

easypod®

Instructions for Use

Model: 3

easypod® autoinjector delivers a pre-set dose of Saizen®.



EMD
SERONO

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Section 1

Introduction to easypod[®]



This section introduces you to easypod[®] and provides important safety information about using easypod[®] to deliver Saizen[®] medication.

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Section 1.1 About the device

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

- easypod® keeps track of your injections. You can review up to 12 months of injections in the History screen (from the current month and previous 11 months).
- 24 hours or more (6 or 7 injections per week) are recommended between injections. To prevent from injecting too often, easypod® warns you if a new injection is attempted less than 18 hours after the previous one.
- easypod® contains no harmful or toxic materials.

- easypod® will not save or transfer any personal information.
- If you have any questions, talk to your doctor or nurse.
- By turning on the "Data transfer" feature in easypod®, you can share your injection history with your doctor or nurse.

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



Section 1.2 Indications and contraindications

Indications for use:

easypod® is a reusable, electromechanical software-controlled autoinjector intended for subcutaneous (under the skin) injection of Saizen® medication (recombinant human growth hormone).

easypod® is indicated for use by patients treated with recombinant human growth hormone (Saizen®). The patient population is comprised predominantly of pediatric patients (treatment of children with growth failure due to growth hormone deficiency (GHD)) but also adult patients with GHD (treatment of adults with either adult onset or childhood onset GHD). Intended users of the product also include the patient's parents and caregivers, as well as their nurse, doctor and medical support staff. easypod® can be operated for self injection by patients who are at least seven years old.

easypod® facilitates the administration of Saizen® treatment, including self-administration for patients at home. In addition, easypod® supports adherence management by allowing the review

of automatically recorded date, time and dose of injections.

Contraindications for use:

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

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

Section 1.3 Safety precautions

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



Before you proceed, review these general warning and cautions.

- Carefully read all instructions in this booklet before using easypod® and follow these Instructions for Use while using easypod®. These Instructions for Use provide important safety information about easypod®.
- **DO NOT** discard these Instructions for Use. Keep this booklet in a safe place for future reference.
- You must be trained by a qualified doctor or nurse before using easypod®. If you have not received training, please contact your doctor or nurse.
- easypod® is a personal device for use by only one patient. **DO NOT** share easypod® with anyone else because other users might have a different treatment.



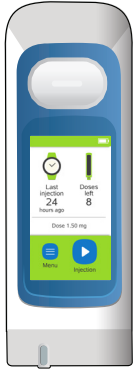
General warning and cautions (continued)



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

Section 1.4 Device and supplies

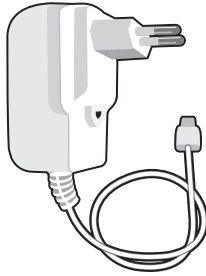
Items provided in device packaging:



1 easypod®
autoinjector



1 Battery



1 Battery charger*



1 Storage box



Instructions for Use**

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

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

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

A distributor list is part of device packaging.



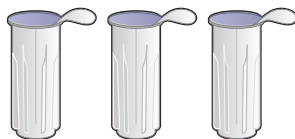
Other supplies needed:



Saizen® cartridges



Alcohol wipes



Serofine® needles



Biohazard (sharps)
container

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

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

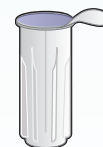
- easypod® autoinjector delivers Saizen® medication



- Saizen® cartridge containing Saizen® medication



- Serofine® needle (29G or 31G) for every injection. Use a new needle for each injection.

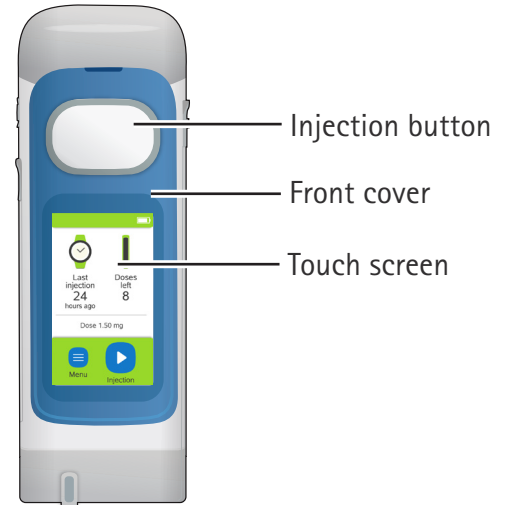


Section 1.4 Device and supplies (continued)

