

AUTOMATIC SOMATROPIN PEN INJECTOR

SciTropin A PEN 10

USER'S MANUAL

SciTropin A PEN 10

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Nemera
we put patients first

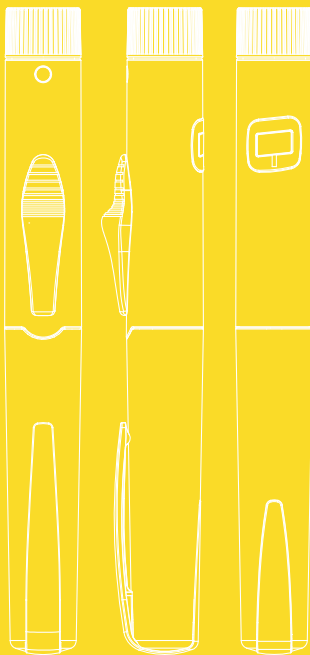


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before the first use

Before the first use of SciTropin A PEN 10 pen injector **carefully read ALL instructions** included in this user's manual.

SciTropin A PEN 10 is a reusable, intuitive automatic somatropin injector. It provides you or your child with a precise, safe and effortless way to administer somatropin doses recommended by the doctor, in the range of:

- from 0.2 to 12.0 units, with incremental dose of 0.2 units;
- from 0.07 to 4 mg, with incremental dose of 0.066 mg. (The scale shows rounded values to two decimal places. $0.07 = 0.066 \text{ mg}$)

- ▶ SciTropin A PEN 10 is intended for use by humans to treat:
 - Short stature due to growth hormone deficiency,
 - Growth disturbance due to Turner syndrome,
 - Chronic renal insufficiency,
 - Growth disturbance in short children born small for Gestational Age,
 - Prader-Willi Syndrome,
 - Growth hormone deficiency in adults.
- ▶ SciTropin A PEN 10 is recommended for use **exclusively with SciTropin A somatropin 1.5 ml cartridges** according to ISO 11608-3.
- ▶ SciTropin A PEN 10 is recommended **for use with disposable needles**: BD 31G (5 mm), BD 32G (4 mm) and BD 31G (8 mm) according to ISO 11608-2.
- ▶ Use a new needle for each injection to ensure sterility, prevent infections or leakage of somatropin and reduce the risk of needle clogging.



before the first use

- ▶ SciTropin A PEN 10 is not recommended for self-administration of somatropin by people who are blind, visually impaired, with severely limited motor skills or children without the assistance of a third party, trained in its use.
- ▶ SciTropin A PEN 10 is intended for use by one person only and should not be shared with others.
- ▶ SciTropin A PEN 10 can be used in the home environment by people from different cultural backgrounds, people of different ethnicity, with all levels of education.
- ▶ **Do not use** SciTropin A PEN 10, if it is not working properly, or any of its parts look damaged.



