

# Instructions for Use

 **Skytrofa® Auto-Injector**

For SKYTROFA cartridges

**Single-patient use**

Watch Video



[www.skytrofa.com](http://www.skytrofa.com)



## Getting Started

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## Step-by-step Instructions for the SKYTROFA Auto-Injector

Read and follow this Instructions for Use that comes with your auto-injector before you start using it. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

The back cover of this Instructions for Use folds out for reference while you read the rest of the instructions.

If you have any questions about the auto-injector, the medicine, or these instructions, please contact your healthcare provider or Ascendis Pharma Customer Support. For contact information

 back cover.

# Getting Started

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## Important Information

### Important information about your SKYTROFA Auto-Injector:

The auto-injector is used to give (administer) SKYTROFA under your skin (subcutaneously).

Do not use the SKYTROFA Auto-Injector for the first time until you receive training from a healthcare provider. If you do not follow the instructions for the auto-injector, you may not get the right dose, cause injury, or get an infection.

The auto-injector should only be used with SKYTROFA cartridges and needles that are prescribed by your healthcare provider. Cartridges and needles come together in the same packaging. Follow the instructions that come with SKYTROFA cartridges. If refrigerated, take the cartridge out of the refrigerator and leave at room temperature for **15** minutes before use.



Your weekly dose may require that you use 2 cartridges.

**Do not** use your auto-injector with other medicines or needles.

**Do not** share your auto-injector with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

**Do not** reuse needles.

**Do not** drop the cartridges because they may break.

### **Keep out of the reach of children.**

This product contains small parts that may present a choking hazard to small children. The cable can present a strangulation hazard. The auto-injector should only be used under the supervision of a caregiver.

**Do not** point the auto-injector at yourself or other people, except when you are ready to inject.

**Do not** use or place the auto-injector closer than 12 inches (30 cm) to microwave ovens or electronic equipment with antennas such as mobile phones and WiFi transceivers.

# Before You Begin

## The SKYTROFA Auto-Injector

The auto-injector is an electronic, reusable device for people needing injections of SKYTROFA. It automates parts of the procedure for injecting SKYTROFA. The auto-injector is designed for personal home use, so that the injections may be given without the assistance of a medical professional.

## The SKYTROFA Cartridge

SKYTROFA comes in a single-use cartridge. The cartridge has 2 chambers, 1 filled with powder and 1 filled with water. The auto-injector automatically mixes the powder and the water during preparation, making it ready for injection.

## The Needle

The single-use needle comes with SKYTROFA cartridges and is used for injecting the medicine.

## Product Overview



Figure A

# Setting Up

1. Remove the SKYTROFA Auto-Injector from the package.
2. Connect the USB (large end of the cable) to the charger (only use the provided charger). Plug the charger into a power outlet. Connect the Micro-USB (small end of the cable) to the back of the auto-injector. For protection, charge the auto-injector with the protective cover on (see Figure B).
  - For more information on charging  page 49.



Figure B

3. Fully charge the auto-injector before using it for the first time. This will take **2 hours and 30 minutes**. When the battery icon located at the base of the auto-injector (see Figure C) is flashing red or green, it is charging. When it shows constant green, the auto-injector is fully charged and is ready to use after the charging cable is unplugged.
  - When fully charged, the battery should last for at least **4** injections.
  - When traveling, bring your charger and the right adaptor for different power outlets depending on your destination.
  - The auto-injector cannot be used when connected to the charger.

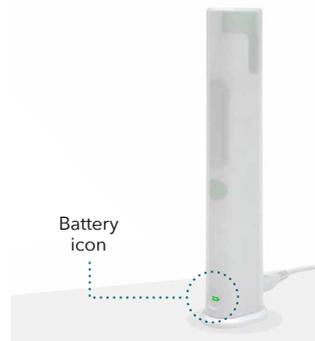


Figure C

# Setting Up

4. Find a quiet place where you can perform your injection.
5. Gather your supplies and place them on a flat, hard, clean surface.

Supplies needed for an injection:

### From SKYTROFA Auto-Injector packaging

(see Figure A):

- 1 SKYTROFA Auto-Injector

### From SKYTROFA packaging

(see Figure D):

- 1 SKYTROFA Cartridge
- 1 Omnican fine 0.25 mm x 4 mm (31G x 5/32") B. Braun needle

### Other supplies (not included)

(see Figure D):

- 1 Alcohol Wipe
- 1 Sharps Container



If your weekly dose requires 2 cartridges, you will need the following additional supplies:

- 1 SKYTROFA Cartridge
- 1 Omnican fine 0.25 mm x 4 mm (31G x 5/32") B. Braun needle
- 1 Alcohol Wipe

## Supplies Needed for Each Injection



Figure D

# How to Use



## Does Your Weekly Dose Require 2 Cartridges?

Your healthcare provider may prescribe a dose that requires use of the medicine in 2 cartridges. If you have been prescribed a dose that requires 2 cartridges:

- Take your first injection (Step 1 to Step 11, pages 14–35).
- Then take your second injection by repeating Step 1 to Step 11 with a new cartridge and needle.
- After your second injection, continue to Step 12 (page 36).

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# Prepare

1

## Check and assemble cartridge and needle

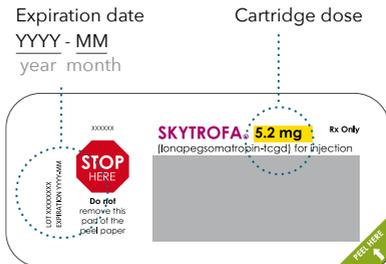


Figure E

- 1.1 Check the expiration date and cartridge dose on the cartridge packaging (see Figure E).