easypod[®] autoinjector

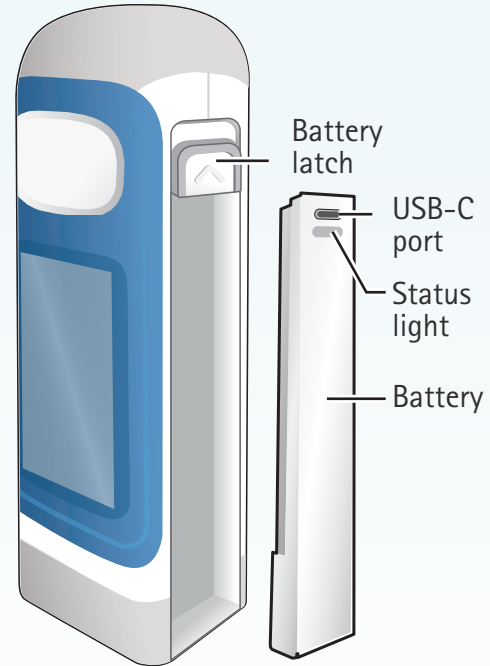
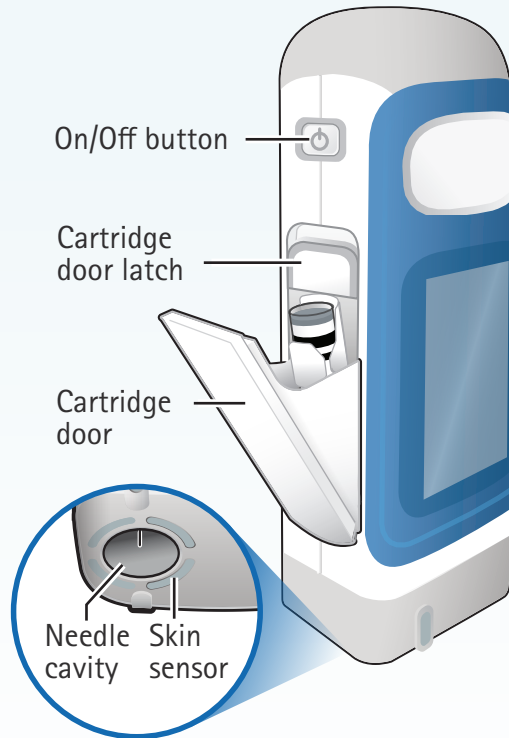
easypod[®] is an electromechanical device that automatically injects the set dose of medication through single-use needles it inserts and retracts on each injection.

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





Side views



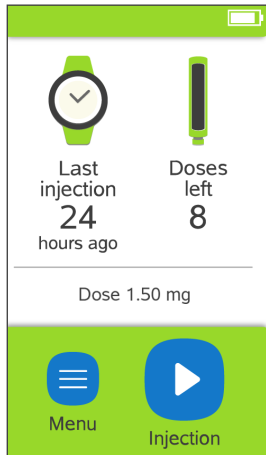
Section 1.4 Device and supplies (continued)

Touch screen

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

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

Buttons on the home screen:



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



On-screen injection button: begins the guided injection process



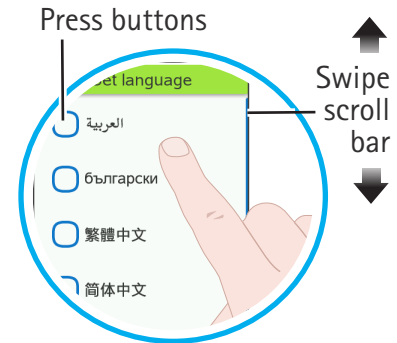
Last injection



Doses left

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

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





Saizen® cartridges

There are three Saizen® cartridge types compatible with easypod®:

- 6 mg (concentration: 5.83 mg/mL)
- 12 mg (concentration: 8.00 mg/mL)
- 20 mg (concentration: 8.00 mg/mL)

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

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

Detailed drug information and the administration of Saizen® is provided in the Saizen® Patient Information Leaflet.



6 mg (5.83 mg/mL)



12 mg (8 mg/mL)



20 mg (8 mg/mL)

WARNING: Make sure to use the correct Saizen® cartridge with your easypod®. Using the wrong cartridge can cause serious harm.

NOTE: DO NOT remove cartridge label. Otherwise easypod® will reject the cartridge.

Section 1.4 Device and supplies (continued)

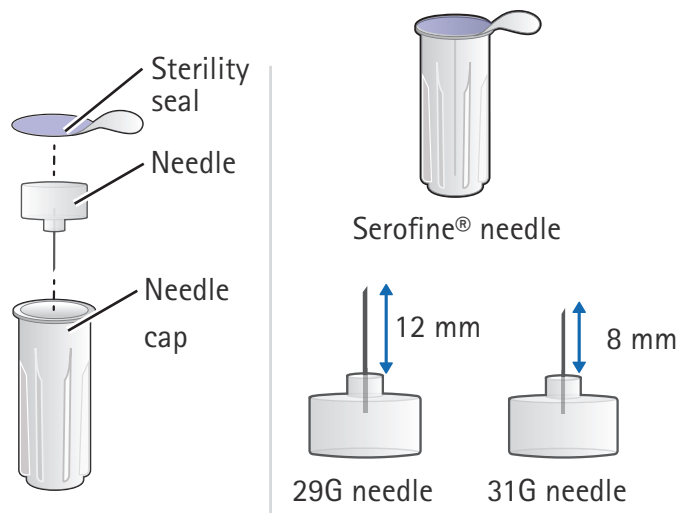
Serofine® needles

There are two Serofine® needle types compatible with easypod®:

- **29G × 1/2"**
(thickness: 0.33 mm × length: 12 mm)
- **31G × 5/16"**
(thickness: 0.25 mm × length: 8 mm)

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

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



WARNING

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



Discard supplies and device

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

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

Refer to Saizen® Patient Information Leaflet for cartridge disposal. Dispose of cartridges in the biohazard (sharps) container if:

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

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

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



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

Section 2

Getting started

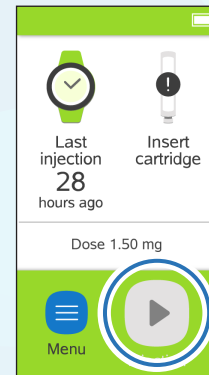


This section provides instructions for setting up the device before administering a first injection.

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

Reminders and tips for getting started with easypod®

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



Injection
button
disabled

Section 2.1 Charging the device

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

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

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



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

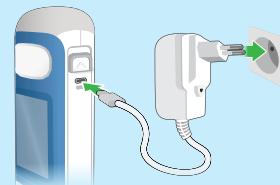
i NOTE: There are two ways to charge the battery:

Charge the battery while it is in the device.

OR

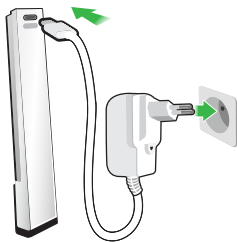
Remove the battery to charge it. Slide and hold the battery latch up, then slide the battery down to remove.

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



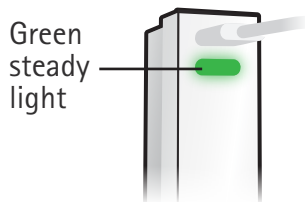
The socket-outlet must be easily accessible.

1 Connect battery to power source



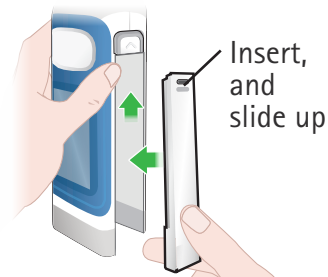
- Plug the battery charger's USB-C plug into the battery port.
- Plug the battery charger into a wall outlet.
- When the status light flashes green, battery is charging.

2 Confirm battery is fully charged



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

3 Insert battery into device



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

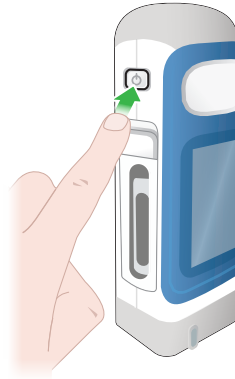
Now that the battery is charged, you can continue with *"Section 2.2 Enter device settings"*



Section 2.2 Enter device settings

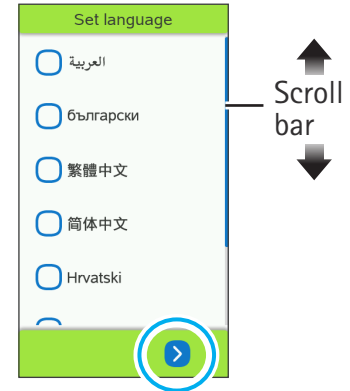
easypod® contains device and injection settings that will need to be set up before you can use the device. These settings can be changed later on at any time as well.

1 Turn on device



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

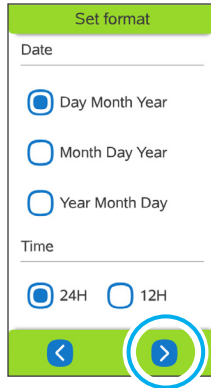
2 Set language



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

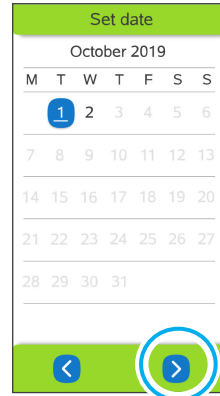


3 Set date format



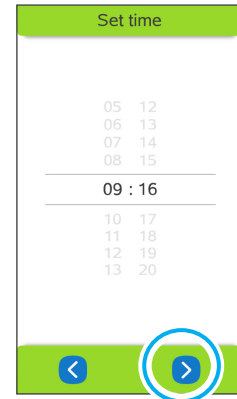
- Press checkbox to select the date format you prefer.
- Press  arrow to continue.