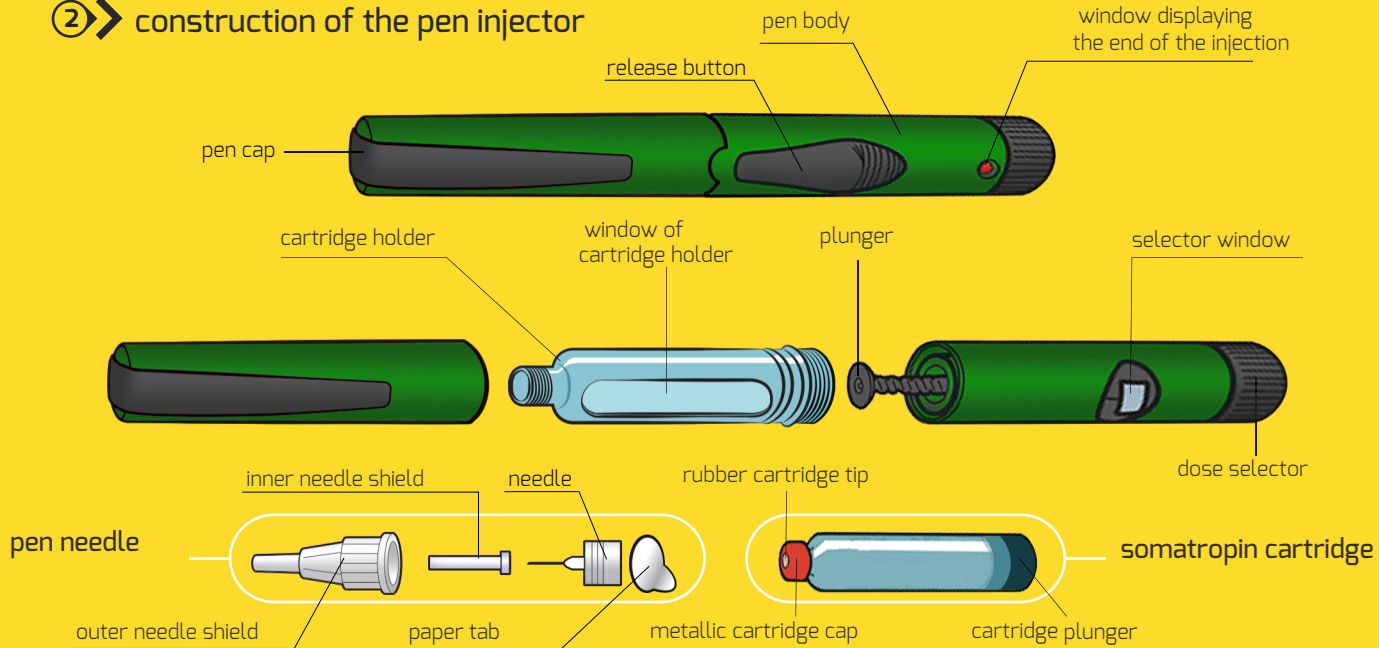
Do not try to repair your SciTropin A PEN 10 or pull it apart.

- ▶ Using SciTropin A PEN 10 without somatropin cartridge may cause defective operation.
- ▶ SciTropin A PEN 10 can't be used by children under 3 years of age resulting from characteristics of the drug.
- ▶ Contraindications:

Do not use SciTropin A PEN 10 in patients with:

- Hypersensitivity to somatropin or to any of its excipients.
- Active Proliferative or Severe Non-Proliferative Diabetic Retinopathy.
- Active Malignancy
- Acute Critical Illness
- Pediatric patients with closed epiphyses
- Pediatric patients with Prader-Willi syndrome who are severely obese, have history of severe upper airway obstruction, or have severe respiratory impairment due to risk of sudden death.

② ➤ construction of the pen injector

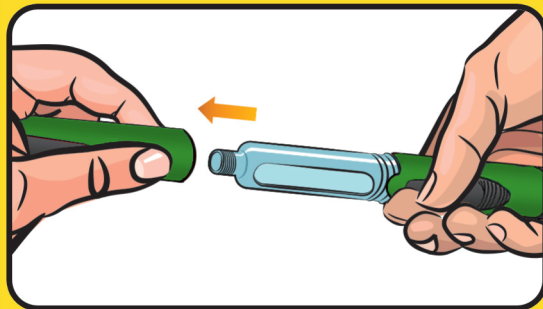


③ ➤ installation of cartridge and pen needle

Wash your hands thoroughly, and make sure that you have the following items:

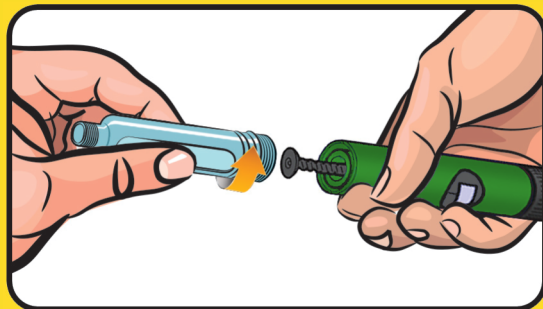
- SciTropin A PEN 10 pen
- injector somatropin cartridge
- new disposable pen needle
- two alcohol swabs

New somatropin cartridge or SciTropin A PEN 10 with cartridge attached should be taken out of the refrigerator 30 minutes prior the planned injection.



