

NordiFlex PenMate®

User Manual

Please read this manual carefully before using your NordiFlex PenMate®



Introduction

This package contains one NordiFlex PenMate® auto-insertion accessory, a case for storage and this user manual.

Please read these instructions carefully before using your NordiFlex PenMate® (called PenMate® in the rest of this user manual). This manual contains instructions for using, storing and cleaning your PenMate®. You should read these instructions even if you have used other Novo Nordisk delivery systems before.



PenMate® is designed to help you inject growth hormone by hiding the needle during the injection with Norditropin NordiFlex® 5, 10 or 15 mg/1.5 ml. Do not use your pen or PenMate® without training from your doctor or nurse. Read the Norditropin NordiFlex® 5, 10 and 15 mg/1.5 ml user manual before using PenMate®.

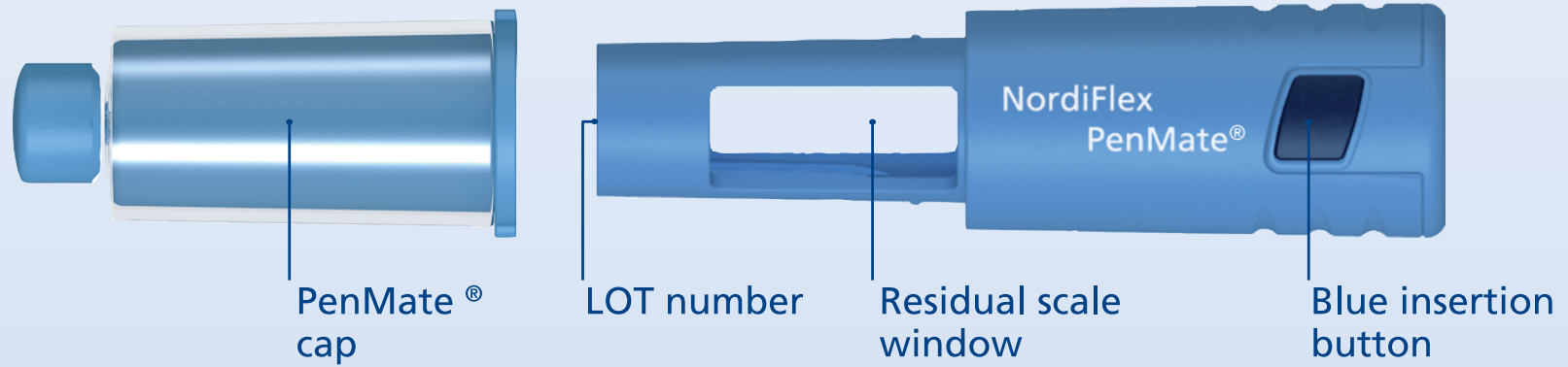
Norditropin NordiFlex® is a pre-filled growth hormone injection pen for single patient use only. Norditropin NordiFlex® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm.

The illustrations in this manual show PenMate® being used with Norditropin NordiFlex® 5 mg/1.5 ml.

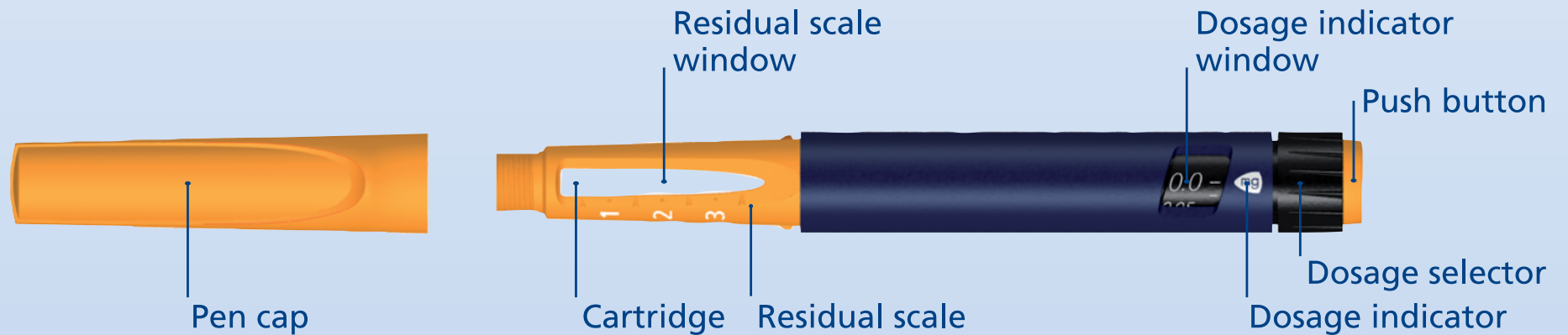
Inside this cover you will find a diagram with the names of the different parts of PenMate®.