Remove the SKYTROFA cartridge from the packaging according to the instructions on its lid.

**Do not** use if the expiration date has passed on the cartridge.

- If you are unsure about your dose, contact your healthcare provider.
- If you are unsure about the medicine expiration date, please call Ascendis Pharma Customer Support. For contact information  back cover.

- 1.2 Check the expiration date on the needle. Remove the paper from the needle (see Figure F).

**Do not** use if the expiration date has passed on the needle.

Expiration date  
YYYY - MM - DD  
year month day



Figure F

- 1.3 Screw the needle straight on the cartridge by turning clockwise until there is a **tight fit** (see Figure G).

**Do not** remove the plastic needle cover. You will need it to insert the cartridge into the SKYTROFA Auto-Injector.



Figure G

# Prepare

2

## Turn on the auto-injector

Press and release the green button to turn on the auto-injector.



(You will hear **2** loud beeps. Battery icon  will light up and green top will start flashing)

Figure H

**2.1** Disconnect the auto-injector from the charger when charged.

- The auto-injector cannot be used when connected to the charger.

**2.2** Find a quiet place where you can give your injection.

**2.3** Remove the protective cover. Place the auto-injector upright on a flat surface.

**2.4** Press and release the green button to turn on the auto-injector (see Figure H).

- You will hear a humming sound. The battery icon  and the **3** icons above the green button will light up. Then all of the icons will turn off, except the battery icon.

- You will hear **2** loud beeps and the green top will start flashing. The auto-injector is ready for use.
- If the auto-injector is not active for **6** minutes, it will turn off. Press the green button to turn it on again.

**2.5** Check the battery icon on the base of the auto-injector to see if it is charged. The battery icon  is green when the auto-injector is ready to use:



### Constant Green

Battery is fully charged.

The auto-injector is ready to use.



### Flashing Green

At least 1 injection remaining, but charging is recommended after use.



### Flashing Red

Battery needs charging.

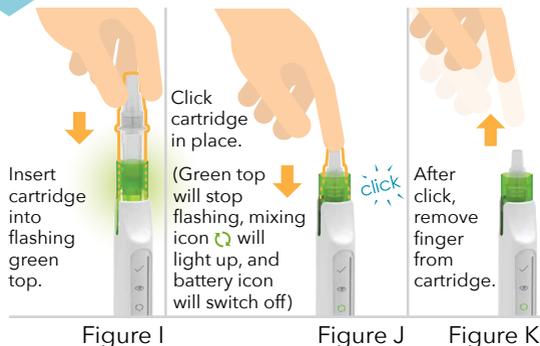
If no icons light up  page 44.

If you see flashing icons (other than the battery)  pages 46–47.

# Prepare

3

## Insert cartridge



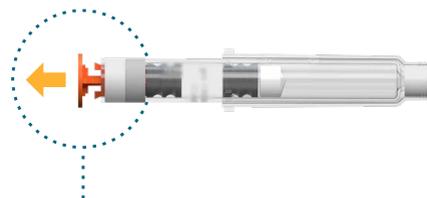
**3.1** Insert the cartridge into the flashing green top by pushing straight down with the needle cover still on (see Figure I).

**3.2** Click the cartridge into place. Make sure the cartridge is pushed all the way down (see Figure J).

- You will hear a click, the green top will stop flashing, the green mixing icon  will light up, and the battery icon  will switch off.
- The cartridge cannot be inserted when the auto-injector is connected to the charger.

**3.3** After the click, remove your finger from the cartridge (see Figure K).

If you cannot insert the cartridge, check if an orange plug is still attached to the cartridge. If an orange plug is still attached to the cartridge, remove it by pulling it straight off (see Figure L). The orange plug only protects the cartridge during transportation.



An orange plug may need to be removed from the cartridge.

Figure L

**Do not** use the auto-injector if you cannot insert the cartridge. Please call Ascendis Pharma Customer Support. For contact information  back cover.



If you see a flashing red mixing icon  page 46.

## 4

### Wait while mixing

Wait 4 to 8 minutes for the auto-injector to mix medicine.

Watch progress bar gradually light up.



Figure M

**4.1** Wait 4 to 8 minutes for the auto-injector to mix your medicine. The progress bar will gradually light up, and you will hear steady ticking during mixing (see Figure M).

- Make sure the auto-injector is standing upright on a flat surface. If the auto-injector is not upright, the medicine mixing will pause.

**4.2** The auto-injector has finished the automatic part of the mixing when you hear **2** loud beeps and the entire progress bar flashes.

**4.3** Continue with Step 5 (page 22) immediately after automatic mixing is completed.

If you wait for more than **2** hours before completing the steps for mixing by hand (Step 5), the auto-injector will automatically cancel the procedure. If this happens, the cartridge will be released and cannot be used. To remove the cartridge, see Step 10 (page 32).

- If you still need to inject after the auto-injector has canceled the procedure, go back to Step 1 and use a new cartridge (page 14).



If you see a slowly flashing green mixing icon and the progress bar is frozen  
 ➤ page 42.



If you see a flashing red mixing icon  
 ➤ page 46.

## 5 Turn the auto-injector up and down

Turn the auto-injector up and down. A tick sound confirms the turns are correct. Turn 5 to 10 times until you hear **2** loud beeps and the progress bar, except the top element, lights up.

