are the different reasons why this warning message may appear:

1. This error message appears during needle attachment:

- Please check the sterility seal is completely removed from the cap.
- Please check you have inserted a new needle and not an empty cap.
- Please check the release button is not pressed during the attachment process (refer to section 4.4 '*Attaching the Serofine™ needle*').
- In case of failure with the 3 solutions above, the needle may be defective, please replace it and proceed with a new needle.

2. This error message appears during needle detachment:

- A needle is already attached to the cartridge. Make sure you place an empty cap and press the release button to detach it. In case of failure, taking great care, remove the needle cap and check the location of the needle. If it is loose and out of place, small pliers can be used to carefully remove the needle from your easypod® and discard it safely. If the needle is still attached to the base of the cartridge, push the needle cap back on. Press **OK** and follow the on-screen instructions to detach the needle safely. →

NOTE:

If this warning appears several times, it can also indicate a problem with the cartridge. If this occurs check the cartridge. Follow the 'Removing a cartridge before it's empty' instructions.

Try a new cartridge, if this fixes the problem, place the defective cartridge in your biohazard (sharps) container and report this to your healthcare professional.



This warning message indicates that a wrong cartridge has been inserted.

Press **OK**.

Remove the cartridge and check your cartridge is the correct medication (Saizen®) and is for the correct dose.

Insert a new cartridge.

If accepted, the device will display **Insert new needle**. Insert a new needle and follow screen instructions to start your injection.

If rejected, the device will show the **Wrong cartridge** warning again. Please contact your healthcare professional for help.



This warning indicates that the device has detected an issue with the needle cap attachment or detachment.

Below are the different reasons why this warning message may appear:

1. This error message appears during the needle attachment operation:

- Please check the needle cap is attached in a correct manner (without delay). Refer to '*Attaching the Serofine™ needle*' section.
- Please check the release button is not pressed during the attachment process (refer to '*Attaching the Serofine™ needle*' section).

2. This error message appears when the device is ready for injection:

- The needle cap must not be inserted while the device prompts **Place on skin. Press injection button.**

3. This error message appears during the needle detachment operation:

- Please check the needle cap is detached in a correct manner (without delay). Refer to '*Detaching the Serofine™ needle*' section.
- Once you have attached an empty cap to initiate the detachment process, press the release button until you hear 2 beeps from your easypod®. →

4. This error message appears when switching on the device:

- The device has been switched off with the needle cap still attached to the device. Please remove the needle cap by pushing it sideways until it clicks free and can be dropped out.



This warning indicates that an error occurred during the needle detachment sequence.

1. This error message appears when switching on the device:

- Remove the cap and check whether the needle is in the cap or left in the device. Press **OK** if the needle has been correctly detached and is in the cap.
- If the needle is still attached to the base of the cartridge, replace the needle cap and press **Repeat** to carry out the needle detachment sequence again.

2. This error message appears during the needle detachment process:

- The needle release button is not pressed correctly (refer to 'Detaching the Serofine™ needle' section) so the needle is still attached to the device.

NOTE:

During the needle detachment sequence, ensure that the needle release button is pressed until easypod® beeps twice. If you still cannot detach the needle, small pliers can be used to carefully remove the needle from your easypod® and discard it safely. Alternatively, contact your healthcare professional for help.



This warning indicates that the connection between your easypod® and the easypod® connect transmitter has failed.

Press **OK**.

With a damp cloth clean the infrared connector of both the easypod® auto-injector and the easypod® connect transmitter.

Then replace your easypod® in the easypod® connect transmitter and follow further instructions as displayed on easypod®.



This warning indicates that the easypod® connect transmitter cannot find any mobile phone signal.

Check network coverage using your mobile phone. If there is no sufficient signal, move the easypod® connect transmitter to a place where network coverage is available. Alternatively ask your healthcare professional to transfer your injection data using a USB cable and a computer.



This warning may be displayed in a number of situations. Some may occur because the transmitter could not connect to the online database due to maintenance work or other problems.

Try connecting again later. If the problem continues, contact your healthcare professional for help.

6.2 Warnings and Cautions (continued)



This warning indicates that the device temperature is below 4°C (39°F) to avoid potential malfunctioning.

Press **Off** to turn off the device and try the device again after leaving it on a table, out of its storage box, for 5 minutes at room temperature.

It is also possible to leave the device turned on.

When the message disappears easypod® is ready to inject.