Step 1

Pull off the cap



Step 2

Unscrew the cartridge holder from the pen body by turning it according to the direction shown on the drawing.

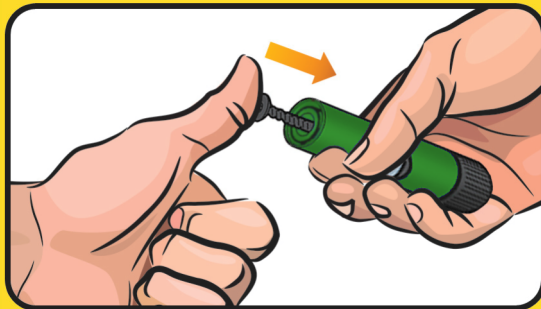
③ ➤ installation of cartridge and pen needle

Step 3

Press the plunger into the pen body.

If the plunger is stuck try to screw it into the pen body clockwise to the first resistance by holding the plunger.

Then push the end of plunger into pen body as much is possible.

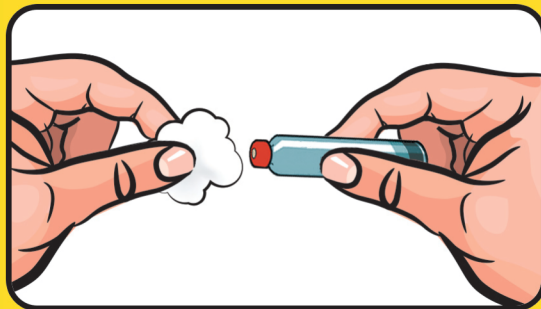


Step 4

Check the somatropin cartridge.

Make sure that it is not cracked or broken, the somatropin solution is clear and transparent and check the medicine expiration date.

Wipe the somatropin rubber cartridge tip with pharmaceutical alcohol swab (isopropyl/ethanol).

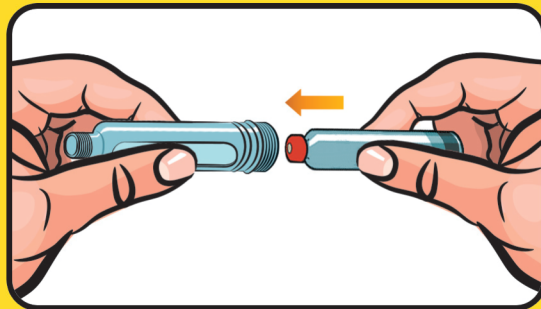


Do not use the somatropin if cartridge is cracked or broken and after the medicine expiration date. Do not manipulate in pen injector mechanism. This may cause malfunction of pen injector.

③ ➤ installation of cartridge and pen needle

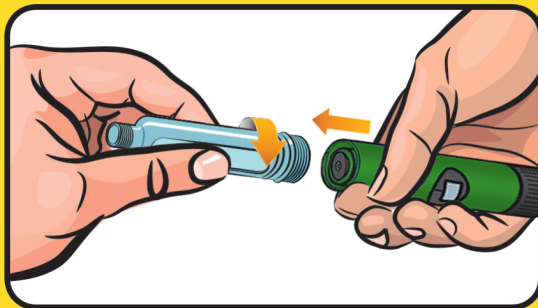
Step 5

Insert somatropin cartridge into the cartridge holder,
metallic tip to the front.



Step 6

Attach the cartridge holder to the pen body by turning
it according to direction shown on the drawing, until
first resistance is met.



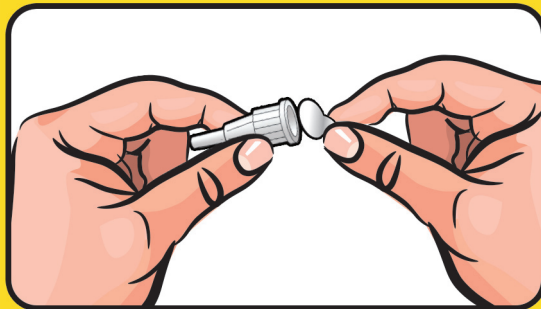
③ installation of cartridge and pen needle

Step 7

Take a new sterile needle and remove the paper tab from the outer needle shield.

