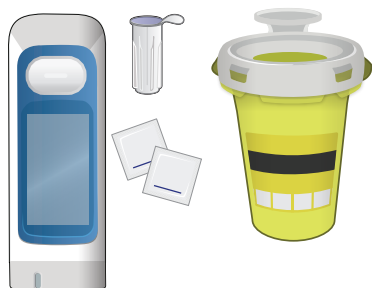# Section 3.1 Prepare for injection

① Gather supplies

Place all items listed below on a stable surface (e.g., a table) within easy reach:

- easypod® containing a cartridge (6, 12, or 20 mg)

- Serofine® needle (29G or 31G)

- Alcohol wipes

- Sharps container

② Check device

Before each injection, check the device. Make sure the cartridge and medication correspond to the Saizen® Patient Information Leaflet, and there are no signs of damage.
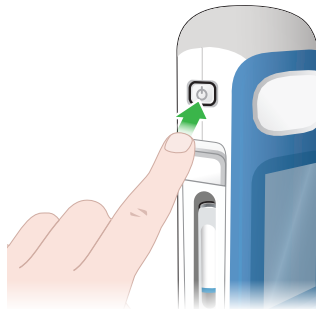
③ Wash hands
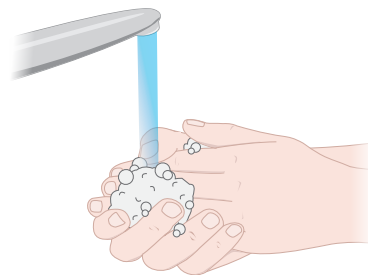
Wash your hands well with soap and water and dry them with a clean towel.

4 Prepare injection site

Select and prepare your injection site as discussed with your doctor or nurse.
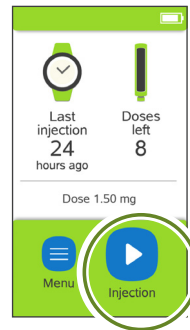
5 Turn on device

Press and hold on/off button until the display switches on.

After a few seconds the welcome screen will appear briefly, followed by the home screen.
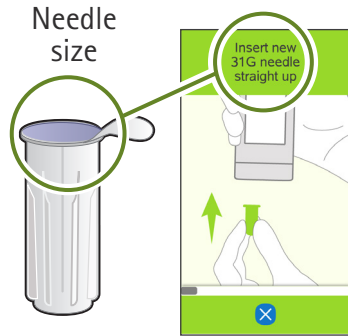
6 Press injection

Press ▶ on-screen injection button to start the injection process. easypod® will guide you step-by-step to administer an injection.

If easypod® displays "Less than 1 dose left" message, refer to *"Section 3.5 Partial dose injection"* to proceed.
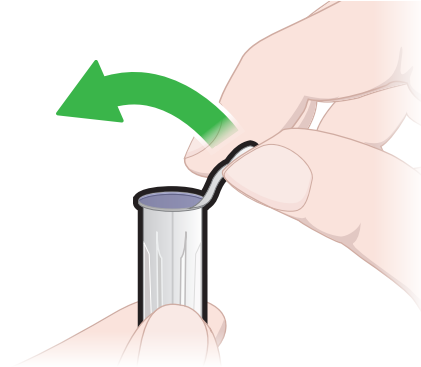
Section 3.2 Attach needle

1 Get a new needle

Needle size

Insert new 31G needle straight up

- Get a new Serofine® needle.
- Check that needle size (gauge "G") on the needle cap's sterility seal is the same as the needle size on easypod® screen.
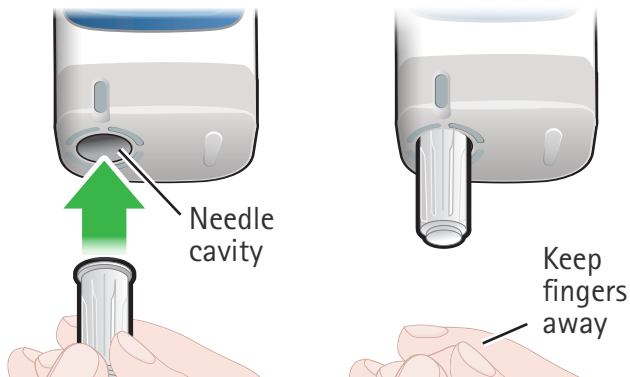- Check that the needle's expiration date has not passed.

2 Remove seal

Pull flap and fully remove sterility seal.