This warning indicates a software or hardware error and your easypod® needs to be restarted.

Press **Off** to switch your easypod® off.

Try turning on your easypod® again to restart. If this message reappears, your easypod® will eventually display a **Device error** warning and you will not be able to use the device.

If you continue to have problems contact your healthcare professional for help.



This warning indicates a permanent software or hardware error and the device needs to be returned.

Contact your healthcare professional for help.

6.3 Dropped device

easypod® has a self-checking mechanism to ensure mechanical problems will not lead to dosing errors. If you have dropped easypod® and it still turns on, you must check the device and the cartridge to make sure there are no signs of cracks or damage.

To confirm the cartridge is not cracked or damaged, remove the cartridge following the *'Removing a cartridge before it's empty'* procedure in section 5.4. Check the cartridge carefully. If there are any signs of damage (such as cracks or cloudiness), remove the cartridge and contact your health care professional. You may send the damaged cartridge back for investigation purposes. If the cartridge breaks inside the device, you should take care not to get hurt by broken glass.

If a cartridge has broken inside your easypod® you should stop using it immediately, as the electronics or mechanics can be damaged by the liquid or pieces of broken glass. Contact your healthcare professional for help.

In the event of a mechanical problem, easypod® will shut down automatically or may display the **Device failure** message. In this case, contact your healthcare professional for a replacement of easypod®.



NOTE:

Do not attempt to repair your easypod®.
No modification of this device is allowed!

6.4 Frequently asked questions

1. What if I cannot turn my easypod® on?

- Ensure that when you turn on easypod®, you hold down the selection button on the right (power on) until the **Welcome** screen appears.
- Leave the device at room temperature for 5 minutes as a very cold fridge can affect the performance of the batteries. Then try switching on the device again. To switch on your device you need to hold the right selection button (power on) for usually about 5 to 7 seconds.
- Check that you are using the correct type of batteries and that they are correctly inserted. If needed, insert a new set of 4 × AAA Lithium batteries and try again.

2. What if I cannot select a different cartridge type?

Only healthcare professionals are allowed to change the cartridge type. Two reasons can prevent changing the cartridge type :

- Another cartridge type is currently inserted in the device.

In this case, remove the cartridge from the device before changing the cartridge type.

- The new cartridge type to be selected is not compatible with the current dose set in the device.

In this case, check the minimum and maximum dose corresponding to the new cartridge type to be selected. Adjust the dose if required.

3. What if easypod® turns off unexpectedly or if it freezes on a screen?

Go to the main menu and select **Battery status** to check the batteries. If the problem persists, insert new lithium batteries.

4. What if I cannot insert the needle cap into my easypod®?

Check that you are using Serofine™ needles and that the sterility seal on the needle cap has been completely removed before insertion as described in the '*Attaching the Serofine™ needle*' section. If you still have difficulties, try using a new needle.

5. What if I cannot attach a needle to my easypod®?

Make sure you are using Serofine™ needles and that the sterility seal on the needle cap has been completely removed. Try re-attaching the needle to your easypod®. If you still cannot attach the needle, try a new needle.

6. If the needle is not properly in place, will easypod® still try to inject?

No, easypod® will only begin an injection sequence once a needle is properly attached. If it is not properly attached, a warning message will be displayed.

7. What if I accidentally press the injection button before I am ready?

The injection button will not work unless the skin sensor is in contact with your skin, so pressing it accidentally while preparing will have no effect.

8. What if I remove easypod® from my skin during an injection?

If you remove easypod® from your skin during an injection (while the injection button light is flashing green), the injection will be interrupted and the needle will automatically retract. Your easypod® will stop administering medication.

easypod® will display a warning message indicating a partial injection has taken place, and the injection button light will turn red. Select **Yes** if you wish to continue with the remaining dose, change the needle and complete the injection. Select **No** if you do not wish to continue with the second part of the injection (but only a partial dose will have been injected).

After 5 minutes easypod® will re-set and the option for a partial injection will be removed.

9. What if I cannot detach a needle from my easypod®?

Check that the needle cap you are using to remove the needle does not already contain a needle (or anything else).

Try detaching the needle again using the needle cap, ensuring that you push the empty needle cap into the needle cavity until it clicks into place. Make sure you are holding the needle release button until you hear the beep to indicate the needle has been released. If you still cannot detach the needle, contact your healthcare professional for help.