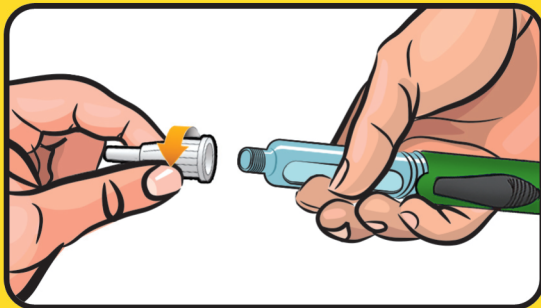


**For each injection use a new needle.
Do not use needles if the paper cover is damaged.
Reuse of the same needle or needle with a damaged unit
pack (paper cover) is not in line with epidemiological
recommendations.**



Step 8

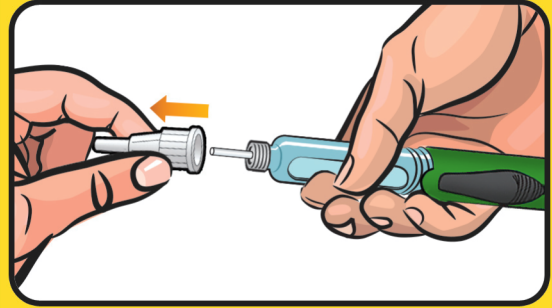
Hold the pen injector by the cartridge holder.
Attach the outer needle shield to the cartridge holder until first
resistance is met, according to the direction shown on the drawing.



③ ➤ installation of cartridge and pen needle

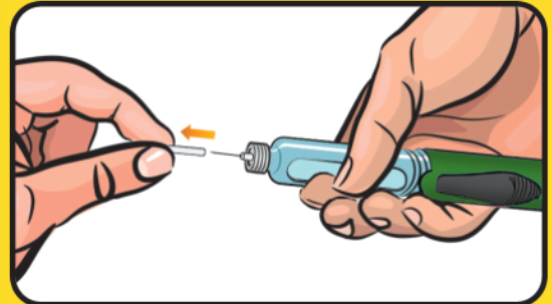
Step 9

Remove the outer needle shield.
Retain it for removal of the needle after
the completion of the injection process.



Step 10

Remove the inner needle shield as
recommended by the manufacturer.



To minimise the risk of unintended needle penetration and transmission of infectious diseases, never reuse the inner needle cap once removed. If by accident you puncture your skin, clean the wounded spot with a skin disinfectant.

④ priming

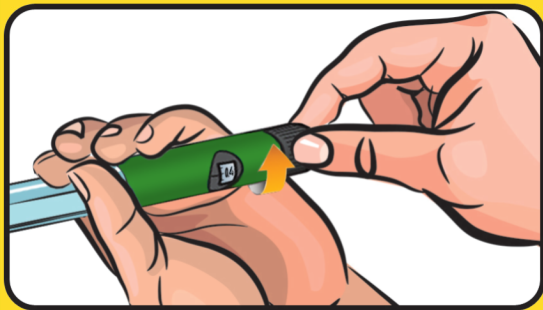
Prime your SciTropin A Pen 10 before each injection.

Step 11

Choose 0.4 units (or 0.13 mg) of somatropin as a test dose.

Test dose selecting methods:

1. Turn the dose selector according to the direction shown on the drawing.
2. Turn the dose selector until figure 0.4 (or 0.13 mg) appears in the dose selector window

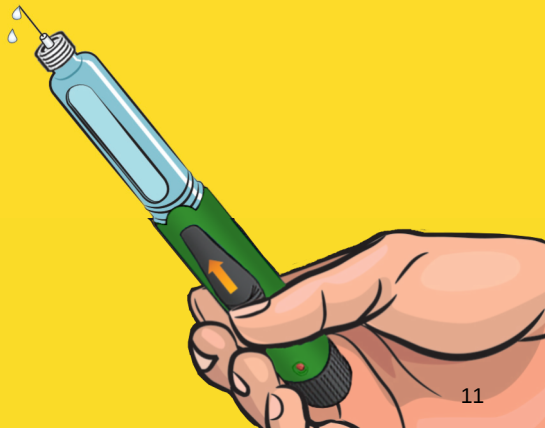


Step 12

Hold the pen with the needle pointing upwards. Using your thumb, slide the release button in the needle direction. **Hold the release button until a red dot appears in the window displaying the end of injection. If a drop of somatropin appears on the tip of the needle the pen injector is ready for use.**



If a drop of somatropin does not appear at the end of the needle, repeat steps 11 and 12. If a drop of somatropin does not appear after several attempts, remove the needle with step 17. Repeat steps 7 through 12, afterwards.