⚠️ **WARNING**

- Handle needles carefully to avoid injury.
- To avoid risks of injury or infection, **DO NOT** use needle if sterility seal is damaged or detached, the needle is expired or the needle gauge is wrong.

3 Insert needle, let go
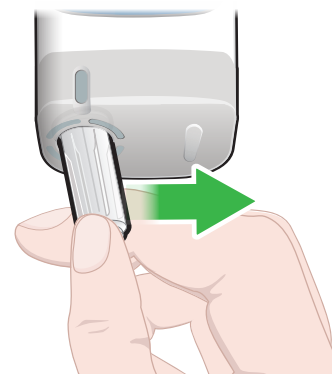

Needle cavity

Keep fingers away

When easypod® screen tells you "Insert new needle":

- Push needle cap with needle straight into the needle cavity until it clicks.

- Let go of the cap while the needle attaches.

⚠️ **WARNING: NEVER** insert fingers into the needle cavity to avoid needle stick injury.

4 Remove cap

When easypod® screen tells you to do so, push the needle cap sideways to remove it.

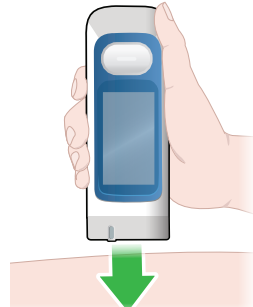**DO NOT** inspect the needle cavity when the device is ready for injection.

⚠️ **WARNING**

- **DO NOT** pull needle cap straight down. This might damage easypod®.

- Save the needle cap to safely remove and dispose the needle after injecting.

Section 3.3 Administer the injection

**1** **Hold device against skin**

Chime sound,
White ready light

Your doctor or nurse will show you how to inject**:**

a. Hold easypod® as straight as possible firmly against injection site, so the skin sensor fully touches your skin (there is no need to pinch the skin at the injection site).

b. When easypod® is in correct position and ready to inject, easypod® plays a chime sound and the injection button light will turn white.

ⓘ NOTE: If you **DO NOT** inject right away easypod® will give you instructions to:

- **After 60 seconds –** continue or cancel injection

- **After 10 minutes –** insert an empty needle cap to unload the expired needle. A new needle will have to be used to continue with the injection.

- **After 30 minutes –** the device will shut down and the cartridge will be rejected. When turned on, the device will ask you to replace the needle and cartridge.

2 Inject medication
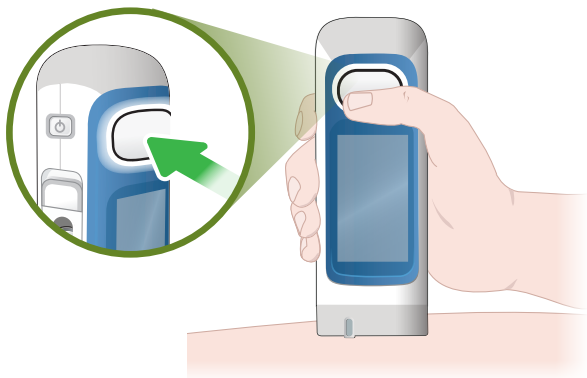
a. Press injection button once to begin injecting. The injection button light flashes white during the injection.

b. Keep easypod® steady and in contact with your skin for the entire injection.

⚠ **WARNING: DO NOT** move during the injection to avoid a needle stick injury.

3 Remove easypod®

Chime sound,
White ready light

a. When the injection is complete, easypod® plays a chime sound and the injection button light will stop flashing and turn off.

b. Lift easypod® from your skin.

c. If some medication remains on the skin after the injection, clean injection site.

Section 3.4 Detach needle and confirm injection

1 Insert needle cap, let go
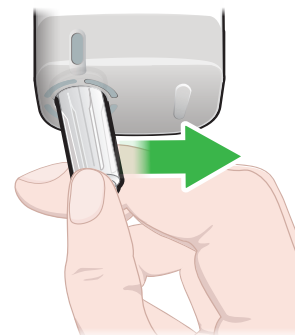
Needle cavity

Empty cap
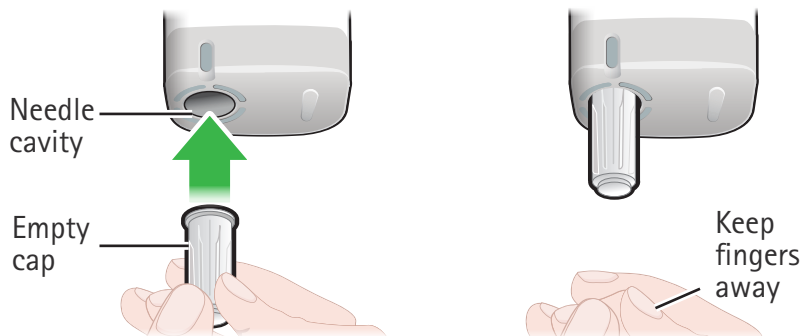
When easypod® screen tells you "Insert needle cap":