10. What if I lose the empty needle cap?

The empty cap is necessary to detach the needle. If you cannot find it, you might be able to detach the needle using small pliers. Carefully remove the needle from your easypod® and discard it safely. Or call your healthcare professional for help.

11. What if I cannot open the cartridge door?

Normally, the cartridge door can only be opened when easypod® is turned on and the cartridge is empty. Do not use any tools to force the cartridge door open. If you need to remove a cartridge before it is empty, use the **Remove cartridge** menu setting. See instructions under section 5.4 *'Removing a cartridge before it is empty'*.

12. When I change the date or time, what happens to the dose history?

Using your easypod® while the date or time are set incorrectly will mean the dose history is wrong.

You can adjust the date or time on your device by going to the **Device settings** option on the menu. Changing the date or time will not affect the previous dose history.

13. What if I need to travel with my device?

Your Saizen® medication needs to be stored according to the Saizen® patient information leaflet. You should insofar as possible leave your cartridge of medication in the fridge or use the travel bag to keep your cartridge within the device at a correct temperature. The device is safe to pass through X-ray airport security gate. It is recommended to remove the cartridge from the device beforehand.

14. What if I notice a drop of Saizen® on my skin after the injection?

If you notice a drop of Saizen® on your skin when you remove your easypod®, you may need to:

- reduce the injection speed, and/or
- increase the injection depth, and/or
- increase the injection time to at least 11 seconds (the available range is 3 to 30 seconds).

You may need to discuss with your healthcare professional how to best adjust these settings.

15. How do I reset the device in English?

If your easypod® is set to a language you don't understand, turn off your easypod®. Next, press and hold down the middle and the right button for 10 seconds. The **Reset to English?** message is displayed. Press **Yes** to reset to English.

6.5 Replacing your easypod®

Your easypod® can be used for up to 3 years after which it **must** be replaced. Please contact your healthcare professional for a replacement.

Record the serial number and date that you first started using your easypod® here:

Day	Month	Year

Serial number (16 digits after Serial number symbol ([SN]) on rear label of easypod®)

--





Additional information for healthcare professionals

The information in this section is a reference guide for healthcare professionals working with **easypod[®]**.

7.1 Healthcare professional tips to train easypod® users

1. Present an overview of the device with general functionalities
2. Injection technique
 - Demonstrate the 3-step injection sequence
 - Allow time for user to perform the injection sequence
 - Perform the injection sequence once more in case the user has any problems
3. Changing the cartridge and battery
 - Demonstrate how to manually remove a non-empty cartridge
 - Demonstrate how to replace batteries
4. Menu demonstration
 - Show how to navigate between the menus
 - Give a brief overview of the different main menus available
 - Go through the dose history log
 - Go through the comfort settings
 - Show how to set date/time and language
5. Inform user how to travel with easypod®
6. Do a quick presentation of the Instructions For Use

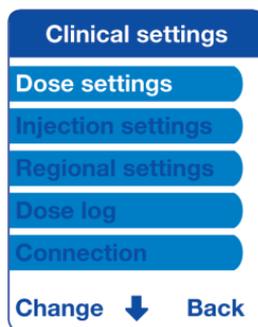
7.2 Clinical settings

IMPORTANT:

Clinical settings have to be adapted to patient treatment otherwise this may lead to wrong dose injection.

Some parameters have to be set by the healthcare professional prior to use of the device by the patient. This includes:

- Daily dose setting
- Dose adjustment setting
- Data transfer reminder setting (only to be activated if patient uses transmitter)



These settings are protected by a PIN code and must not be changed by the user.

IMPORTANT:

Do not change the settings listed above unless you are a qualified healthcare professional.

NOTE:

The default settings are:

- needle speed: medium
- injection speed: medium
- injection depth: 6 mm
- injection time: 5 s



To change a clinical setting:

1. Choose **Menu > Clinical settings** and press **Open** to select.

The **Changes can affect treatment** warning message is displayed. easypod® beeps three times to highlight the warning.

2. Press **OK** to continue (or **Exit** to return to the main menu).

The PIN code screen is displayed.

3. Use the **↑** button to select the number you need.
4. Press **OK** to select and move the cursor forward.
5. Repeat steps 3 and 4 until you have selected your PIN code and then return to the **Clinical settings** menu.

Dose settings

easypod® offers three options to set the daily dose:

- Input in mg
- By weight
- By body surface

The dose range available in these settings depends on the type of cartridge selected.

