

INSTRUCTION FOR USE

ADVAPEN[®]

Automatic insulin pen injector
for insulin, subcutaneous use

Your pen comes with 0.6 mL of insulin.



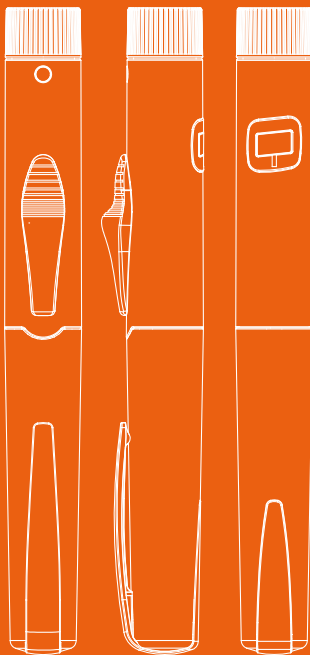


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1. Before the first use

Before the first use of Advapen carefully read ALL instructions included in this user's manual, carefully as there may be important indications that the user of the pen should be aware of.



Failure to follow the instruction may have serious consequences for your health.

Advapen is reusable, variable dose, automatic insulin pen injector. It provides you or your child with a precise, safe and effortless way to administer insulin doses recommended by the doctor, in the range from 1 to 60 units, with incremental dose of 1 unit (0.01ml) of insulin.

Indication for use:



- > Advapen is intended to use by people to treat diabetes;
- > with 3.0 mL insulin cartridges recommended by the drug manufacturer which meet the requirements of ISO 11608-3;
- > with disposable needles KD-PENOFINE 31G 0.25 x 5mm and 0.25 x 6mm recommended
by the drug manufacturer which meet the requirements of ISO 11608-2;
- > by one person only and should not be shared with other people, even if the needle has been changed.



- > Advapen is intended for use by adults and children. Children should use the Advapen with the adult's, trained third party assistance.

» 1. Before the first use

Use Advapen:



- > with a new needle for each dose to ensure sterility, prevent infections or leakage of insulin and reduce the risk of needle clogging;
- > under good lighting conditions that allow for good visibility and proper handling.

Contraindications for use:

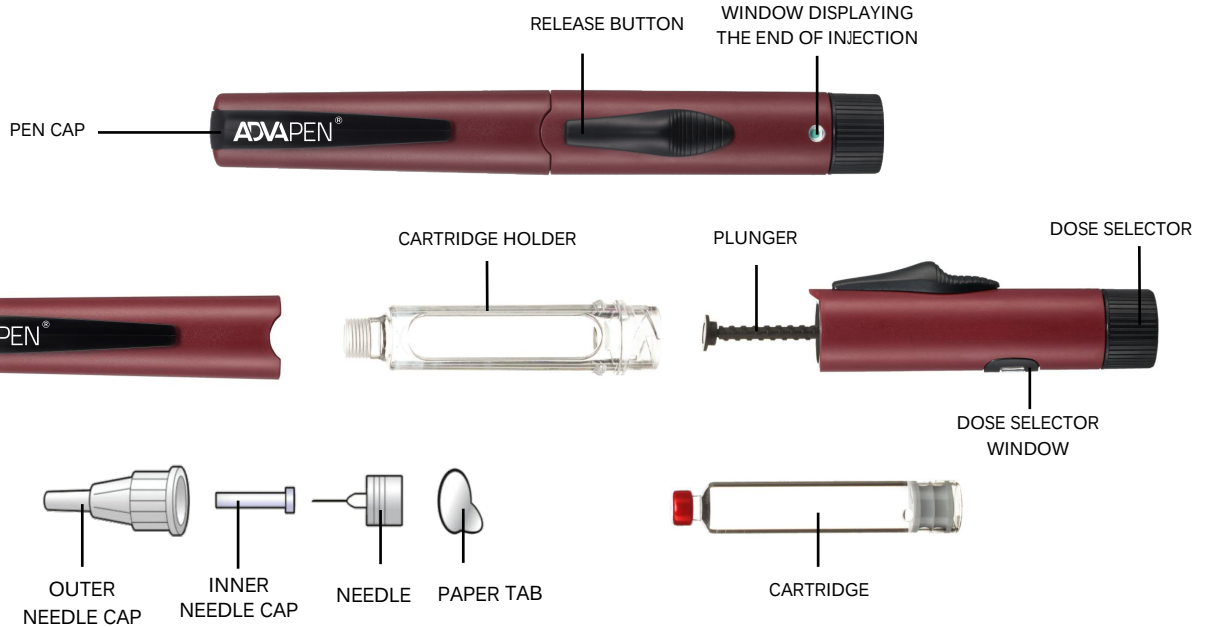


- > Advapen is intended for use by person humans to treat the diabetic patients who require insulin to maintain proper glucose metabolism.
- > There are also contraindications resulting from characteristics of the drug.
- > Advapen is not recommended for use by people, who are blind or visually impaired or with very limited motor activity without the assistance of a trained third party.



- > Do not use Advapen if it is not working properly, any of its part look damaged or if it will be damaged during use.
- > If in doubt, contact the manufacturer or distributor.
- > Do not try to repair your Advapen or pull it apart.

>> 2. Construction of Advapen



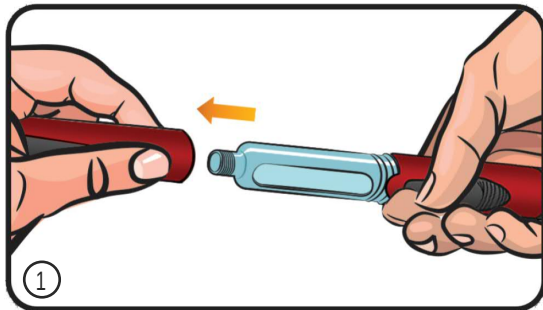
3. Preparing the Advapen for use

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

- > Advapen injector
- > insulin cartridge
- > new disposable needle
- > two alcohol swabs

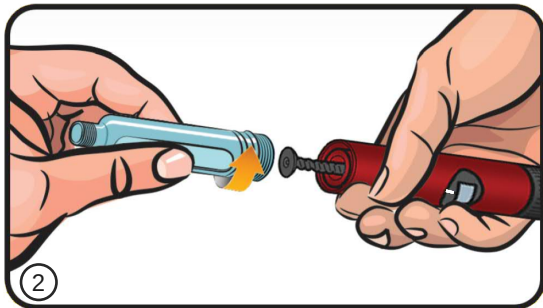
Step 1

Pull off the pen cap (see figure 1).



Step 2

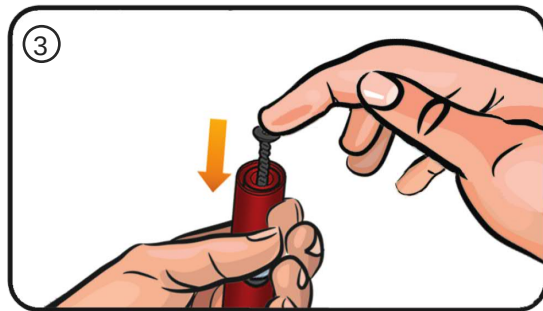
Unscrew the cartridge holder from the pen body by turning it according to the direction shown on the figure 2.



» 3. Preparing the Advapen for use

Step 3

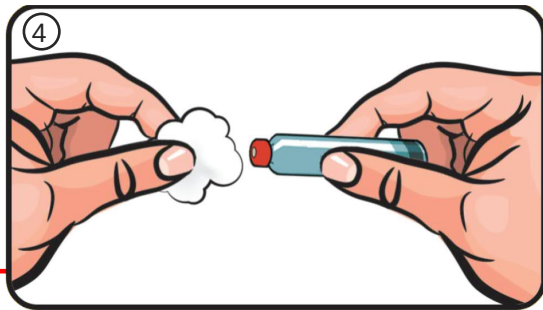
Press the plunger into the pen body as show in figure 3, until the first resistant is met. Do not bend the plunger sideways. If the plunger is stuck try to screw it into the pen body clockwise to the first resistance by holding the plunger. Then push the end of plunger into pen body as much is possible. In case of problems, stop using the pen and contact with it's manufacturer.