- Push empty needle cap straight into the needle cavity until it clicks.

- Let go of the cap while the needle detaches.

Keep fingers away

⚠ **WARNING**

- Always detach needle after injection using empty needle cap.

- **NEVER** insert fingers into the needle cavity to avoid needle stick injury.

2 Remove needle

When easypod® screen tells to, push the needle cap sideways to remove it.

⚠ **WARNING:** DO NOT pull needle cap straight down. This might damage easypod®.
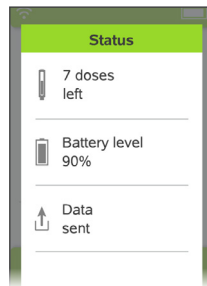
3 Dispose needle

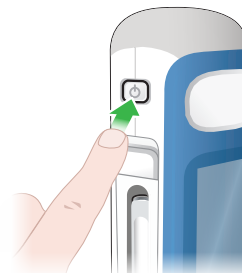Dispose of cap with needle in a biohazard (sharps) container.

> ⚠️ **WARNING**
> - Improper disposal may result in a needle stick injury to you and others.
> - **DO NOT** re-use needles to avoid risks of infection.

4 Confirm injection

a. Review the amount of doses left and battery charge on the screen.

b. Press ✓ to confirm the injection.

5 Power off and store device

a. Press and hold the on/off button until the display switches off.

b. Store easypod® upright in its storage box, and with cartridge inside as required by the Saizen® Patient Information Leaflet.

See *"Section 4.1 Storing device and cartridges"*.
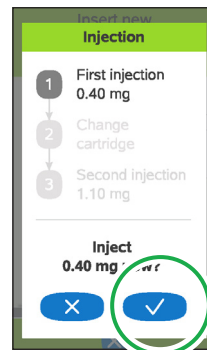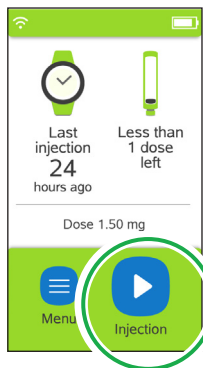
Section 3.5 Partial dose injection

easypod® can deliver a partial dose injection if your current cartridge does not contain enough medication for a full injection.

> ## ⓘ NOTE
>
> If the medication left in the current Saizen® cartridge is **not** sufficient for a full dose, easypod® will display "Less than 1 dose left".
>
> You can use the remaining medication to deliver a partial dose, or you can insert a new cartridge.
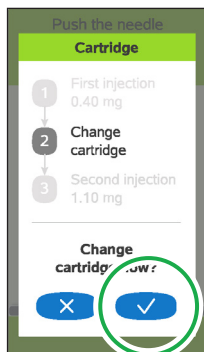
❶ Inject a partial dose

Continue to next steps

a. Press ▶ to start the injection process.

b. Press ✓ to confirm you want to take steps to use the rest of the cartridge for a partial dose.

Or, you can press ✕ and go to the Device settings to change the cartridge now, then inject a full daily dose at once.
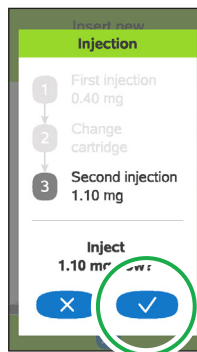
c. Attach a new needle and deliver a partial dose.

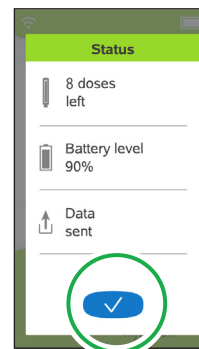See "Sections 3.1 to 3.4" for full injection instructions.

② Change cartridge, then change needle and inject remaining dose

a. Press ✓ to change cartridge now.

b. Press ✓ to change needle and deliver the remaining dose.