**Do not** press the green button.

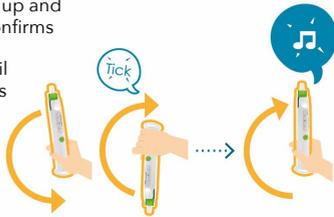


Figure N

**5.1** Turn the auto-injector up and down to mix the medicine by hand. You will hear a 'tick' sound each time you turn the auto-injector up and down correctly. To mix the medicine correctly:

- Each turn up and down should take no more than **2** seconds.
- The auto-injector should point straight down and straight up (see Figure N).

The progress bar, except the top element, will light up as you turn the auto-injector up and down correctly.

**Do not** press the green button when you turn the auto-injector up and down.

After 5 to 10 correct turns, you will hear **2** loud beeps and the progress bar, except the top element, will light up.

**5.2** Continue with Step 6 (page 24) immediately after you finish mixing by hand.

If you wait more than **2** hours before preparing and doing the injection (Step 6 to Step 9, pages 24-31), the auto-injector will automatically cancel the procedure. If this happens, the cartridge will be released and cannot be used. To remove the cartridge, see Step 10 (page 32).

- If you still need to inject after the auto-injector has canceled the procedure, go back to Step 1 and use a new cartridge (page 14).



If you see a flashing red mixing icon  
 page 46.

## 6

### Finish mixing

Keep upright until you hear **2** loud beeps and the entire progress bar lights up.



Figure O

- 6.1** Keep the auto-injector upright for automatic air removal (see Figure O). Wait until you hear **2** loud beeps and the entire progress bar lights up.



If you see a slowly flashing green mixing icon and the progress bar is frozen

➡ page 42.



If you see a flashing red mixing icon

➡ page 46.

Pull off the needle cover.

**Do not** twist.

**Keep** needle cover for later.

(Eye icon  will light up)



Figure P

- 6.2** Pull off the needle cover (see Figure P). The green eye icon  will light up. Removing the needle cover will allow you to check the mixed medicine in the inspection window (Step 7 on page 26).

**Do not** twist the needle cover off. If you have trouble removing the needle cover, gently pull up the green top.

**Keep** the needle cover for later use. It is needed to safely remove the cartridge after injection.

### Check mixed medicine

Medicine is ok to use if it is colorless and clear (some air bubbles are ok). Go to Step 8.

**Do not** use the mixed medicine if it has visible particles. Press the green button for **3** seconds and go to Step 10.



Figure Q

**7.1** Check the mixed medicine in the inspection window on the side of the auto-injector (see Figure Q). The medicine should look colorless and clear. Some air bubbles are okay.

**Do not** inject the medicine if there are visible particles (medicine is not dissolved) or the mixed medicine is discolored.

If you see visible particles or the medicine is discolored:

- Cancel the injection procedure by pressing and holding the green button for **3** seconds. This will unlock the cartridge. Go to Step 10 (page 32).
- Get a new cartridge. Follow the instructions beginning at Step 1 (page 14).



If you see a flashing red mixing icon  
➡ page 46.

### Prepare for injection

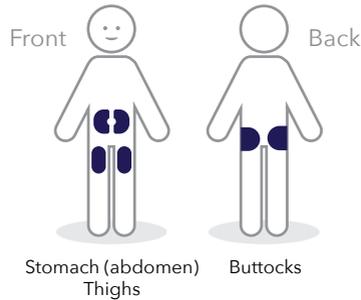


Figure R

**8.1** Choose an injection site. There are **3** areas of your body you can inject into (see Figure R):

- Stomach (abdomen)
- Thighs
- Buttocks

Change the injection site for every injection.

**8.2** Wash your hands with soap and water (see Figure S).



Figure S

**8.3** Clean the injection site with an alcohol wipe (see Figure T).

**Do not** inject through clothes. Inject directly into the skin.

**Do not** touch the cleaned area before injecting.

**Do not** fan or blow on the cleaned area.

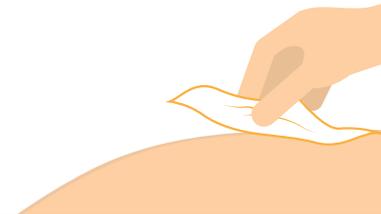
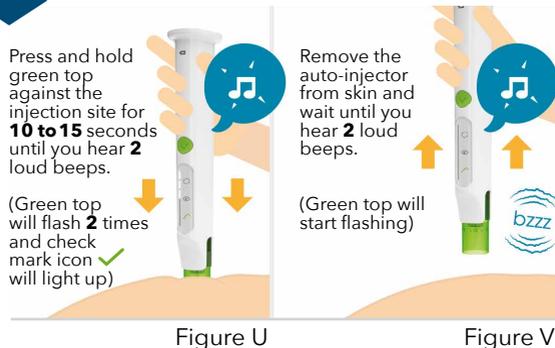


Figure T

# Inject

9

## Inject medicine



**9.1** Press and hold the green top against the skin of the injection site to inject (see Figure U). Hold for **10 to 15** seconds until you hear **2** loud beeps and the green top flashes **2** times. The green check mark icon ✓ will light up.

- The medicine is injected automatically when you press the green top against the skin.
- You will hear steady ticking and the progress bar will light up as you inject.

**Do not** remove the auto-injector from the injection site until the injection is finished to ensure you get your full cartridge dose.