Leave it unfolded when following the instructions in this manual.

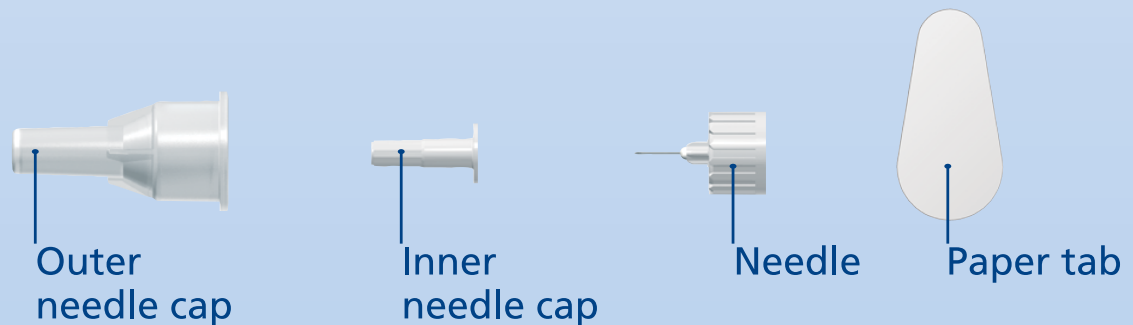
NordiFlex PenMate®



Norditropin NordiFlex® 5 mg/1.5 ml (example)

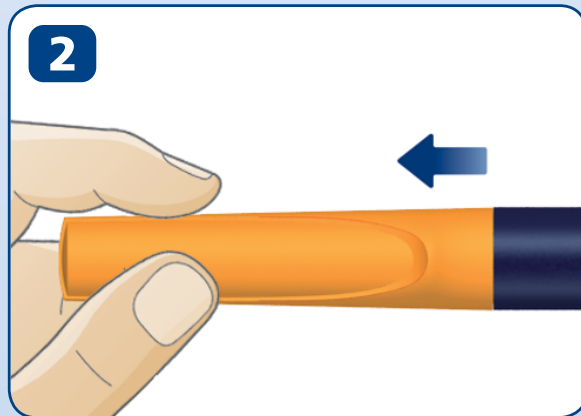
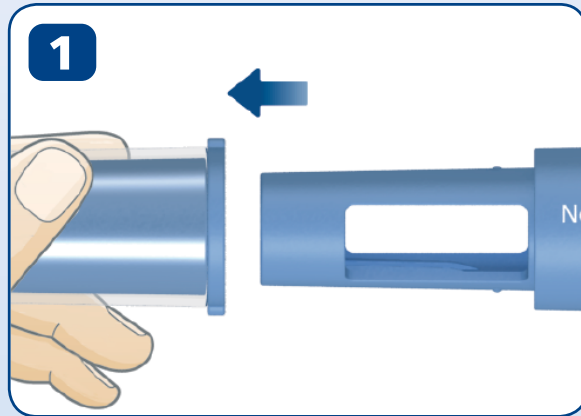


Needle (example)



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4 Getting started | Preparing your PenMate®



Preparing your PenMate®

Check the name, strength and coloured label of your Norditropin NordiFlex® pen to make sure that it contains the growth hormone strength you need.