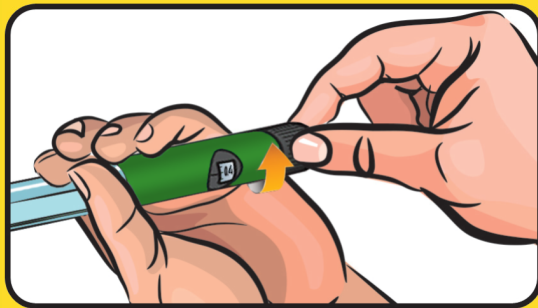


⑤➤ injecting a dose

Step 13

Select a dose of somatropin you want to inject. To do that, turn the dose selector according to the direction shown on the drawing, until the desired figure corresponding to the number of somatropin units appears in the dose selector window.

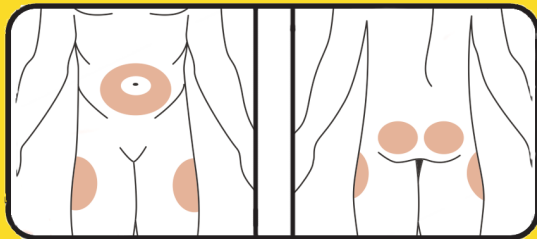
Make sure that dose selector window shows the correct number of doses. If the dialled dose is too high you can correct it by turning the dose selector backwards.



Step 14

Select the injection site (abdomen, thighs, buttocks) and wipe your skin with a pharmaceutical alcohol swab (isopropyl/ethanol).

Rotate your injection sites daily.



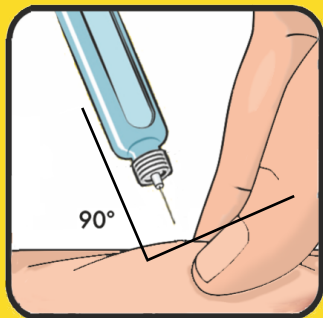
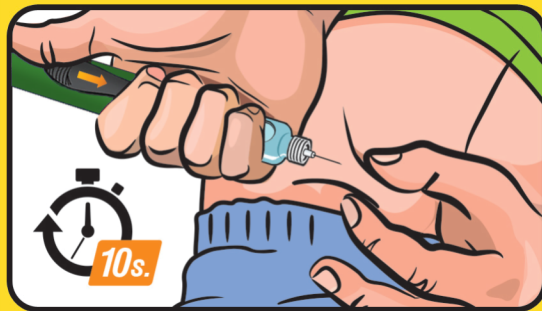
If by accident you inject yourself a dose higher than prescribed, immediately contact your doctor.

⑤ ➤ injecting a dose

Step 15

Gently hold a fold of the skin and insert the tip of the needle into subcutaneous tissue in a 90 degrees angle.

Using your thumb slide the release button in the needle direction, hold the release button until a red dot appears in the window displaying the end of injection. Wait at least 10 seconds, while **not removing the needle from the skin**.



If the red dot does not appear, it means that there is no somatropin in the cartridge. Note the number of units remaining, as it corresponds to the number of units of somatropin which you must inject to complete the injection. Attach the outer needle shield and remove the needle.

Replace the old cartridge with a new one, accordingly to Section 7 - replacing a cartridge. Prepare the pen injector to use accordingly to the actions described in steps 7 to 10. Perform the priming dose injection.