See *"Sections 3.1 to 3.4"* for full injection instructions. Or, you can press ✕ to exit and record only the partial dose.

c. Press ✓ to confirm and complete the dose.

⚠ **CAUTION:** Administer second partial dose injection (calculated by easypod®) **directly after** the first injection to complete the full daily dose. If you cancel the second partial dose injection, the next injection will be a full dose.

Section 4
Caring for the device

This section gives you instructions on how to take care of easypod® when traveling, storing, replacing easypod®, or changing a cartridge.

Reminders and tips to care for your easypod®

⚠️ **CAUTION: DO NOT** attempt to modify, or repair it, or an incorrect dose might be delivered. Contact your doctor or nurse in case of device malfunction.

- Only use Saizen® cartridges with easypod® that are stated in your prescription. easypod® will reject a wrong cartridge.

- easypod® containing a Saizen® cartridge should be stored according to the Saizen® Patient Information Leaflet.

- **DO NOT** remove cartridge label. easypod® will reject a wrong cartridge.

Section 4.1 Storing device and cartridges

General storage instructions
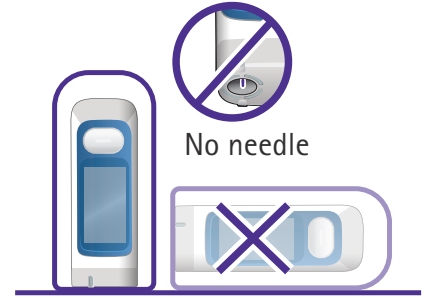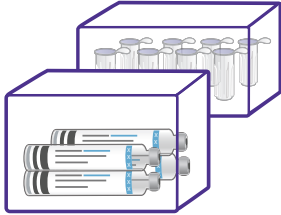
No needle

- Keep the unused Saizen® cartridges and Serofine® needles in their original packaging until you need them.

- Saizen® cartridges should be stored according to the Patient Information Leaflet (PIL).

- Discard each cartridge within **28 days after first injection** to avoid expired medication. easypod® will inform you when 28 days have passed.

- Before storing easypod®, make sure there is no needle in the device. Always store device upright, in its storage box, to avoid drops of Saizen® causing malfunction.

- If a cartridge is in the device, also refer to the storing conditions in the Saizen® PIL.

Section 4.2 Taking care of your device

If the device is dirty and you would like to wipe it, perform the following steps on the right.

If easypod® has been exposed to liquid, wipe it with a clean, dry or slightly damp cloth, then check for error messages (see section 6).

> ### ⓘ NOTE
>
> - **DO NOT** use any chemicals, cleaning solvents, detergents, or alcohol solutions, because this can damage the device.
>
> - **DO NOT** rinse or immerse any part of easypod® in water or any liquid.
>
> - **DO NOT** wipe easypod® more than once per week

To wipe the device
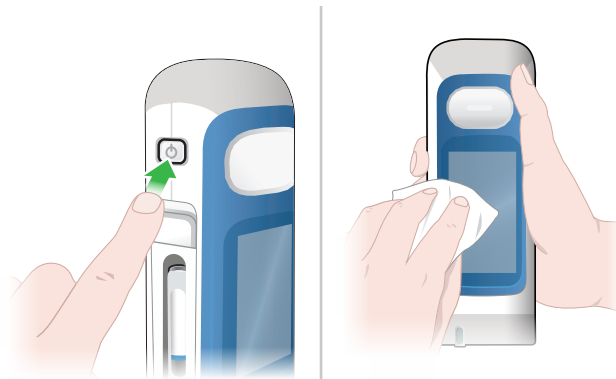
a. Make sure easypod® is turned off. If easypod® is on, press and hold on/off button to turn it off.

b. Wipe it with a dry or slightly damp cloth.

Section 4.3 Changing cartridge

Only change the cartridge inside easypod® if:

- You did not store the Saizen® cartridges according to the Patient Information Leaflet.

- The cartridge is empty or expired (28 days after first use). easypod® will display "Cartridge empty" or "Cartridge expired" message (see right image).

- easypod® displays the "Less than 1 dose left" message (see left image) and you **do not** want to administer a partial dose injection.

- You dropped easypod®, the cartridge might be damaged and needs to be replaced.