Cartridge content	concentration	cartridge
Saizen® 6 mg	5.83 mg/ml	Solution for injection 
Saizen® 8 mg click.easy®*	5.83 mg/ml	Powder and solvent for solution for injection 
Saizen® 12 mg	8.00 mg/ml	Solution for injection 
Saizen® 20 mg	8.00 mg/ml	Solution for injection 

**may not be available in all countries*

For more information on how to set the cartridge type see the 'Setting the cartridge type' section further down in the same chapter.

Dose range

The dose range depends on the type of cartridge selected:

- 5.83 mg/ml concentration cartridge: range can vary between 0.15 mg to 4.66 mg in 0.01 mg increments.
- 8.00 mg/ml concentration cartridge: range can vary between 0.50 mg to 6.40 mg in 0.01 mg increments. Solution for injection formulation only.

Setting input in mg

This setting allows the healthcare professional to set the daily dose in milligrams.

To change this setting:

1. Choose **Clinical settings** > **Dose settings**.
2. Press **OK** to select **Input in mg**. The **Daily dose** screen is displayed showing the current daily dose.

-
3. Use the **↑** button to select the number you need.
 4. Press **OK** to confirm and move the cursor forward.
 5. Repeat steps 3 and 4 until the new daily dose is displayed.
 6. The **Frequency** menu is displayed.
 7. Use the **↓** button to select either **6 days/week** or **7 days/week**.
 8. Press **OK** to confirm, the **Dose confirmation** screen is displayed. This shows the dose setting you have selected. If it is correct, press **OK** to confirm and continue. If you need to change it, press **Back**.
 9. Pressing the **OK** button displays the **Dose adjustment** menu. See under the '*Dose adjustment*' section further down in the same chapter for information on this setting.

Setting by weight

This allows the healthcare professional to set the daily dose per kilogram of the patient's body weight. If the dose is set by weight, then the device does the calculation based on weight and injection frequency in order to ensure that the total weekly dose [based on 7 days] is met. To change this setting:

1. Choose **Menu > Clinical settings > Dose settings**.
2. Use the **↓** button to scroll to **By weight** and press **OK** to select. The **By weight** screen is displayed showing the current daily dose, patient weight, current posology and frequency.
3. Press **Change** to make changes to these settings. The **Weight** screen is displayed showing the patient's weight.
4. Use the **↑** button to set the first digit of the weight.
5. Press **OK** to confirm and move the cursor forward.
6. Repeat steps 4 and 5 until the new weight is displayed.
7. Press **OK** until the **Posology** screen is displayed.
8. Use the **↑** button to set the first digit of the daily dose in milligrams per kilogram body weight.

9. Press **OK** to confirm and move the cursor forward.
10. Repeat steps 8 and 9 until the new setting is displayed.
11. The **Frequency** menu is displayed.
12. Use the **↓** button to select either **6 days/week** or **7 days/week**.
13. Press **OK** to confirm, the **Dose confirmation** screen is displayed. This shows the dose setting you have made. If it is correct press **OK** to confirm and continue. If you need to change it, press **Back** to return to the **By weight** menu or **Change** to return to the **Dose settings** menu.
14. Pressing **OK** displays the **Dose adjustment** menu. See the '*Dose adjustment*' section further down in the same chapter for information on this setting.

Setting by body surface

This allows the healthcare professional to set the daily dose per square meter of the patient's body surface. If the dose is set by body surface then the device does the calculation based on body surface and schedule in order to ensure that the total weekly dose [based on 7 days] is met.

To change this setting:

1. Choose **Menu > Clinical settings > Dose settings**.
2. Use the **↓** button to scroll to **By body surface** and press **OK** to select. The **By body surface** screen is displayed showing the current daily dose, patient height, patient weight, current posology and frequency.
3. Press the **Change** button to make changes to these settings. The **Height** screen is displayed showing the patient's height.
4. Use the **↑** button to set the first digit of the height.
5. Press **OK** to confirm and move the cursor forward.
6. Repeat steps 4 and 5 until the new height is displayed.
7. The **Weight** screen is displayed showing the patient's weight.

