

AUTOMATIC SOMATROPIN PEN INJECTOR

[®]
HHT PEN 20mg

USER'S MANUAL

HHT [®] PEN 20mg

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 **Nemera**

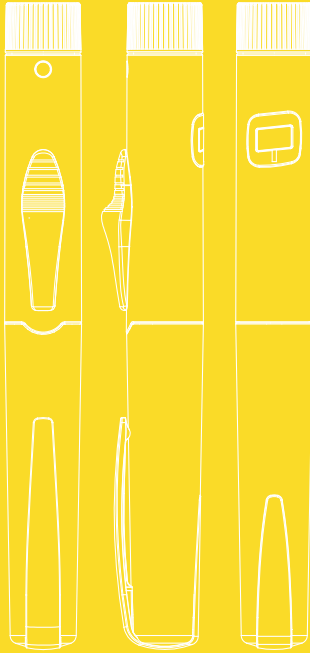


Table of contents

- 1 before the first use
- 2 construction of pen injector, pen needle and cartridge
- 3 installation of cartridge and pen needle
- 4 priming your HHT®PEN 20mg
- 5 injecting a dose
- 6 removing a needle
- 7 replacing a cartridge
- 8 replacing a needle
- 9 storage and cleaning
- 10 information from the manufacturer



before the first use

Before the first use of HHT®PEN 20mg pen injector carefully read ALL instructions included in this user's manual.

HHT®PEN 20mg 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 0.07 mg (0,01mL) to 4.00 mg (0,6mL), with incremental dose of 0.07 mg (0,01mL).

Indications for use:

- ▶ HHT®PEN 20mg is intended for use by humans to treat:
 - a) Kids
Growth disturbance associated with insufficient secretion of growth hormone and growth disturbance associated with Turnersyn-drome or chronic renal failure.
 - b) Adults
Replacement therapy in adults with pronounced growth hormone deficiency.
- Growth hormone deficiency in adults.
- ▶ HHT®PEN 20mg is intended for use exclusively with XXX 3,0 ml somatropin cartridges recommended by manufacturer according to ISO 11608-3.
- ▶ HHT®PEN 20mg is designed 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.

1 >> before the first use

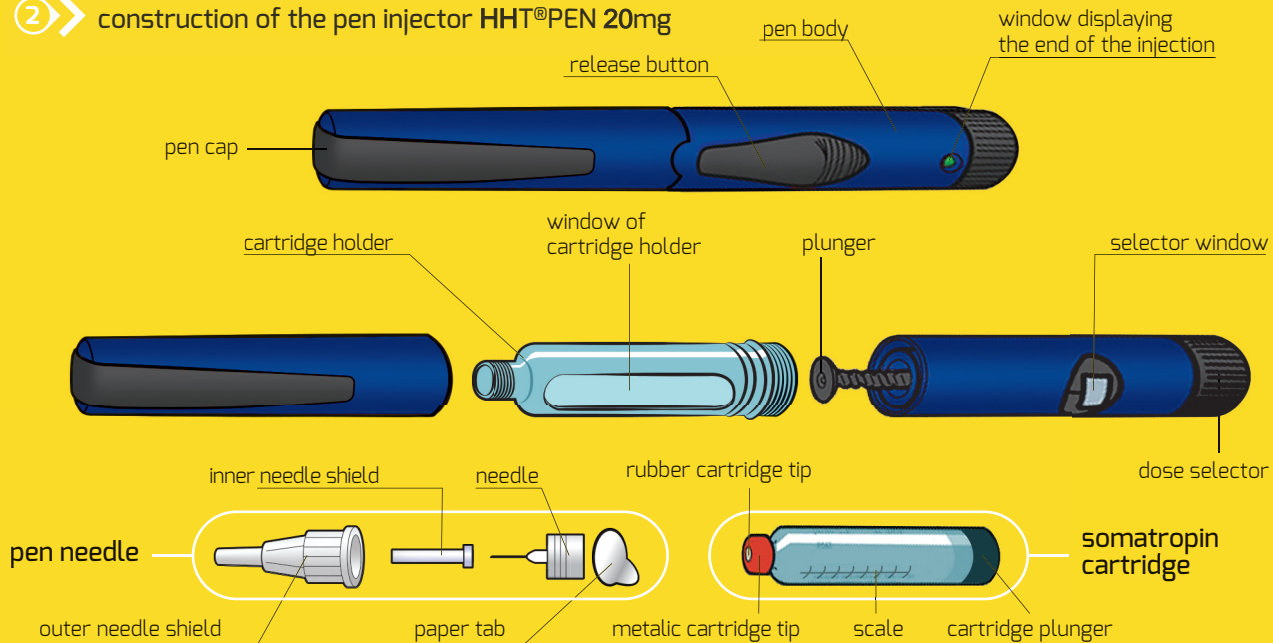
- >> HHT®PEN 20mg can be used in the home environment by people from different cultural backgrounds, people of different ethnicity, with all levels of education.
- >> Use HHT®PEN 20mg only with the somatropin recommended by your doctor. HHT®PEN 20mg is intended for use by one person only and should not be shared with others.
- >> Use HHT®PEN 20mg only at the dosage recommended by your doctor. If you or your child have administered a dose that is too high, proceed according to information provided by the somatropin manufacturer.