**The injection is finished when you hear 2 loud beeps and the green top flashes 2 times. The green check mark ✓ will light up.**

**9.2** Remove the auto-injector from the skin after the injection is finished (see Figure V).

- After the injection is finished, the auto-injector makes a buzzing sound as it unlocks the cartridge. Wait until you hear **2** loud beeps, and the green top starts to flash.

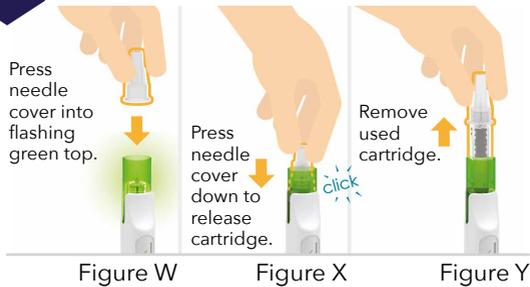
 If you see a slowly flashing green check mark icon and the progress bar is frozen  page 43.

 If you see a flashing red check mark icon  page 46.

# After Injection

10

## Remove cartridge



**10.1** Press the needle cover back on when the green top flashes (see Figure W).

Be careful when handling needles to reduce the risk of needlestick injury and infection.

**10.2** Press the needle cover down to release the cartridge.

- You will hear a click and the green top will stop flashing (see Figure X).

**Do not** twist the cartridge.

**10.3** Remove the used cartridge by pulling straight up (see Figure Y). Only remove the cartridge by using the needle cover.

- After you remove the cartridge, the battery icon  will display the battery level. The auto-injector turns off automatically.

**Do not** use the auto-injector if you cannot remove the cartridge as instructed. Please call Ascendis Pharma Customer Support. For contact information  back cover.

# After Injection

11

## Check cartridge and throw away

Check that cartridge is empty.

Put used cartridge and needle in a sharps disposal container.



Figure Z

**11.1** Check that the cartridge is empty of medicine (see Figure Z).

**Do not** use the auto-injector if there is medicine left in the cartridge after injection. Please call Ascendis Pharma Customer Support. For contact information  back cover.

**11.2** Put your used cartridge and needle in an FDA-cleared sharps disposal container right away after use (see Figure Z).

**Do not** throw away (dispose of) loose needles and cartridges in your household trash.

**Do not** recycle your used sharps disposal container.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out
- Upright and stable during use
- Leak-resistant
- Properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how to throw away used needles and syringes. For more information about safe sharps disposal, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Healthcare providers, relatives, and other caregivers should follow this Instructions for Use for removal and throwing away (disposal) of needles to prevent needlestick injury and infection.

# After Injection



## Does Your Weekly Dose Require 2 Cartridges?

Then take the second injection by repeating Step 1 to Step 11 (pages 14-35) with a new cartridge and needle before continuing to Step 12.

12

## Store the auto-injector

Put on the protective cover.

Store at room temperature between 59°F to 86°F (15°C to 30°C), to be ready for next use.

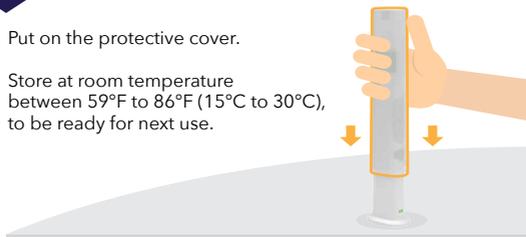


Figure AA

**12.1** Make sure that the auto-injector is clean. If it is dirty or if medicine has been spilled onto it, clean with a damp cloth.

**Do not** place the auto-injector under water. For more information on cleaning ➤ page 48.

**12.2** Put the protective cover on the auto-injector by sliding it straight down (see Figure AA).

**12.3** Charge the auto-injector if the battery icon has been flashing before or after the injection. For more information about how to charge the auto-injector ➤ page 49.

**12.4** Store the auto-injector at room temperature between 59°F to 86°F (15°C to 30°C), between use. Store with the protective cover on until the next injection. For more information about how to store the auto-injector ➤ page 50.

**12.5** Write down the date of every weekly dose taken under Keep Track of Your Injections ➤ back cover fold out.

- When the auto-injector reaches its expiration date, maximum number of injections, or needs replacing, return it to the Ascendis Pharma Customer Support. For more information, see Expiration ➤ page 56.

# Troubleshooting and Care

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# Troubleshooting

- What do you see?

## Green flashing icons

If you see any of these



► pages 42-43.

## Green battery icon

If you see any of these



► page 44.

If you see no icons lighting up at all

► page 44.



## Red flashing icons

If you see any of these

► pages 46-47.



## Red battery icon

If you see this

► page 45.

✓ You see slowly flashing **green mixing icon** and the progress bar is frozen.



You hear a repeating warning sound.



You see a slowly flashing **green check mark icon** and the progress bar is frozen.



You hear a repeating warning sound.

**Mixing paused** (Step 4 on page 20). If the SKYTROFA Auto-Injector is not in an upright position, mixing or air removal will pause (see Figure AB).

**Do this:** Place the auto-injector in an upright position and the mixing or air removal will continue.

**Injection paused** (Step 9 on page 30). If the green top is removed from the skin before completing the injection, the auto-injector will pause the injection (see Figure AC).

**Do this:** Press the green top against skin and the injection will start again. If the injection is not completed within **15 minutes**, the auto-injector automatically cancels the injection.