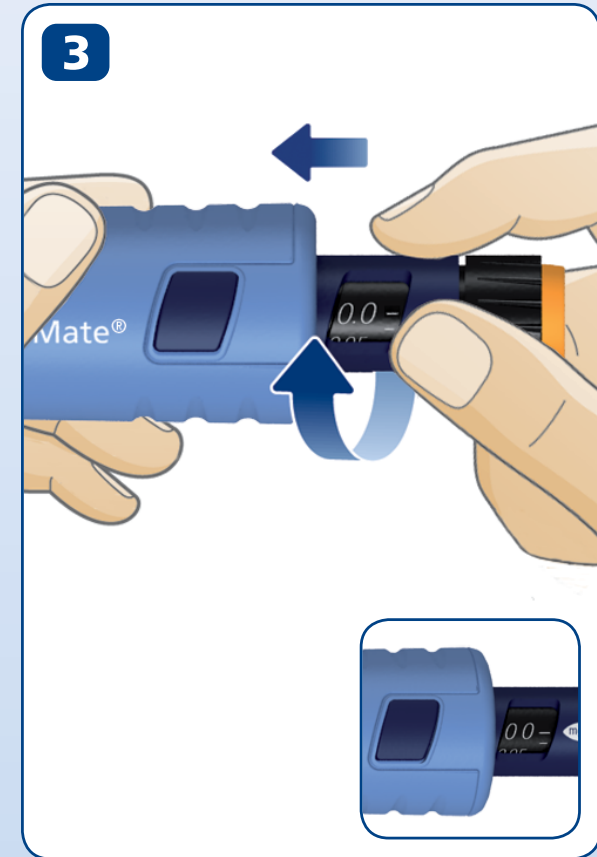
1 Pull off the PenMate® cap.

2 Pull off the pen cap.
You will not need it with your PenMate®.

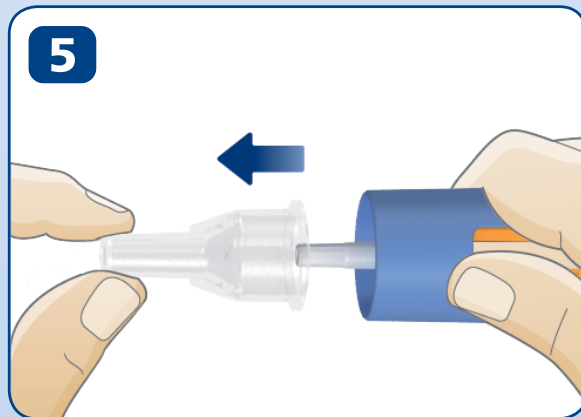
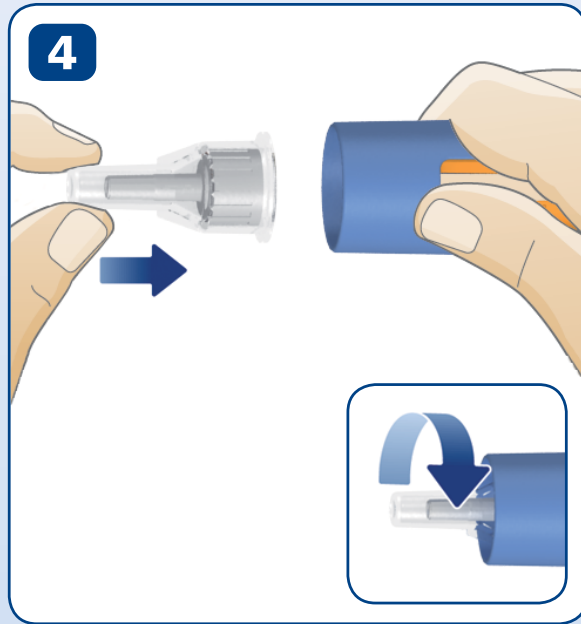
Check that the solution inside the cartridge is clear and colourless by tipping the pen upside down once or twice.

Do not use the pen if the solution inside the cartridge is unclear or cloudy.

- 3 Insert the pen into PenMate® and screw them together, without touching the blue insertion button or the push button, until you hear or feel a 'click'. The dosage indicator window on your pen must align with the blue insertion button on your PenMate®.



6 Getting started | Preparing your PenMate®



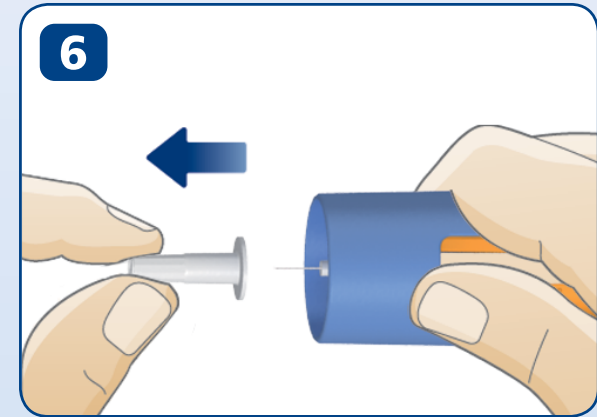
Remove the paper tab from a new needle.