Contraindications for use:

- >> Using HHT®PEN 20mg without somatropin cartridge may cause defective operation.
- >> HHT®PEN 20mg 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.
- >> Do not use HHT®PEN 20mg if it is not working properly, or any of its parts look damaged.
- >> Do not try to repair your HHT®PEN 20mg, manipulate in it or pull it apart
- >> Damaged or outside the period of use specified by the manufacturer Eqpen should be disposed according to the instruction of your doctor/healthcare provider/pharmacist/ or local regulations.



② construction of the pen injector HHT®PEN 20mg



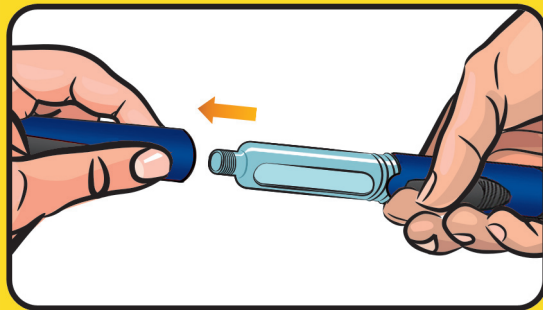
3 >> installation of cartridge and pen needle

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

- > HHT®PEN 20mg
- > somatropin cartridge
- > new pen needle
- > alcohol swab

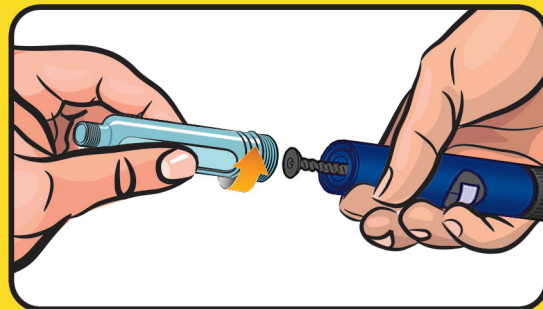
New somatropin cartridge or HHT®PEN 20mg with cartridge attached should be taken out of the refrigerator 30 minutes prior the planned injection.

Step 1
Pull off the cap



Step 2

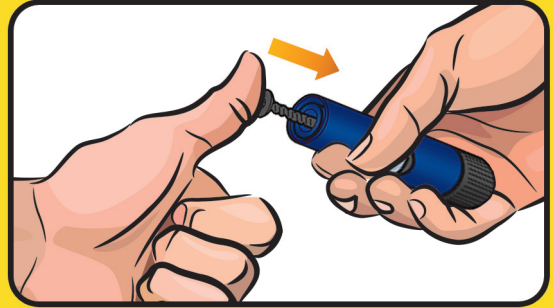
Unscrew the cartridge holder from the pen body by turning it according to the direction shown on the drawing.



3 >> instalation of cartridge and pen needle

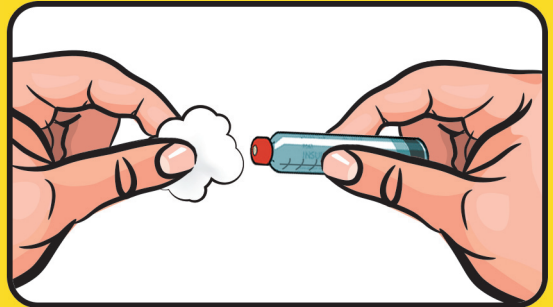
Step 3

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 as 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 rubber somatropin cartridge tip with the swab

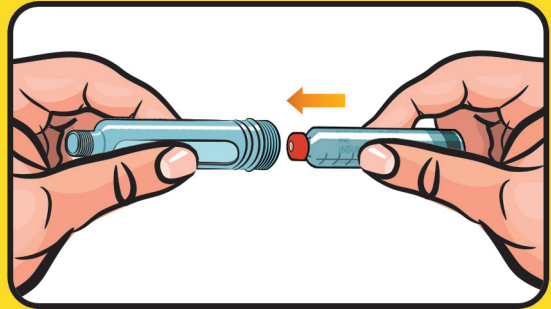


Do not use the somatropin if cartridge is cracked or broken and after the medicine expiration date. Do not manipulate in pen injector mechanism. This may cause malfunction of pen injector.