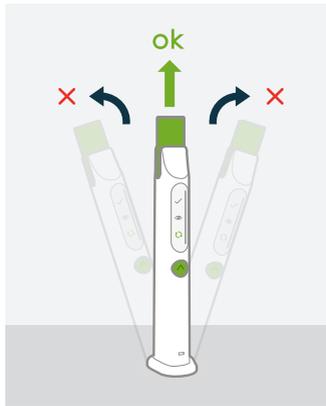


Figure AB

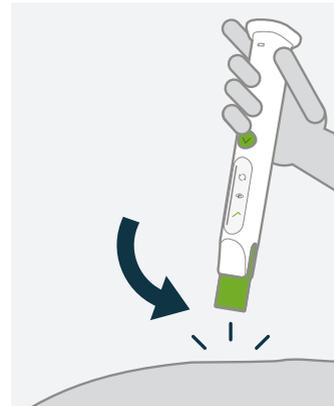


Figure AC

 **You see a flashing green battery icon.**

**Charging recommended.** There is enough battery for at least **1** injection.

**Do this:** Charge the auto-injector after the next injection.

 **You see a constant green battery icon.**

**Battery is fully charged.** The auto-injector is ready to use (the battery icon turns off while the auto-injector is in use).

**Do this:** If you are charging the auto-injector, disconnect it from the charger.

**You see no icons lighting up at all.**

**Either the auto-injector has turned off** (the auto-injector will turn off if it is not active for **6** minutes without a cartridge loaded or for **3** minutes with a cartridge loaded) **or the battery needs charging.**

**Do this:** Press the green button to turn it on again. If you see a flashing red battery icon, the battery needs charging. Read more  page 45.

 **You see a flashing red battery icon.**  
**You hear a warning sound.**

**The battery needs charging.**

**Do this:** Charge the auto-injector.

Insert the charger cable into the auto-injector at rear lower side and connect to a power outlet (see Figure AD). When the auto-injector has charged for **15** minutes and the battery icon flashes green, the auto-injector is ready to use after the charging cable is unplugged.

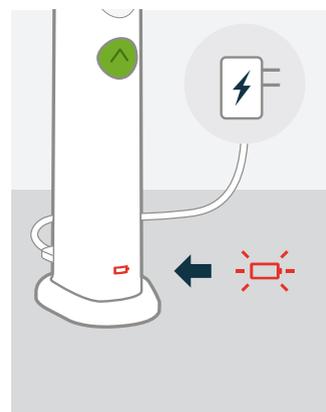


Figure AD

-  You see a flashing **red mixing icon**.
-  You **hear** an error sound.
- 

-   You see 3 flashing **green** and **red icons**.
-   You **hear** a repeating error sound.
-  

Either you have inserted a used or damaged cartridge, or you have canceled the mixing, or the auto-injector has canceled the injection. The auto-injector cancels the injection **2** hours after automatic mixing (Step 4, page 20) or **2** hours after manual mixing (Step 5, page 22) is completed.

**Do this:** Remove the cartridge and wait for the device to turn off. Start again with a new, unused cartridge and make sure to screw on the needle straight and tightly.  
Read more  page 14.

The auto-injector is near its expiration. The first time you see this, either there are 5 injections left or the auto-injector expires in 1 month.

**Do this:** The auto-injector can be used as usual for the remaining injections. When there are no more injections left or the expiration date has passed, the auto-injector cannot be used. Please contact a healthcare provider or Ascendis Pharma Customer Support to receive a new auto-injector. For Ascendis Pharma contact information  back cover.

-  You see a flashing **red check mark icon**.
-  You **hear** an error sound.
- 

Either an injection error has happened (the needle is not screwed on tightly, or it is bent or blocked), or you have canceled the injection, or the auto-injector has canceled an injection that was not completed within 15 minutes.

**Do this:** Remove the cartridge and wait for the auto-injector to turn off. Start again with a new, unused cartridge and make sure to screw on the needle straight and tightly.  
Read more  page 14.

-   You see 3 flashing **red icons**.
-  You **hear** an error sound.

Either the auto-injector has expired (the maximum number of injections has been reached or the lifetime of 5 years has passed) or a critical error has occurred.

**Do this:** Try to turn the auto-injector on (press and release the green button). If you still see 3 flashing red icons, the auto-injector needs to be replaced. For disposal information  page 57. Please contact a healthcare provider or Ascendis Pharma Customer Support to receive a new auto-injector. For Ascendis Pharma contact information  back cover.

## Cleaning and Maintenance

### Cleaning the SKYTROFA Auto-Injector

If the auto-injector is dirty or if medicine has been spilled onto it, clean with a damp cloth. Before cleaning, the cartridge must be removed.

The green top needs to be cleaned on the outside and on the reachable part of the inside.

If medicine is spilled inside the auto-injector, turn it upside down to let the medicine run out.

**Do not** place the auto-injector in liquid.

**Do not** clean the auto-injector while charging.

**Do not** sterilize the auto-injector.

### Maintenance of the SKYTROFA Auto-Injector

The battery is not replaceable.

**Do not** open, try to repair, or change the auto-injector. Please call Ascendis Pharma Customer Support. For contact information ► back cover.

## Charging and Charger Cable

### Charging the SKYTROFA Auto-Injector

Connect the USB (large end of the cable) to the charger. Plug the charger into a power outlet. Connect the Micro-USB (small end of the cable) to the rear of the auto-injector. For protection, charge the auto-injector with the protective cover on. Read more ► pages 8-9.