Step 4

Check the insulin cartridge.

Make sure that it is not cracked or broken, the insulin solution is clear and transparent. Check the insulin expiration date.



Wipe the insulin rubber cartridge tip with the alcohol swab (see figure 4).



Advapen should not be used if the solution of insulin is cloudy, colored, or contains particles. Do not use insulin cartridge when is cracked or broken and after the medicine expiration date.

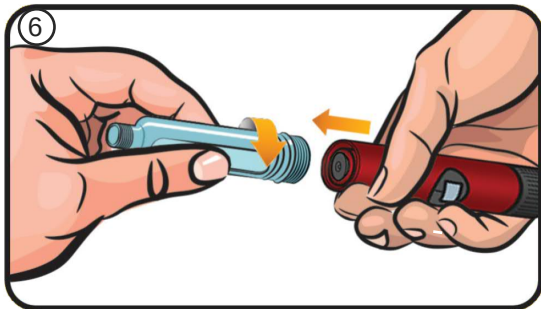
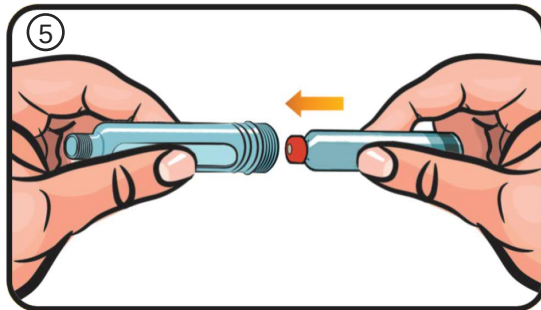
» 3. Preparing the Advapen for use

Step 5

Insert insulin cartridge into the cartridge holder, metallic tip to the front (see figure 5).

Step 6

Attach the cartridge holder to the pen body by turning it according to direction shown on the figure 6, until first resistance is met.



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Step 7

When using cloudy insulin, mix the cartridge content by turning the pen up and down at least 10 times until insulin looks entirely mixed (see figure 7).

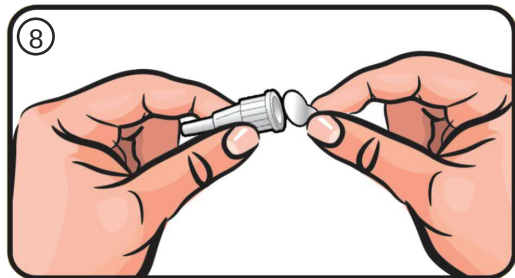
3. Preparing the Advapen for use

Step 8

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

Do not use the needle after the expiry date and/or with a damaged paper tab.

Remove the paper tab from the outer needle shield (see figure 8).

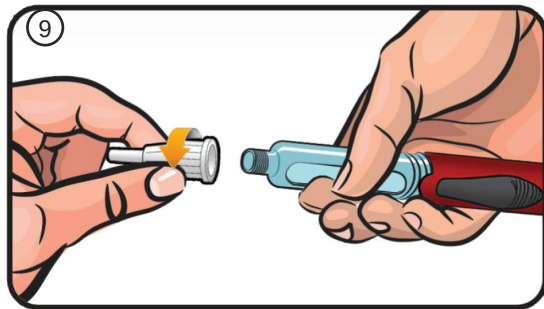


For each injection use a new needle. This will help prevent contamination. Do not use needles if the paper tab is damaged. Reuse of the same needle or needle with a damaged unit pack (paper tab) is not in line with epidemiological recommendations.

Step 9

Hold the pen injector by the cartridge holder.