③ installation of cartridge and pen needle

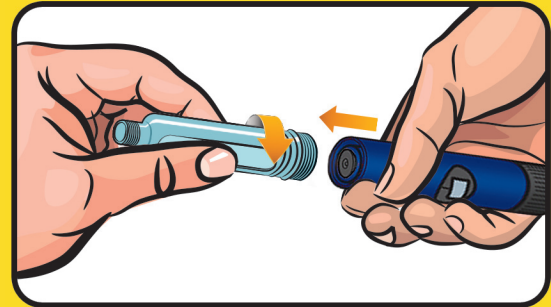
Step 5

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



Step 6

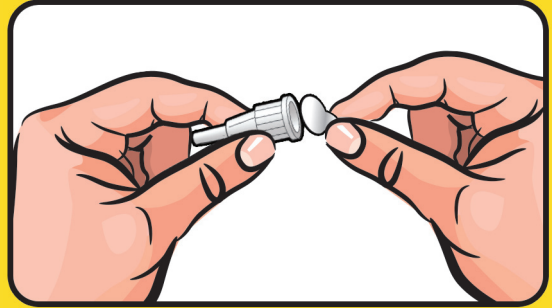
Attach the cartridge holder to the pen body by turning it according to direction shown on the drawing, until **first resistance is met**.



3 >> instalation of cartridge and pen needle

Step 7

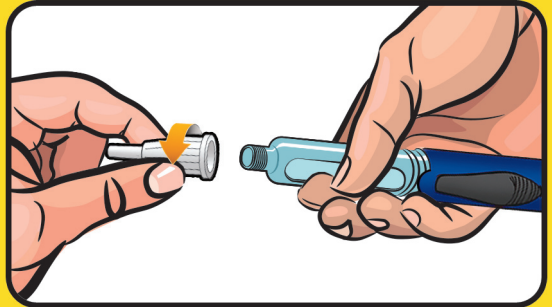
Take a new sterile needle. Check the needle expiration date and the paper tab on the outer needle shield. Remove the paper tab from the outer needle shield.



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

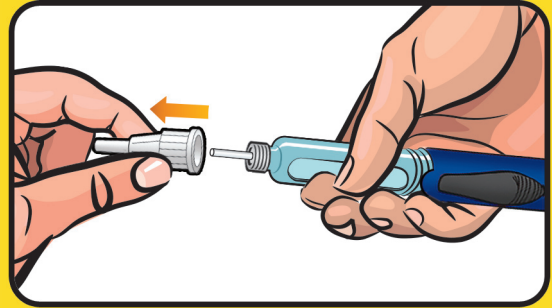
Hold the pen injector by the cartridge holder. Attach the outer needle shield to the cartridge holder until first resistance is met, according to the direction shown on the drawing.



3 >> instalation of cartridge and pen needle

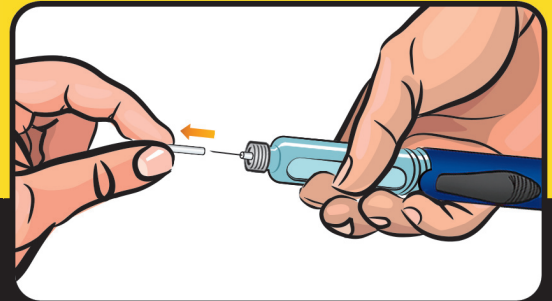
Step 9

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.



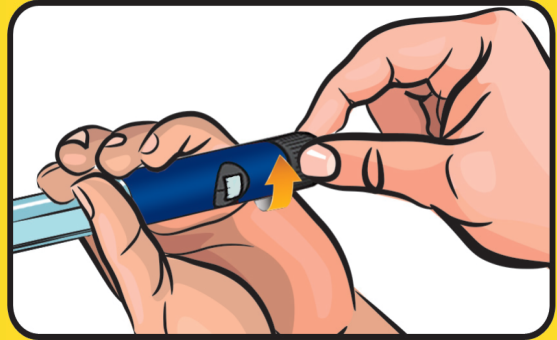
To minimise the risk of unintended needle penetration and transmission of infectious diseases, never replace the inner needle cap once removed. If by accident you puncture your skin, clean the wounded spot with a skin disinfectant.