Only charge the auto-injector when the battery icon is flashing green or red. Read more ► pages 44-45.

**Do not** attempt to use any charging adaptor or charging cables other than those included with your auto-injector. Other adaptors or cables may create problems and may interfere with device operation.

**Do not** clean the auto-injector while charging.

The auto-injector cannot be used when connected to the charger.

If a cartridge is inserted in the auto-injector, the Micro-USB cannot be connected to the auto-injector. Likewise, a cartridge cannot be inserted into the auto-injector if the Micro-USB is connected to the auto-injector.

# Storing

## Storing the SKYTROFA Auto-Injector

Remove the cartridge from the auto-injector before storing.

Store with the protective cover on.

It is recommended to store the auto-injector at room temperature between 59°F to 86°F (15°C to 30°C), between use. If the auto-injector is stored at higher or lower temperatures, you should keep it at room temperature for 30 minutes before use with a cartridge. The auto-injector can be stored between 14°F to 104°F (-10°C to 40°C) if not in use.

Keep the protective cover on when traveling with the auto-injector.

**Do not** store the auto-injector closer than 12 inches (30 cm) to microwave ovens or electronic equipment with antennas such as mobile phones and WiFi transceivers.

Keep the auto-injector away from dirt, dust, and humid or wet places.

Keep the auto-injector, the charger, and the charging cable away from pets and pests.

Avoid refrigerating or freezing the auto-injector between use.

Avoid exposing the auto-injector to direct sunlight and extreme temperatures.

For technical details of the conditions under which the auto-injector can be used, stored, and transported ► pages 60–61.

# Product Information

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## Product Safety

**Do not** use the SKYTROFA Auto-Injector if the SKYTROFA cartridge cannot be inserted or removed, or if the cartridge was not completely emptied during the last attempted injection.

**Do not** use the auto-injector if you think it may be damaged.

**Do not** open or change the auto-injector. The auto-injector comes with a battery that cannot be replaced.

**Do not** drop or step on the auto-injector. Extreme vibrations, pressure, or shock, such as a fall onto a hard surface, may damage the auto-injector.

**Do not** drop the cartridges because they may break.

**Do not** clean the auto-injector while charging. Keep the auto-injector dry.

**Do not** place the auto-injector in liquid.

**Do not** wash the auto-injector in a dishwasher.

**Do not** expose the auto-injector to extreme temperatures. Keep the auto-injector away from heat and open flames. Keep it out of direct sunlight.

Keep the auto-injector away from microwave ovens.

**Do not** use or place the auto-injector next to portable RF equipment with antennas such as mobile phones and WiFi transceivers. The auto-injector may not work the right way. Keep RF equipment at least **12 inches (30 cm)** away from the auto-injector when it is being used.

Keep the auto-injector away from areas with high oxygen levels, such as areas where supplemental oxygen is in use.

## Expiration

The SKYTROFA Auto-Injector has an expiration date (5 years after the manufacturing date) or a maximum of 210 injections, whichever comes first. The expiration date is located at the bottom of the auto-injector and is indicated by year (YYYY), month (MM), and date (DD), printed as YYYY-MM-DD.

When there are 5 injections or less than 1 month left, the auto-injector will indicate this when turned on. Read more  page 47.

The auto-injector may be used for the remaining 5 injections. After the final injection or after the expiration date, your auto-injector has to be replaced. Please contact a healthcare provider or Ascendis Pharma Customer Support to receive a new auto-injector. For contact information  back cover.



The auto-injector contains electrical and electronic components, including a non-replaceable battery.

**Do not** throw away (dispose) in household trash.

When the auto-injector reaches its expiration date, maximum number of injections, or needs replacing, return it to the Ascendis Pharma Customer Support. Contact Ascendis Pharma Customer Support for instructions on how to return properly. For contact information  back cover.

# EMC Compliance Levels

Electromagnetic Compatibility (EMC) Compliance Levels	Basic EMC Standard
EMC - RF Field radiated emission in 10 m (maximum): a) 30 MHz to 230 MHz: ≤ 30 dB (μV/m) quasi-peak. b) 230 MHz to 1 GHz: ≤ 37 dB (μV/m) quasi-peak. c) Internal source <108 MHz	IEC / EN 60601-1-2, 4-th Edition CISPR 11 / EN 55011
EMC - RF Field radiated immunity - Electrical field: a) 10 V/m 80-2700 MHz. 1 kHz 80% AM	IEC / EN 60601-1-2, 4-th Edition IEC 61000-4-3
EMC - Power Frequency Magnetic field, Immunity: a) 30 A/m	IEC / EN 60601-1-2, 4-th Edition IEC 61000-4-3
EMC - Fast transients and bursts: a) Fast transients and bursts ±2 kV ac mains b) Surge ±1 kV Line-to-Line ac mains c) Conducted immunity disturbance by RF fields 3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio bands) d) Conducted emission 150 kHz-30 MHz 120 V @ 60 Hz	IEC / EN 60601-1-2, 4-th Edition IEC 61000-4-4 IEC 61000-4-5 IEC 61000-4-6 IEC 61000-4-11