After inserting a new cartridge you can start *"Section 3 Injecting medication with easypod®"*.

easypod® displays the cartridge status in the top right corner:
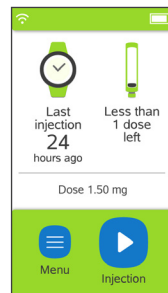
Less than 1 dose left
(You might **not** want
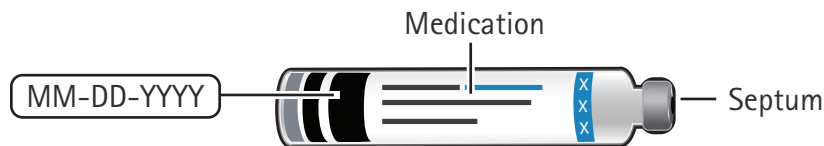to do a partial dose)
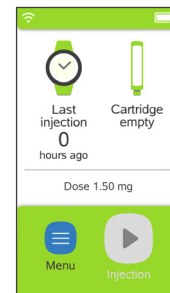
Cartridge is
empty

> **ⓘ NOTE**
>
> - **DO NOT** force open the cartridge door, this might damage the cartridge door.
>
> - Contact your doctor or nurse if the cartridge is different from what you have been prescribed.

1 Get a new cartridge and inspect

Medication

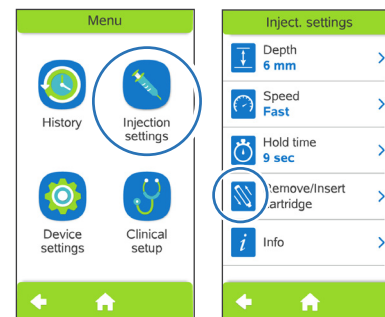MM-DD-YYYY

Septum

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 discolored, 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.

2 Unlock cartridge door

Menu	Inject. settings
History	Injection settings	Depth **6 mm**
Device settings	Clinical setup	Speed **Fast**
		Hold time **9 sec**
		Remove/Insert cartridge
		Info

To unlock the cartridge door:

a. Open ☰ menu.

b. Select 💉 injection settings.

c. Select 🖊 remove cartridge.

ℹ **NOTE:** You can only remove and insert cartridge by clicking Remove/Insert Cartridge on the screen to unlock and open the cartridge door.
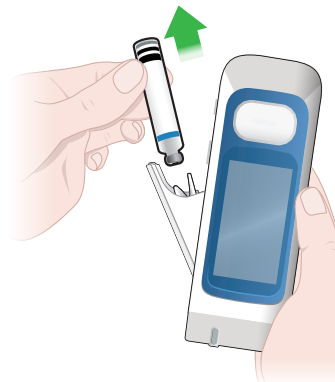
③ Open cartridge door

No needle

- Make sure there is no needle inside. If there is see section 3.4 for instructions to detach needle.

- Slide cartridge door button up to open door.

If the cartridge door button is locked, see step 2.

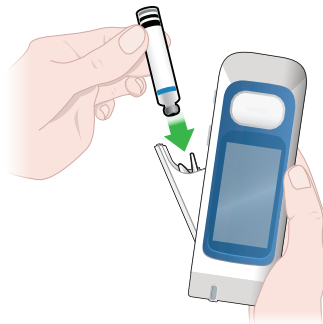### ④ Remove cartridge

Remove cartridge from cartridge holder.

⚠ **WARNING: DO NOT** use easypod® if a cartridge has broken inside the device. A broken cartridge and any remaining liquid may harm the user or damage the device.

5 Discard cartridge

Discard the empty, expired or broken cartridge in a biohazard (sharps) container.

6 Insert new cartridge

Insert new cartridge into cartridge holder with metal tip pointing down.

7 Close cartridge door

Push cartridge door to close it.

Section 4.4 Replacing device

easypod® has been built to last 5 years. The expiration date is printed on the device label. The device does not require any special maintenance. Starting 6 months before the expiration date, easypod® will regularly present messages to remind you of the expiration date.

Contact your doctor or nurse when it is time to replace your easypod®.

> ⚠ CAUTION
>
> - **DO NOT** use easypod® if it is not working properly and do not attempt to repair it, or an incorrect dose may be delivered.
>
> - Contact your doctor or nurse in case of device malfunction.

Section 4.5 Travel with device

You are allowed to travel with the device.

If you are going to travel with easypod®, remember:

- Travel with the device in your carry-on luggage. **DO NOT** travel with the device in your check-in luggage. It is recommended to store easypod® in the storage box when traveling.