4 Set date



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

5 Set time



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

Section 2.2 Enter device settings (continued)

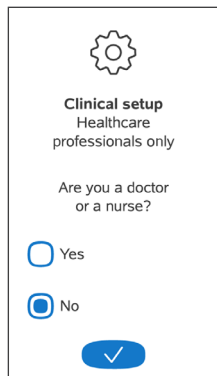
6 Your doctor or nurse must enter clinical settings



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

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

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




Clinical setup
Healthcare
professionals only

Are you a doctor
or a nurse?

☐ Yes

☒ No



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

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

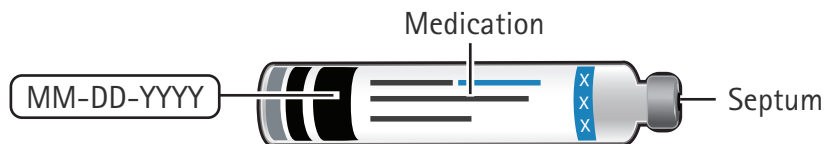
Section 2.3 Inserting cartridge

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

i NOTE

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

1 Get a new cartridge and inspect



Check that the:

- Packaging and cartridge label have the medication and dosage of Saizen® (6, 12, or 20 mg).
- Cartridge's expiration date has not passed.
- Cartridge is not cracked.
- Cartridge and medication correspond to the description in the Saizen® Patient Information Leaflet (PIL).



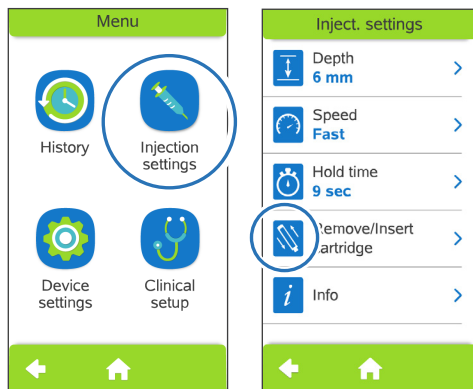
WARNING

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



Section 2.3 Inserting cartridge (continued)

2 Unlock cartridge door



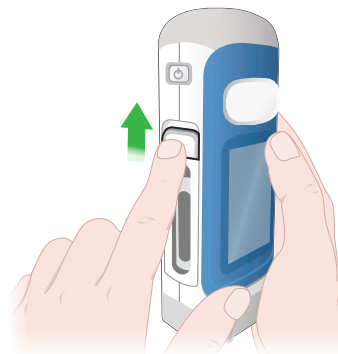
To unlock the cartridge door:

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

i NOTE: A screen might appear during first use prompting you to insert a cartridge.

DO NOT force open the cartridge door, this might damage the cartridge door.

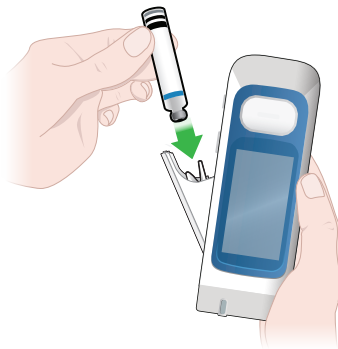
3 Open cartridge door



Slide cartridge door latch up to open door.

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

4 Insert cartridge



Insert cartridge into cartridge holder with metal tip pointing down.

5 Close cartridge door



Push cartridge door to close it.

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



Section 3

Injecting medication with easypod®



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

3.1 Prepare for injection	32
3.2 Attach needle	34
3.3 Administer the injection	36
3.4 Detach needle and confirm injection	38
3.5 Partial dose injection	40

Reminders and tips for injecting with easypod®

CAUTION

- DO NOT use easypod® if it is not working properly.
 - DO NOT attempt to modify, or repair the device, or an incorrect dose might be delivered. Contact your doctor or nurse in case of device malfunction.
 - DO NOT put the device or medication into the microwave to warm it up.
 - Adolescents must be supervised by a caregiver.
-
- If easypod® is stored in the refrigerator, it might be very cold, you may want to take out the device from the storage box and put it on a stable surface. Wait at least 30 minutes to let the device and the medication warm up to room temperature.
 - If condensation appears on easypod®, wipe it off with a clean cloth.
 - If the remaining content of the Saizen® cartridge is not enough for a full dose, easypod® will let you know (you can also see "*Section 3.5 Partial dose injection*").
 - There is no need to pinch skin at injection site.
 - easypod® will let you know if you try to inject too soon. You can also check the History menu to ensure you are taking your Saizen® injections about 18 hours apart.