EMC - Voltage dips and interruptions: a) <5% UT for 5 sec b) <5% UT for 0.5 cycles c) 70% UT for 25 cycles d) 40% UT for 5 cycles	IEC / EN 60601-1-2, 4-th Edition IEC 61000-4-11
EMC - RF Field Immunity to Proximity fields from Wireless communication equipment, Immunity at 0.3 m separation: a) 27 V/m @ 380-390 MHz b) 28 V/m @ 430-470 MHz c) 9 V/m @ 704-787 MHz d) 28 V/m @ 800-960 MHz e) 28 V/m @ 1700-1990 MHz f) 28 V/m @ 2400-2570 MHz g) 9 V/m @ 5100-5800 MHz	IEC / EN 60601-1-2, 4-th Edition IEC 61000-4-39
ESD immunity: a) ± 8 kV contact b) ± 2, 4, 8 and 15 kV air	IEC / EN 60601-1-2, 4-th Edition IEC 61000-4-2

# Technical Specification

SKYTROFA Auto-Injector	
Lifetime	Expiration date ► page 56.
Serial Number (SN)	Please refer to the bottom side of your auto-injector, marked after  .
Size	7.09 x 1.46 x 1.06 in (180 x 37 x 27 mm).
Weight	5.29 oz (150 g).
Display	Light-emitting diodes (LED).
Power source	Mains charger: 100 to 240 V AC.
Power supply	1 rechargeable internal Li-ion battery.
Full capacity charging time	2 hours and 30 minutes. Charging time for 1 injection: 15 minutes.
Full capacity	4 weeks with 1 injection per week.
Electromagnetic compatibility	SKYTROFA Auto-Injector meets the requirements of IEC / EN 60601-1-2, 4-th Edition. Like most electronic devices, using SKYTROFA Auto-Injector in the immediate vicinity of mobile phones or microwave appliances may result in impaired functioning. Use and store SKYTROFA Auto-Injector outside such an environment.
Protection against electric shock	Type BF.
Dose accuracy	According to ISO11608-1:2015.
Ingress protection	IP22: IP2X: Ingress protection of solid foreign objects, ≥ 12.5mm diameter. IPX2: Ingress protection of water with harmful effects, dripping (15% tilted). Both put together called IP22.
Cable	USB to Micro-USB cable, 1m.
Charger	
Model	ASSA54a-050100.
Input	100-240V - 50-60Hz.
Output	5.0V = 1.0A.

Use Conditions for SKYTROFA Auto-Injector	
Operation temperature (with medicine)	59°F to 86°F (15°C to 30°C) (marking on device bottom).
Storage & Transportation temperature	14°F to 104°F (-10°C to 40°C) (marking on device cover).
Charging temperature	59°F to 86°F (15°C to 30°C).
Operation humidity	15 to 90% relative humidity, non-condensing.
Storage & Transportation relative humidity	Up to 93% relative humidity, non-condensing.
Atmospheric pressure	10.15 psi to 15.37 psi (700 hPa to 1060 hPa).

## Use Conditions for Cartridge with Medicine and Needles

The use conditions provided here are for the SKYTROFA Auto-Injector device. The use conditions for SKYTROFA cartridges with medicine and needles may be different. To see the use conditions for cartridges with medicine and needles, please see the information provided with your medicine.

## Side Effects

For information on side effects, please see the information provided with your medicine.

## Waste

**Regular waste:** Packaging material (not including cartridges) may be thrown away with your household waste.

**Electronic waste:** The auto-injector, including battery, must be returned to the manufacturer. Contact Ascendis Pharma Customer Support for instructions on how to return properly ► back cover.

Charger and USB cable must be disposed of following local regulations for disposal of electronic waste.

# Symbols

These symbols are found on the SKYTROFA Auto-Injector, the packaging, and the Instructions for Use.

	Manufacturer.
	Unique serial number of SKYTROFA Auto-Injector.
	Manufacturer catalogue number for identification.
	Manufacturer batch code for identification.
	Expiration date.
	See Instructions for Use.
	Applied parts SKYTROFA Auto-Injector is a type BF device and provides protection against electrical shock and electrical current leakage. Applied parts on the device are the green top, the housing, and the button.
	Warning! When this symbol is seen, safety instructions must be followed.
Rx only	Caution: Federal law restricts this device for sale by or on the order of a physician.

	Operation temperature.
	Storage & Transportation temperature.
	Keep dry.
	SKYTROFA Auto-Injector complies with the requirements of The Medical Device Directive (MDD 93/42/EEC) and the RoHS (Restriction of Hazardous Substances) directive (2011/65/EU).
	SKYTROFA Auto-Injector contains electrical and electronic components, including a battery that cannot be replaced, and must not be disposed of using standard waste collection.
	SKYTROFA Auto-Injector packaging material is suitable for household waste.
	DC (Direct Current).
	The Unique Device Identifier (UDI) that appears on the carton is shown by a barcode and human readable format: (01) Device Identifier (10) Batch Number (17) Expiry date in YYMMDD format (21) Serial Number
	(01) 05713495000077 (10) 800052690 (17) 211031 (21) 18110000123456

## Warranty

After the expiration date, your SKYTROFA Auto-Injector must be replaced. Please contact a healthcare provider or Ascendis Pharma Customer Support to receive a new auto-injector. For contact information ► back cover.

The expiration date is located at the bottom of the auto-injector and is indicated by year (YYYY), month (MM), and date (DD), printed as YYYY-MM-DD.

## Disclaimer

The correct application of SKYTROFA according to the information provided with your medicine remains your responsibility.

Ascendis Pharma Endocrinology Inc. shall have no liability for incidental or consequential damages.

We reserve the right to modify technical specifications and documentation.