4 >> priming your HHT®PEN 20mg

Prime your HHT®PEN 20mg before each injection.

Using the dose selector, choose 0.13 mg of somatropin. Turn the dose selector clockwise until the figure 0.13 appears in the selector window.

Step 11



Take the pen with the needle pointing upwards. Using your thumb, slide the release button in the direction of the needle.

Hold the release button until a green dot appears in the window displaying the end of the injection. If a drop of somatropin appears on the tip of the needle the pen injector is ready for use.

Step 12



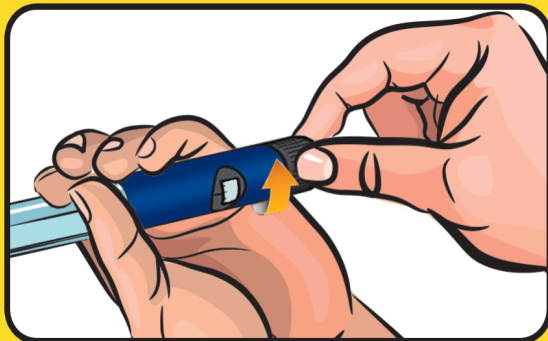
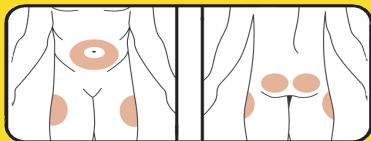
If a drop of somatropin does not appear at the end of the needle, repeat steps 11 and 12. If a drop of somatropin does not appear after several attempts, remove the needle in accordance with step 17. Repeat steps 7 through 12, afterwards.

Prime your HHT®PEN 20mg before each injection.

5 >> injecting a dose

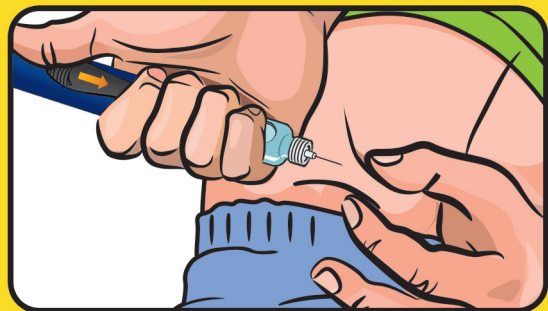
Step 13

Turn dose selector to your desired dose.
Example: 0.13 mg shown in the drawing.
If you dial too many units, you can correct the dose
by turning the dose selector backwards.



Step 14

Select the injection site (abdomen, thighs, buttocks) and
wipe your skin with an alcohol swab.
Rotate your injection sites daily.
Insert the end of the needle into the subcutaneous
tissue. 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 direction of the needle.



5 >> injecting a dose

Step 15

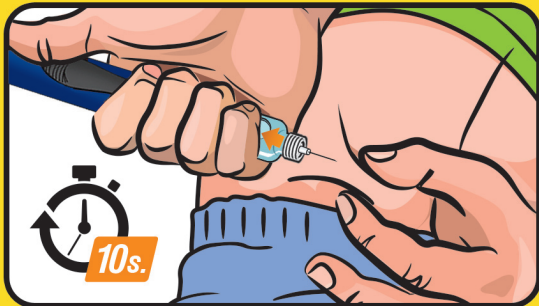
Hold the release button **until a green dot appears in the window** displaying the end of the injection.



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



If the green 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 enter to complete the injection. Perform the actions described in steps 16 through 18. Prepare your HHT@PEN 20mg for injection by proceeding in accordance with steps 7 through 12. To complete the interrupted dose delivery, turn the selector clockwise until the figure, which you have seen in the selector window, appears, then perform the actions described in steps 14 through 15.



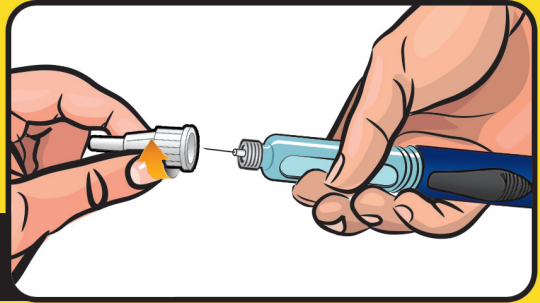
Step 16

Count at least to ten. Remove the needle from the skin at the same angle it was inserted into subcutaneous tissue.