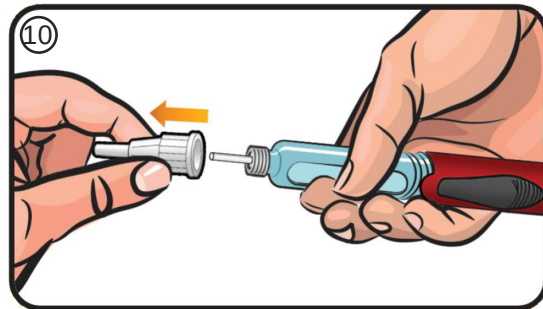
Attach the outer needle shield to the cartridge holder in the direction shown on the figure 9 until first resistance is met.



» 3. Preparing the Advapen for use

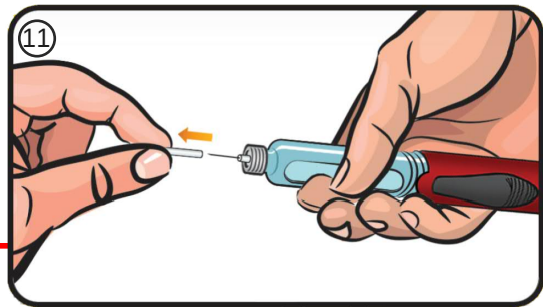
Step 10

Remove the outer needle shield (see figure 9).
Retain it for removal of the needle after the completion of the injection process.



Step 11

Remove (see figure 11) 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 shield once removed.

If by accident you puncture your skin, clean the wounded spot with a skin disinfectant.

» 4. Priming your Advapen

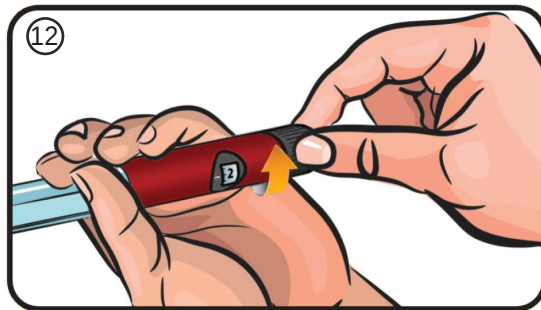
Prime your Advapen before each injection.

Step 12

The number in the dose selector window corresponds to the drug volume in units. Choose 2 units of insulin as a test dose.

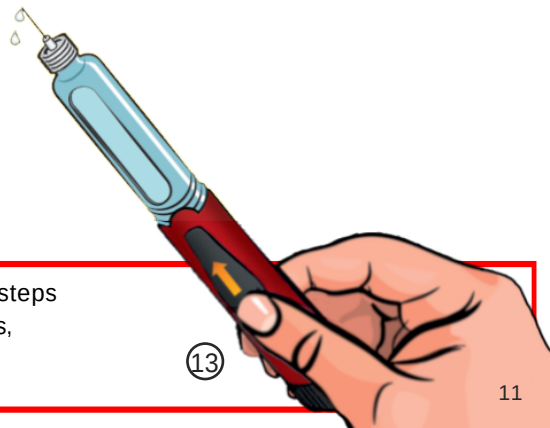
How to select the test dose?

1. Turn the dose selector according to the direction shown on the figure 12.
2. Turn the dose selector until figure 2 appears in the dose selector window.



Step 13

Hold the pen with the needle pointing upwards (see figure 13). Using your thumb, slide the release button in the needle direction. Hold the release button until a green dot appears in the window displaying the end of injection. If a drop of insulin appears on the tip of the needle the Advapen is ready for use.



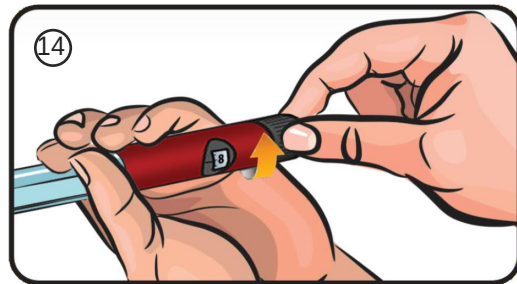
If a drop of insulin does not appear at the end of the needle, repeat steps 11 and 12. If a drop of insulin does not appear after several attempts, remove the needle with step 21. Repeat steps 8 through 12, afterwards.