## Patent Information

[www.ascendispharma.us/products/patents](http://www.ascendispharma.us/products/patents)

## Status Icons



**Green Check Mark**  
Injection successfully completed



**Green Eye**  
Mixed medicine is ready for inspection in window



**Green Mixing**  
Medicine mixing is in progress

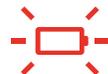
► Read more about status icons on pages 18-33 (and pages 40-47 for troubleshooting)



**Constant Green**  
► Battery is fully charged  
► The auto-injector is ready to use



**Flashing Green**  
► At least 1 injection remaining, but charging recommended after use



**Flashing Red**  
► Battery needs charging

► Read more about battery status icons on page 17

**Green Top**  
Starts injection when pressed against skin

**Inspection Window**  
Allows for inspection of mixed medicine

**Status Icons**

**Progress Bar**  
Shows progress of mixing and injection

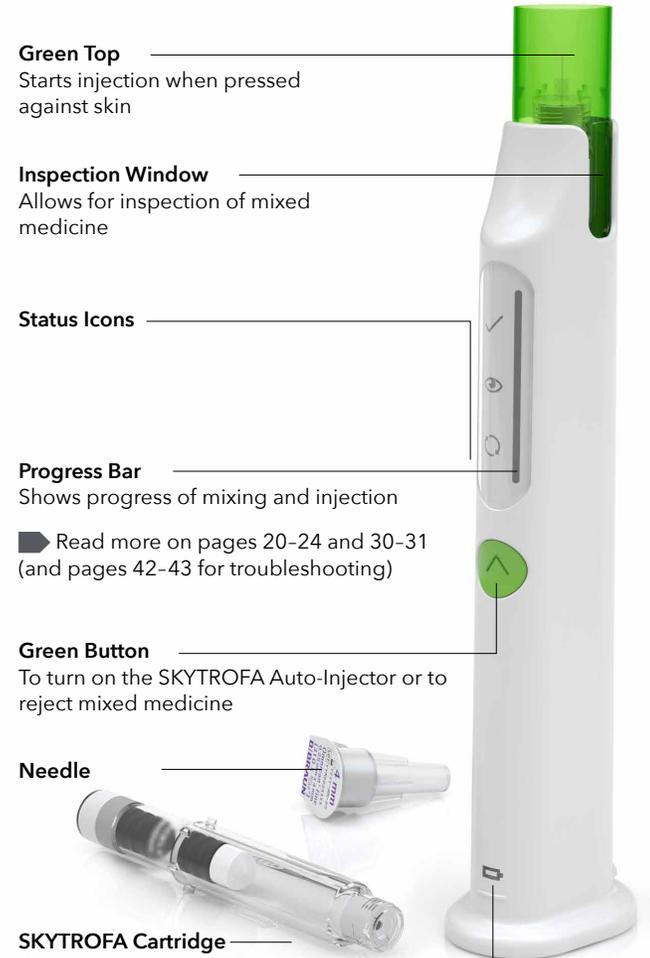
► Read more on pages 20-24 and 30-31 (and pages 42-43 for troubleshooting)

**Green Button**  
To turn on the SKYTROFA Auto-Injector or to reject mixed medicine

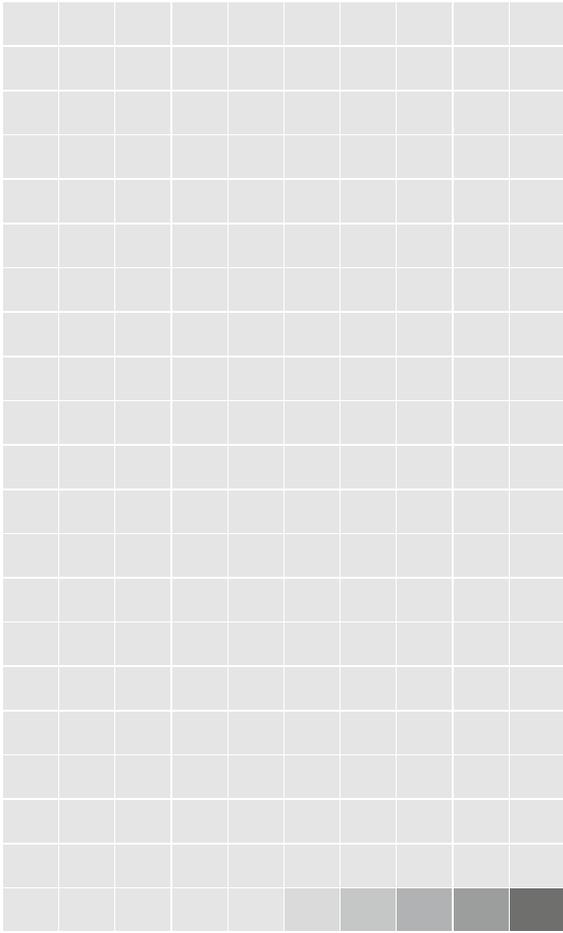
**Needle**

**SKYTROFA Cartridge**  
Contains medicine and water for injection

**Battery Icon**



# Keep Track of Your Injections



Device expiration

## This is your Instructions for Use

- For quick overview of steps, read your Quick Reference Guide
- For training video, go to [www.skytrofa.com](http://www.skytrofa.com)



Instructions for Use



Quick Reference Guide



[www.skytrofa.com](http://www.skytrofa.com)

Training Video

Ascendis Pharma Customer Support



1-844-44ASCENDIS  
(1-844-442-7236)



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

Approved: August, 2021