6 >> removing a needle

Step 17

Put the outer needle shield on the needle. Rotate the outer needle shield counterclockwise. Remove the used needle. Dispose of it in accordance with information provided by the manufacturer of the needle. Put the cap on the pen injector.

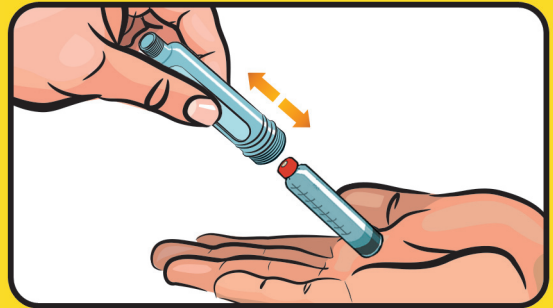


Used needles and empty somatropin cartridges are classified among the potentially dangerous waste, which can cause microbiological contamination. Dispose them with accordance to manufacturer recommendations or local laws. Keep them out of the reach of children.

7 >> replacing a cartridge

Step 18

Perform the action described in step 2. Shake the empty cartridge to eject it from its holder and dispose of it according to the information supplied by the manufacturer of somatropin. Set the dose selector to "0" position by turning it counterclockwise. Follow steps 3 through 6



8 >> replacing a needle

Step 19

Follow the guidelines described in step 17. Then perform the procedures described in steps 7 through 8.

Problem:

The crystallisation of somatropin at the needle tip.



Possible cause:

The needle is not replaced with each injection.

HOW TO ELIMINATE:

Use a new needle with each injection.

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

HOW TO ELIMINATE:

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

Clogged pen needle.

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 steps 16 through 18 . 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.

10 >> storage and cleaning

- ▶ Always keep your HHT®PEN 20mg and needles out of the reach of other people, especially children.
- ▶ HHT®PEN 20mg should be protected against major physical forces.
- ▶ HHT®PEN 20mg should always be stored and carried with the top cap on, without a needle.
- ▶ HHT®PEN 20mg should be stored in its case.
- ▶ Clean your HHT®PEN 20mg every day. Use only a damp cloth for cleaning. Do not immerse the pen injector into water. Do not use alcohol, hydrogen peroxide, disinfectants or lubricants to clean the pen injector.
- ▶ HHT®PEN 20mg with the somatropin cartridge should be refrigerated at +2°C to +8°C.
- ▶ HHT®PEN 20mg should not be stored at more than 70°C or below (-40)°C. Keep the pen injector far from extreme temperatures, humidity, dust and direct sun exposure.



Do not immerse
HHT®PEN
20mg
into water.



Do not freeze HHT®PEN 20mg and do not use, if it has been frozen.

11 information from the manufacturer

- ▶ **Package contents:** HHT®PEN 20mg automatic somatropin pen injector, pen case, user's manual. HHT®PEN 20mg meets the requirements of ISO 11608-1 standard with respect to general requirements, dosing accuracy and robustness.
- ▶ HHT®PEN 20mg is intended for use with disposable needles: BD31G (5mm), BD32G (4mm) and BD31G (8mm) as per ISO 11608-2.
- ▶ HHT®PEN 20mg should be replaced after about 3 years of use, when decided by the physician or in any case when there are doubts as to its functionality.
- ▶ HHT®PEN 20mg is made of materials that do not make reactions on patient's skin.

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

Particular attention should be paid to the information preceded by this sign



which will ensure safe and comfortable use of the device.



Manufacturer:

Nemera Szczecin sp. z o.o.

3 Tytanowa Street

70-856 Szczecin, Poland

plszc_info@nemera.net

www.nemera.net

Distributor/Importer:

legend



Indicates the medical device manufacturer



(yellow color) 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

 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 HHT[®]PEN 20mg.

1st use on:

<input type="text"/>	<input type="text"/>	—	<input type="text"/>	<input type="text"/>	—	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Throw away after:

<input type="text"/>	<input type="text"/>	—	<input type="text"/>	<input type="text"/>	—	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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AUTOMATIC SOMATROPIN PEN INJECTOR

[®]
HHT PEN 20mg

USER'S MANUAL



Read the instructions carefully before using HHT[®]PEN 20mg

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.