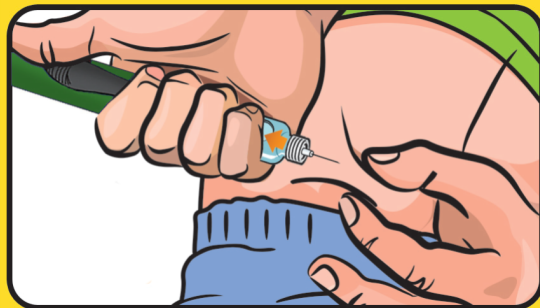
Next, complete the interrupted dose delivery by turning the dose selector according to the direction shown on the drawing until the figure, which you have seen in the selector window, appears. Perform accordingly the actions described in steps 14 to 15.



⑤➤ injecting a dose

Step 16

Remove the needle from the skin at the same angle it was inserted into subcutaneous tissue.

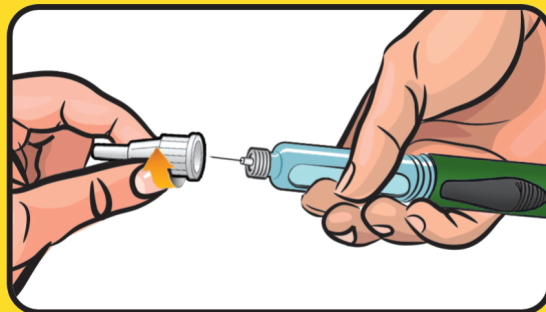


⑥➤ removing a needle

Step 17

After the injection put the outer needle shield on the needle. Holding the cartridge holder rotate the outer needle shield according to the direction shown on the drawing. Remove the used needle.

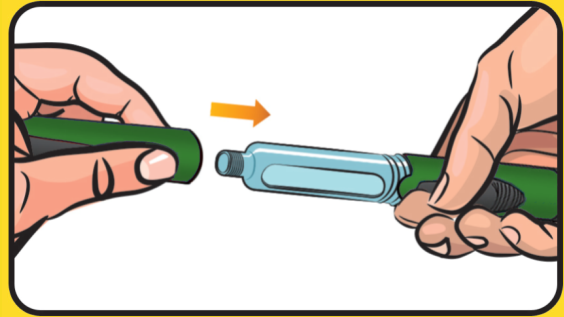
Dispose of it in accordance with information provided by the manufacturer of the needle.



Used needles and empty somatropin cartridges are classified among potentially dangerous waste, which can cause microbiological contamination. Keep them out of the reach of children.

Step 18

Put the cap on the pen injector. The somatropin injection has been completed.

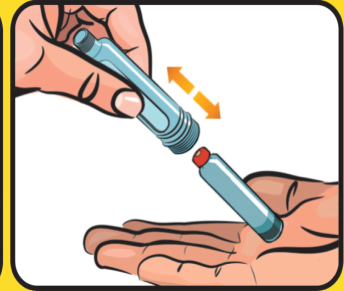


⑦➤ replacing an empty cartridge

Remove the cartridge holder from the pen body by turning it according to the direction shown on the drawing.
Shake the empty cartridge and remove it in accordance with information provided by the manufacturer of somatropin.



Set the dose selector to "0,0" position by turning it according to the direction shown on the drawing. Follow steps 3 through 6.



⑧ ➤ storage and cleaning

- Always keep your SciTropin A PEN 10 and needles out of the reach of other people, especially children.
- SciTropin A PEN 10 **should always be stored and carried with the pen cap on, without a needle.**
- SciTropin A PEN 10 **with the somatropin cartridge** should be refrigerated at **+2°C to +8°C.**
- SciTropin A PEN 10 **without the somatropin cartridge**, can be stored at **-20°C to +25°C.** Keep the pen injector far from extreme temperatures, humidity, dust and direct sun exposure.



Do not freeze SciTropin A PEN 10 and do not use, if it has been frozen.

- SciTropin A PEN 10 should be stored in its case.
- Clean your SciTropin A PEN 10 daily. Use only a damp cloth for cleaning. **Do not immerse the injector into water. Avoid contact the pen injector with alcohol, hydrogen peroxide, disinfectants or lubricants.**
- SciTropin A PEN 10 should be protected against major physical forces.