» 5. Injecting a dose

Step 14

Select a dose of insulin you want to inject. To do that, turn the dose selector according to the direction shown on the figure 14, until the desired number of insulin appears in the dose selector window.

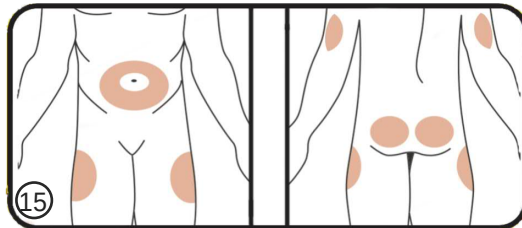
Make sure that dose selector window shows the correct dose. If the dialled dose is too high, you can correct it by turning the dose selector backwards.



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

Step 15

Select the injection site (abdomen, thighs, arms - see figure 15) as instructed by your healthcare professional and wipe your skin on the injection site with an alcohol swab.

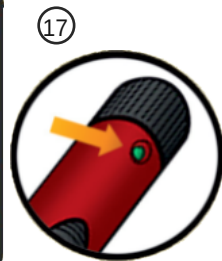
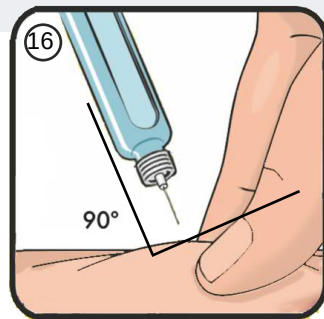


Before injecting each dose, clean the injection site with an alcohol swab. Change the injection site each time to lessen injury under the skin.

» 5. Injecting a dose

Step 16

Gently hold a fold of the skin and insert the tip of the needle into subcutaneous tissue in a 90 degrees angle (see figure 16). Using your thumb slide the release button in the needle direction, hold the release button until a green dot appears in the window displaying the end of injection (see figure 17). Count to 10 slowly. Do not remove the needle from the skin.



If the green dot does not appear (see figure 18)... it means that there is no insulin in the cartridge and the full dose has not been dispensed. Note the number of units remaining in the dose selector window, as it corresponds to the number of units of insulin which you must inject to complete the injection. Attach the outer needle shield and remove the needle according to step 21. Replace the old cartridge with a new one, accordingly to Section 7- Replacing a cartridge. Prepare the pen injector for use accordingly to the actions described in steps 3 to 11. Perform the priming dose injection as described in steps 12 and 13. Next, complete the interrupted dose delivery by turning the dose selector until the correct dose in units (remaining to complete the full dose) appears on the dose selector window. Follow steps 14 to 15 to complete the injection.



For example, if the green dot does not appear (see figure 18), and there is number "10" in the dose selector window (see figure 19), it means that after replacing a cartridge with a new one, you must refill the dose and administer 10 unit of insulin.

» 5. Injecting a dose

Step 17

Remove the needle from the skin at the same angle it was inserted into subcutaneous tissue (see figure 20).

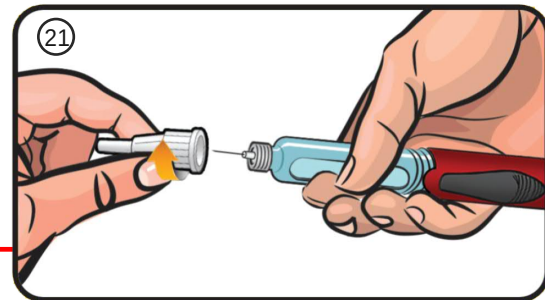


» 6. Removing a needle

Step 18

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 figure 21.

Remove the used needle and dispose as instructed by your healthcare provider or in accordance with information provided by the manufacturer of the needle.



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

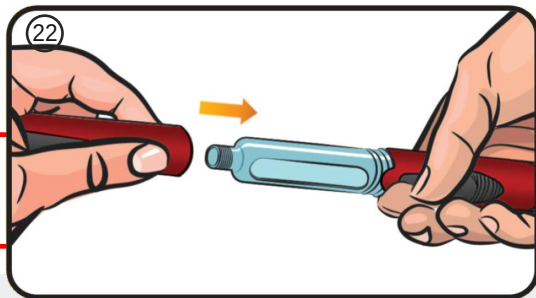
Step 19

Put the cap on the pen injector (see figure 22).