- Ask your doctor or nurse for documentation, if applicable, that will ensure you are allowed to keep the device with you as carry-on luggage.

- Make sure to store your Saizen® medication at the appropriate temperature according to the Saizen® Patient Information Leaflet, whether the cartridge is inserted in the device or not. Consider using a travel cooling bag that will keep within Saizen® cartridges and your device at the correct temperature.

- The device is safe to pass through X-ray airport security gates with the Saizen® medication inserted.

- Do not turn the device on while in the airplane.

- It is not recommended to inject while in a moving vehicle. If a planned injection will happen while you are in a moving vehicle, please contact in advance your doctor or nurse to update your injection schedule.

- easypod® will search for a cellular network to transmit data if you have turned this feature on when setting up easypod®. First-time connection from another country might take longer.

Section 5
Settings

This section instructs you on how to change easypod® settings.

Reminders and tips to change your easypod® settings

> ⚠ **CAUTION:** **DO NOT** change the injection settings on easypod® until you have discussed it with your doctor or nurse.

- Clinical setup features can only be changed by your doctor or nurse. Contact your doctor or nurse if you want to change any of these items.

- Data transfer to the database accessible by your doctor or nurse includes only injection data and technical data related to your easypod® autoinjector device, such as version and serial number. No personal identifiable information such as your name or address are transferred. The data transfer is anonymous.

- The transfer of your data is protected by applying well established security standards as mutual authentication, and encryption. Local data protection laws and directives are strictly followed.

- **DO NOT** remove the battery or power off the device while changing settings without saving. This may cause unsaved changes or loss of data.

Section 5.1 Menu overview

Press the ▤ button on the home screen to access the main menu. You can press the 🏠 button to return to the home screen.

Each section provides access to a number of feature and settings.

The main menu contains:

- History
- Injection settings
- Device settings
- Clinical setup

History

- Calendar view
- List view
- Clinical summary

Device settings

- Data transfer
- Personalize
- Volume
- Language
- Date/Time
- System info

Injection settings

- Depth
- Speed
- Hold time
- Remove/Insert cartridge
- Info

Clinical setup
(Doctor or nurse only)

Section 5.2 History

Use the history menu to review your total number of injections including the time, date, dose injected and number of times you have changed the cartridge.
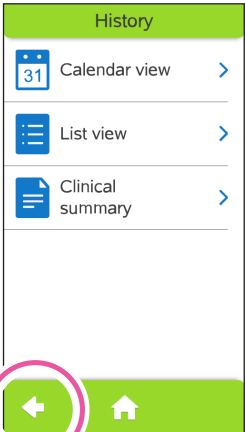
There are three ways to view your injection history: Calendar, List, and Clinical summary.

To access the History menu:

a. Open ☰ menu from the home screen.

b. Select 🕐 History.

History

History	
📅 Calendar view	›
☰ List view	›
📄 Clinical summary	›

Press to Exit

📄 Clinical summary

Clinical summary	
Last month	
Planned (mg)	Actual (mg)
35.90	32.60
	(91%)
Last 3 months	
Planned (mg)	Actual (mg)
102.50	97.30

The clinical summary is for your doctor or nurse to review. It shows your dosing patterns over multiple months, which your doctor or nurse can use to give you further guidance.

Event icons in each view

- **Full dose delivered**
- **Interrupted injection**
- **Partial dose delivered**
- **Cartridge changed**
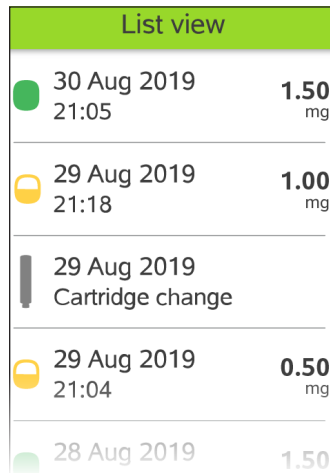- **Orange dot: Notable event (e.g., more than one full dose in one day)**

Calendar view

Calendar view						
August 2019						
M	T	W	T	F	S	S
			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	

Calendar view shows your daily injections one month at a time. For details on injection days, click the date on the calendar.

Injection List view

List view	
30 Aug 2019 21:05	**1.50** mg
29 Aug 2019 21:18	**1.00** mg
29 Aug 2019 Cartridge change	
29 Aug 2019 21:04	**0.50** mg
28 Aug 2019	1.50

List view shows a chronological list of events.