**Do not
immerse
SciTropin A PEN 10
into water.**



Problem:

The crystallisation of somatropin at the needle tip.



Possible cause:

The needle is not replaced daily.

HOW TO ELIMINATE:

Use a new needle every day.

Problem:

A higher dose was dialled then required.



Possible cause:

User error.

HOW TO ELIMINATE:

You can correct the dose by turning the dose selector in the opposite direction.

Problem:

Cannot attach the cartridge holder onto the pen body.



Possible cause:

Incorrectly insert somatropin cartridge.

HOW TO ELIMINATE:

Check if the cartridge was properly insert into the cartridge holder (metallic cap first)

Pushed out plunger

Push the plunger back into the pen body.

Problem:

Despite a number of priming procedures a drop of somatropin has not appeared on the end of the needle.



Possible cause:

Incorrectly installed somatropin cartridge

Clogged pen needle.

HOW TO ELIMINATE:

Check if the cartridge was properly installed. There should be no space between the plunger and the cartridge.

Replace the needle with a new one

Problem:

After the injection the red dot did not appear in the the window displaying the end of injection



Possible cause:

There was not enough somatropin in the cartridge to inject the full set dose .

HOW TO ELIMINATE:

Note the number of units remaining, as it corresponds to the number of units of somatropin which you must inject to complete the injection. Attach the outer needle shield and remove the needle. Replace the old cartridge with a new one, accordingly to Section 7. Prepare the pen injector to use accordingly to the actions described in steps 7 to 10. Perform the priming dose injection. complete the interrupted dose delivery by turning the dose selector until the figure, which you have seen in the selector window, appears. Follow steps 14 through 15.

information from the manufacturer

- **Package contents:** SciTropin A PEN 10 automatic somatropin pen injector, pen case, user's manual.
- SciTropin A PEN 10 meets the requirements of ISO 11608-1 standard with respect to general requirements dosing accuracy and robustness.
- SciTropin A PEN 10 in **intended for use with disposable needles:** BD 31G (4 mm), BD 32G (5 mm) and BD 31G (8 mm).
- SciTropin A PEN 10 should be replaced:
 - after **3 years in use**
 - when decided by your doctor or
 - **in any case where there are doubts as to SciTropin A PEN 10 functionality.**
- SciTropin A PEN 10 is made of materials safe for the health of patients.

Particular attention should be paid to the information preceded by this sign which will ensure safe and comfortable use of the device.



In the events of serious incidents, this should be reported to the manufacturer and to the competent authority.



Damaged or outside the period of use specified by the manufacturer SciTropin A PEN should be disposed according to the instruction of your doctor / healthcare provider / pharmacist / or local regulations.



Manufacturer:
Nemera Szczecin p. z o.o.
ul. Tytanowa 3
70-856 Szczecin



plszc_info@nemera.net
www.nemera.net.

Distributor/Importer:

legend of pictograms used in instruction for use, labels and package



Indicates the medical device manufacturer



Indicates that caution is necessary when operating the device or control close to where the symbol is placed or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences



Indicates the need for the user to consult the instructions for use



Patient information website

● legend of pictograms used in instruction for use, labels and package



Indicates the date that medical device was manufactured



Temperature limit - Indicates the temperature limits to which the medical device can be safely exposed



Humidity limitation - Indicates the range of humidity to which the medical device can be safely exposed



Indicates the item is a medical device



Batch code - Indicates the manufacturer's batch code so that the batch or lot can be identified



Catalogue number - Indicates the manufacturer's catalogue numbers so that the medical device can be identified



Keep dry - Indicates a medical device that needs to be protected from moisture



Distributor - Indicates the entity distributing the medical device into the locale

notes



disposal of pen injector

Remember to dispose Your pen injector 3 years after first use. Below note the date of first and last use of SciTropin A PEN 10

1st use on:

		—			—				
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Throw away after:

		—			—				
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AUTOMATIC SOMATROPIN PEN INJECTOR

SciTropin A PEN 10

USER'S MANUAL



Read the instruction carefully before using SciTropin A PEN 10. Failure to follow of these instructions may have serious consequences to your health.

Using the device in a different way from the process described in this manual is not recommended.