The insulin injection has been completed.



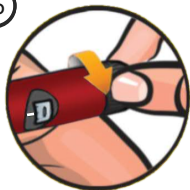
Always remove and dispose of the needle after each injection and store the pen injector in its case. This will reduce the risk of contamination, infection, leakage of solution and clogged needles.



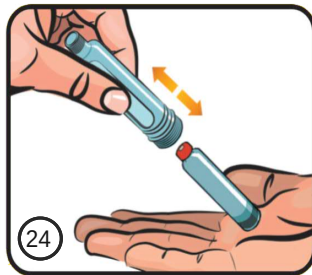
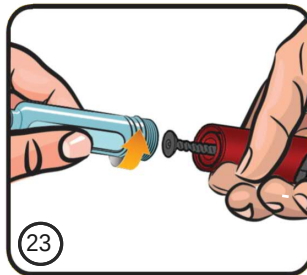
» 7. Replacing a cartridge

Remove the cartridge holder from the pen body by turning it according to the direction shown on the figure 23. Shake the empty cartridge (see figure 24) and dispose it as instructed by your healthcare provider or in accordance with information provided by the manufacturer of insulin.

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Set the dose selector to "0" position by turning it according to the direction shown on the figure 25. Follow steps 3 through 6.



Before attempting to replace a cartridge, be sure that the pen needle has been removed from the pen injector.

» 8. Storage and cleaning

> Advapen with insulin cartridge should be stored according to the insulin manufacturer requirements.

> Advapen without the insulin cartridge can be stored -40°C to +70°C.



Always keep your Advapen injector, needles and insulin cartridges out of the reach of other people, especially children.

> Advapen should always be carried with the pen cap on, without a needle.

Store your Advapen:

- with the pen cap on, without a needle;
- with an insulin cartridge, according to drug manufacturer recommendation described in the drug leaflet for patients;
- far from extreme low or high temperatures, light, humidity, dust, dirt, liquids and direct sun exposure;
- in case.



Do not freeze Advapen and do not use, if it has been frozen.

> Clean your Advapen daily. Use only a damp cloth for cleaning.

> Do not immerse the injector into water. Avoid contact of the pen injector with alcohol, hydrogen peroxide, disinfectants or lubricants.

> Advapen should be protected against major physical and gravity forces.



Do not immerse
Advapen
into water.



9. Troubleshooting

Problem:

- The needle is clogged.



Solution:

- The needle is not replace daily. Use a new needle every day

Problem:

- There is at least a drop of medicine seen on the tip of the needle after its installation.



Solution:

- The drop of medicine seen on the needle tip will not affect your dose. Continue to take your dose as described in the user manual.

Problem:

- A higher dose of insulin was dialled than equired.



Solution:

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

Problem:

- How can I tell if my Advapen delivery device properly delivered a full set dose?



Solution:

- After the injection the 0 unit is shown in the dose selector window and green dot is appears in the window displaying the end of injection to indicate that the full dose of insulin has been injected.



10. Information from the manufacturer

- > Package contents: Advapen automatic insulin pen injector, pen case, user's manual.
- > Advapen meets the requirements of ISO 11608-1 standard with respect to general requirements dosing accuracy and robustness.
- > Advapen should be replaced:
 - after 2 years in use;
 - when decided by your doctor or in any case where there are doubts as to Advapen functionality.
- > In the event of serious incidents, these should be reported to the manufacturer and to the competent authority.



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

> Advapen 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.

Manufacturer:



Nemera Szczecin sp. z o.o.
3 Tytanowa Street
70-856 Szczecin, Poland
phone: +48 91 351 81 00



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 number 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 2 years after first use. Below note the date of first and last use of Advapen

1st use on:

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Throw away after:

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INSTRUCTION FOR USE

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Automatic insulin pen injector
for insulin, subcutaneous use

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