4 Screw the needle straight onto the pen. Make sure the needle is on tight.

5 Pull off the outer needle cap and keep it to correctly remove the needle from the pen after the injection.

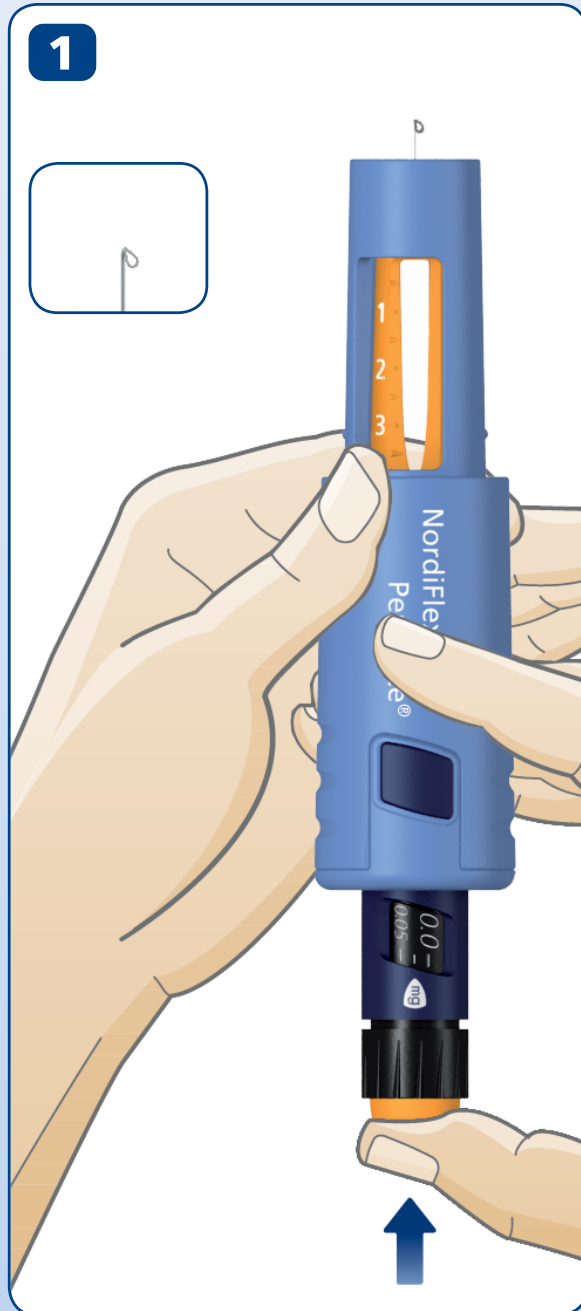
! Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of solution, blocked needles and inaccurate dosing. Never bend or damage the needle.

- 6** Carefully remove the inner needle cap and dispose of it properly.



-
- !** Never put the inner needle cap back on once you have removed it from the needle. You may accidentally stick yourself with the needle.
 - !** The needle is covered by two caps. You must remove both caps. If you forget to remove both caps you will not inject any growth hormone.

8 Checking the flow



- 1** To ensure proper dosing and to avoid injection of air, check the flow before your first injection with each new pen, as described in the leaflet in your Norditropin NordiFlex® pack.

Selecting your dose

Check that the dosage indicator on the pen lines up with 0.0.