-
8. Use the **↑** button to set the first digit of the weight.
 9. Press **OK** to confirm and move the cursor forward.
 10. Repeat steps 8 and 9 until the new weight is displayed.
 11. Press **OK**, the **Posology** screen is displayed.
 12. Use the **↑** button to set the first digit of the dose in milligrams per square meter of surface per day.
 13. Press **OK** to confirm and move the cursor forward.
 14. Repeat steps 12 and 13 until the new setting is displayed.
 15. The **Frequency** menu is displayed.
 16. Use the **↓** button to select either **6 days/week** or **7 days/week**.
 17. Press **OK** to confirm, the **Dose confirmation** screen is displayed. This shows the dose setting you have selected. If it is correct, press **OK** to confirm and continue. If you need to change it, press **Back** to return to the **By body surface** menu or **Change** to return to the **Dose settings** menu.
 18. Pressing **OK** displays the **Dose adjustment** menu. See the '*Dose adjustment*' section further down in the same chapter for information on this setting.

Dose adjustment

Dose adjustment is a feature designed to minimize the wastage of medication when, as a cartridge gets close to being finished, there is not enough medication left for a full daily dose. Using this setting enables easy pod[®] to be set to use almost all the medication from the cartridge, even if it is not a full dose.

There are two settings: **Off** and **Automatic**.

1. Dose adjustment is set to **Off**:

When easypod® detects that the cartridge contains less than the full daily dose, you can either:

- Change the cartridge, injecting the full daily dose from a new cartridge

or

- Inject the remaining medication and record this partial dose as the daily dose

or

- Make two injections which amount to the full daily dose.

The first injection uses the medication remaining in the current cartridge. The second injection is made with a new cartridge. easypod® calculates the correct partial dose to complete a full dose.

2. Dose adjustment is set to **Automatic**:

The **Dose spread** menu is displayed. Using the settings from this menu, easypod® will calculate the dose as close as possible to the selected 'required dose' while optimizing the use of the cartridge contents, leaving a minimal amount unused.

There are two choices on the **Dose spread** menu, which allow the healthcare professional to set the amount of variation in the dose:

- <10%: easypod® will allow an automatic $\pm 10\%$ dose adjustment of the daily dose setting.
- <25%: easypod® will allow an automatic $\pm 25\%$ dose adjustment of the daily dose setting.

Press **OK** to select a setting and the **Automatic adjustment** screen will be displayed showing the new, adjusted, daily dose.

Check settings

This allows healthcare professionals to check the current dose settings. To check the settings:

1. Choose **Menu > Clinical settings > Dose settings**.
2. Use the **↓** button to scroll to **Check settings** and press **OK** to select.
3. The **Current dose settings (1)** screen is displayed, this is the first of two information screens.
4. Press **Next** to view the **Current dose settings (2)** page which shows the current Dose adjustment settings or press **Back** to return to the **Dose settings** menu.

Injection settings

These settings enable a healthcare professional to choose settings for the cartridge and the needle.

Setting the cartridge type

The **Cartridge settings** enable a healthcare professional to set the cartridge type. easypod® can be used with two Saizen® cartridges:

Cartridge content	concentration	cartridge
Saizen® 6 mg	5.83 mg/ml	Solution for injection 
Saizen® 8 mg click.easy®*	5.83 mg/ml	Powder and solvent for solution for injection 
Saizen® 12 mg	8.00 mg/ml	Solution for injection 
Saizen® 20 mg	8.00 mg/ml	Solution for injection 

**may not be available in all countries*

The cartridge type must be set when there is NO cartridge in the device:

1. Choose **Menu > Clinical settings > Injection settings**.
2. Press **Change** to open the **Cartridge** menu.

3. Use the **↓** button to scroll to the cartridge type.
4. Press **OK** to confirm.
5. The **Cartridge** screen shows the cartridge type which has been set.
6. Press **OK** to confirm and return to the **Injection settings** menu.

When you have finished making changes, choose **Back > Back > Exit** to return to the information screen.

Setting the needle type

The **Needle type** setting enables healthcare professionals to set the needle type. easypod® must only be used with Serofine™ single-use, disposable sterile needles (not included).

easypod® can use three needle types:

- 0.33 mm × 12 mm (29G × 1/2")
- 0.30 mm × 8 mm (30G × 5/16")
- 0.25 mm × 8 mm (31G × 5/16").

To set the needle type:

1. Choose **Menu > Clinical settings > Injection settings**.
2. Use the **↓** button to scroll to **Needle type** and press **Change** to select.
3. Press **OK** to confirm and return to the **Injection settings** menu.
4. Choose **Back > Back > Exit** to return to the information screen.

Regional settings

This setting allows the healthcare professional to configure easypod® for use in a specific region. easypod® can be set to one of three regions:

- Canada
- International
- Japan

The **Regional settings** option affects the following easypod® settings:

- The expiration date for the powder and solvent dried formulation Saizen® cartridges. Once the expiration date has been reached, easypod® will display a **Cartridge expired** warning message and the cartridge will have to be changed.
- The language can be re-set to another language through the **Device settings > Language** option.

To select a regional setting:

1. Choose **Menu > Clinical settings > Regional settings**.
2. Use the **↓** button to scroll to the required regional setting (**Canada, International, Japan**).
3. Press **OK** to confirm. The Confirmation screen is displayed, showing the new regional setting.
4. Press **OK** to confirm and return to the **Clinical settings** menu.
5. Choose **Back > Exit** to return to the information screen.

Dose log

easypod® records the date and time of every injection, enabling healthcare professionals to monitor the dose history. This recording function can be switched on or off using the **Dose log** option. See the '*Dose history*' section for details on dose history information.

NOTE:

When the Dose log function is switched off, easypod® will still record the injection data, which can be transferred to the easypod® connect database (see below).

To switch the **Dose log** on or off:

1. Choose **Menu > Clinical settings > Dose log**.
2. Use the **↓** button to scroll to **ON** or **Off**.
3. Press **OK** to confirm and return to the **Clinical settings** menu.
4. Choose **Back > Exit** to return to the information screen.

Connection

Using easypod® connect transmitter, easypod® can transfer injection history and additional technical information to a database used by healthcare professionals.

To connect to the Transmitter:

1. Choose **Menu > Clinical settings > Connection**.
2. Use the **↓** button to scroll to **Transmitter**.
Press **Yes** to confirm.



The **Place in transmitter** message will be displayed.

1. Press **Yes**. Place easypod® in the transmitter cradle with the screen facing you.
2. The **Infrared connection** message will be displayed while easypod® connects to the transmitter. You may also see the hour glass timer.
3. When a connection has been successfully made, data transfer will begin. easypod® displays the **Transfer to database** message while the transfer takes place.
4. When completed easypod® displays the **Data transfer completed** message. Refer to transmitter Instructions for Use (IFU) booklet.
5. You can transfer data from the transmitter to your computer via a USB cable. Please refer to easypod® connect transmitter IFU.

NOTE:

- Do not use this data for diagnostic purposes.
- Data transmission can only take place 10 times per day.

Setting the data transfer reminder

easypod® has a reminder function to help users to remember to make weekly data transmissions. This reminder can be switched on or off. Switch off the reminder function if your patient does not use the easypod® connect transmitter.

To activate a data transfer reminder in order to alert the user to the need to upload data:

1. Choose **Menu > Clinical settings > Connection > Reminder** and press **Open** to confirm.
2. Use the **↓** button to scroll to **ON** or **Off** to turn the reminder function on or off.
3. Press **OK** to confirm and press **Back** to return to the **Connection** menu.
4. Choose **Back > Back > Exit** to return to the information screen.

PIN code

NOTE:

The initial easypod® PIN code is provided to healthcare professionals separately from the IFU. It should only be changed by a healthcare professional and only with great care. If the PIN code has been lost or forgotten, the healthcare professional can obtain upon request an override PIN code from the easypod® local representative.

This setting can be used to change the PIN code used to access the **Clinical settings**. To change the PIN code:

1. Choose **Menu > Clinical settings > PIN code**.
2. The **PIN code** screen is displayed showing the current PIN code.
3. Use the **↑** button to select the first digit.
4. Press **OK** to confirm and move to the next digit.
5. Repeat steps 3 and 4 until the new PIN code is displayed.
6. Press **OK** to confirm and return to the **Clinical settings** menu.
7. Choose **Back > Exit** to return to the information screen.





Technical data & Appendix

8

8.1 Technical data

Brand/ Product name	easypod®		
Model	6.0		
Weight	280 g (10.3 oz)		
Dimensions	H: 128 mm × W: 66 mm × D: 37.15 mm		
Voltage supply	6 VDC		
Supply	4x Batteries Energizer Type L92 Ultimate Lithium, size AAA, FR03, 1,5V		
Battery life	approx. one year with lithium batteries		
Serial number	number with 16 digits printed after the Serial number symbol (SN) on the device label (under the rear cover)		
Software version	6.x or higher		
Compatibility	easypod® connect transmitter; and easypod® connect software.		
Medical device classification	MDD 93/42/EEC Class IIa		
Electrical classification	IP 52 (protection against dust and dripping water when held in normal position). Applied part type BF on the whole device 		
Electromagnetic compatibility	in accordance with EN60601-1-2 (see EMC tables at the end of the instruction manual)		
Operating environment	7°C to 30°C (45°F to 86°F), 20% RH to 90% RH, at least 800 hPa		
Transport and storage conditions	In between uses	When the cartridge is inserted	Refer to Saizen® Patient Information Leaflet and <i>storing your easypod®</i> section. Note: After storage at extreme conditions and when placed at room temperature (20°C), your easypod® may take up to 1h30 to reach its operating conditions.
		Without the cartridge	-20°C to 60°C (-4°F to 140°F), 0% to 90% RH, 800hPa to 1060hPa
	Before first use	-20°C to 60°C (-4°F to 140°F), 20% to 75% RH, 800hPa to 1060hPa	
Memory	All data (except date & time) is stored permanently in the device		
Cartridge	Merck Saizen® growth hormone 3 ml cartridges		
Maximum injection volume	0.800 ml		
Dose accuracy	+/-10% for dose above 0.250 ml and +/-0.025 ml for dose below 0.250 ml		
Needles	Serofine™ needles 0.33 mm × 12 mm (29G × 1/2"); 0.30 mm × 8 mm (30G × 5/16") or 0.25 mm × 8 mm (31G × 5/16").		

Opening the device will void any guarantee.

Explanation of symbols

	Refer to instruction manual/booklet		Direct Current
	Power on/off		Date of manufacture
	Manufacturer		Applied part type BF (electrical isolation)
	Keep dry	CE2797	CE marking of conformity
	Use by date		Store upright
	Do <u>not</u> freeze		Temperature limit
	Humidity limitation		Atmospheric pressure limitation
REF	Catalogue number	SN	Serial number
	The distributor of the product contributes to the cost of recycling of the packaging.		
	<p>Dispose of safely according to your local regulations.</p> <p>Collection and treatment of electrical and electronic equipment*</p> <p>This symbol indicates that this product should not be disposed with household waste. It has to be returned to a local authorized collection system. By following this procedure you will contribute to the protection of the environment and human health. The recycling of the materials will help to conserve natural resources.</p> <p><i>* valid in the EU member states and in any countries with corresponding legislation.</i></p>		

Explanation of images on the cardboard box



For Saizen® solution for injection formulation, the cartridge label must not be removed. Check that the label with the information strips is present and undamaged; otherwise the device will reject the cartridge.



For Saizen® click.easy® powder and solvent formulation, make sure the peel-off label on the cartridge is removed. Check that the second label with information strips is present and undamaged, otherwise the device will reject the cartridge.

Essential Performances

The essential performances of the easypod® auto-injector are cartridge recognition and dose accuracy.

8.2 Appendix

easypod® is intended for use in a Home Healthcare environment having the characteristics specified below. User shall ensure that easypod® is used under the following conditions in order to maintain its essential performances. Should easypod® be operated outside of the specified conditions, the device might stop working.

⚠ WARNING

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the auto-injector, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of easypod® adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, easypod® and the other equipment should be observed to verify that they are operating normally. easypod® can be used with the easypod® connect transmitter device.

Electromagnetic Emissions		
Conducted and radiated RF emission according to CISPR 11	Group 1	easypod® uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
	Class B	easypod® is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Electromagnetic Immunity

Immunity test	EMC standard	Compliance level	Guidance
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	-
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to the following table	-
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital Environment.
Electrical fast/transient bursts	IEC 61000-4-4	-	Not applicable
Surges (line-to-line/line-to-ground)	IEC 61000-4-5	-	
Conducted disturbances induced by RF fields	IEC 61000-4-6	-	
Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11	-	
Voltage interruptions	IEC 61000-4-11	-	
Electrical transient conduction along supply lines	ISO 7637-2	-	

Immunity to proximity fields from RF wireless communications equipment						
Test Frequency (MHz)	Band (MHz)	Service	Modulation*	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5 500						
5 785						

*carrier modulated using a 50% duty cycle square wave signal

easypod® will sustain its EMC performances throughout its lifetime without any specific maintenance.









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