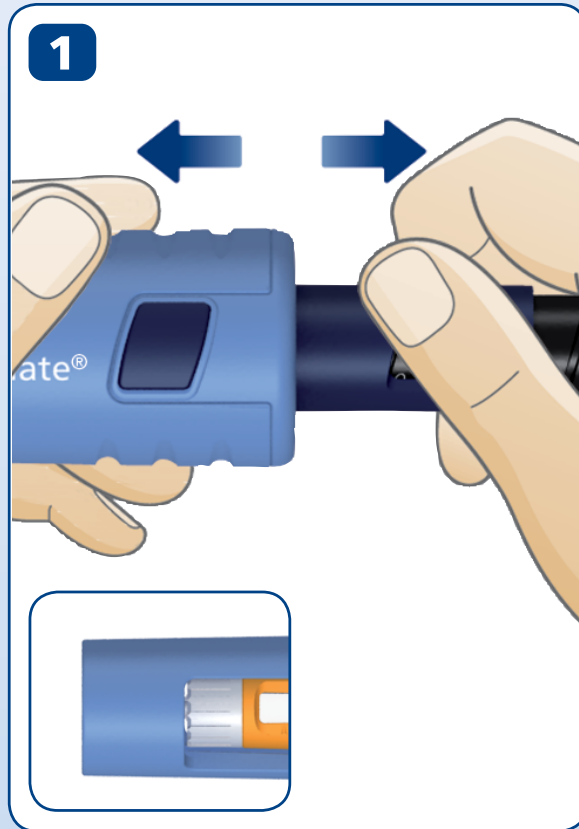
- 1 Select the number of mg your doctor has prescribed for you.

The dose can be increased or decreased by turning the dosage selector in either direction. When turning the dosage selector backwards, be careful not to press the push button as solution will come out.

You cannot set a dose larger than the number of mg left in the pen.



10 Activating your PenMate®



Activating your PenMate®

- 1 To activate your PenMate®, grip both PenMate® and pen, without touching the blue insertion button or the push button and pull in opposite directions until you hear a click.

Now the needle is hidden in PenMate®.

Making your injection

Use the injection technique shown to you by your doctor or nurse. Vary the area you inject so you do not harm your skin.

- 1** Hold PenMate® against your skin. Press the blue insertion button with your finger. The needle will automatically enter your skin.

Check that the dosage indicator lines up with the dose you selected.



12 Making your injection



- 2** To inject, press the push button completely in until 0.0 lines up with the dosage indicator. Keep the push button fully depressed and let the needle remain under the skin for at least 6 seconds. This will ensure that you get the full dose.


Once the injection is completed carefully withdraw the needle from the skin.


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- !** Always press the push button to inject the growth hormone. Turning the dosage selector will not inject growth hormone.

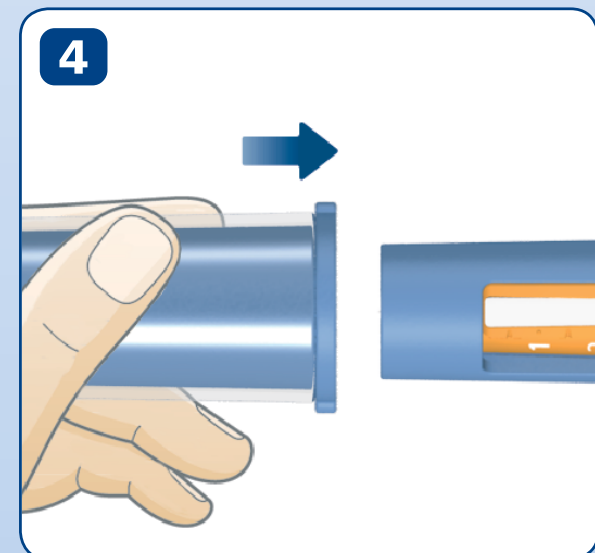
- 3** Carefully put the outer needle cap back on the needle without touching the needle.

Unscrew the needle and throw it away carefully as instructed by your doctor or nurse.

- 4** Put the PenMate® cap back on after every use.

 Caregivers must be very careful when handling used needles – to reduce the risk of needle sticks and cross-infection.

 Always remove and dispose of the needle after each injection and store the pen in PenMate® without the needle attached. This reduces the risk of contamination, infection, leakage of solution, blocked needles and inaccurate dosing.



What to do when Norditropin NordiFlex[®] is nearly empty

You cannot set a dose larger than the number of mg left in the pen. If you need more growth hormone than the amount left in the pen, you must split your dose over two injections:

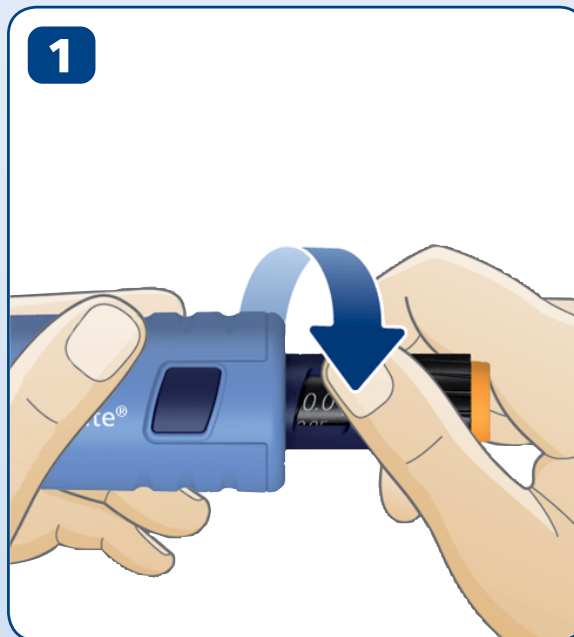
- Inject the growth hormone left in the pen, making a note of the number of mg you inject.
- Unscrew the needle and throw it away carefully as instructed by your doctor or nurse.
- Replace the used pen with a new one as described on *page 15*.
- Check the flow as described in the leaflet in your Norditropin NordiFlex[®] pack. Select and inject the number of mg still needed to complete your dose.

Replacing an empty Norditropin NordiFlex®

- 1** When the pen is empty, unscrew it and gently pull it out of PenMate®. Throw the empty pen away without a needle on as advised by your doctor or nurse and local authorities.

Screw a new pen and your PenMate® together as described on *pages 4 and 5*.

To prepare for a new injection, continue as described on *pages 6 to 10*.



What to do if...

Here are the answers to some questions you might ask when using your PenMate®.

Question

Answer

No growth hormone appears at the needle tip when I check the flow.

The needle may be blocked.

- Screw on a new disposable needle and check the flow until growth hormone appears at the needle tip (see pages 6 to 8).

Norditropin NordiFlex® may be damaged.

- Unscrew the needle (see page 13). Unscrew the pen and replace it with a new one (see page 15). Attach a new disposable needle and check the flow.
-

I want to change the selected dose before injection.

- The dose can be increased or decreased by turning the dosage selector in either direction. Turn the dosage selector until the number of mg you need lines up with the dosage indicator.

Question

The push button stops during the injection, before 0.0 lines up with the dosage indicator.

Answer

The needle may be blocked.

You did not receive the selected dose of growth hormone. To complete your dose, you must inject the remaining number of mg as described below:

- Check the dosage indicator window. The number that lines up with the dosage indicator is the number of mg that you need to inject to complete your dose. Make a note of this number.
- Turn the dosage selector until 0.0 lines up with the dosage indicator.
- Screw on a new needle and check the flow as described on *pages 6 to 8*.
- Select the number of mg you need to complete your dose. This is the number that you made a note of. Activate PenMate® as described on *page 10*.
- Inject as described on *pages 11 to 13*.

18 What to do if...

Question

Answer

I turn the dosage selector but my Norditropin NordiFlex® does not release any growth hormone.

This is normal.

- Always press the push button to inject growth hormone. Turning the dosage selector will not inject growth hormone.

When selecting a dose the dosage selector stops before I have selected the required number of mg.

Either, you are trying to select more growth hormone than there is left in the pen or you are trying to select a dose larger than the maximum dose of more than 60 clicks for one injection.

- If you need more growth hormone than the number of mg left in the pen, follow the instructions on *page 14*.
- If you need more mg than the maximum dose for one injection, you must split your dose over two injections.

Questions**Answer**

My Norditropin NordiFlex[®] and/or my PenMate[®] has been dropped or knocked.

or

I am not sure that my Norditropin NordiFlex[®] and/or my PenMate[®] is working properly.

- Unscrew the pen and pull it gently out of PenMate[®]. Check that the pen and/or PenMate[®] is intact.
- Check that the cartridge is intact, e.g. no cracks or fissures.
- Screw PenMate[®] and the pen together as described on *page 5*.
- Screw on a new needle (*see pages 6 and 7*).
- Check the flow as described in the leaflet in your Norditropin NordiFlex[®] pack.

Caring for your PenMate®

Storage and handling

Your Norditropin NordiFlex® and PenMate® must be handled with care:

- Do not drop your PenMate® or pen or knock them against hard surfaces. If you drop them or suspect that something is wrong with them, always screw on a new needle and check the flow before you inject.
 - Do not try to repair your PenMate® or pull it apart.
 - Protect your PenMate® and pen against water, dust, dirt, frost, direct sunlight and extreme temperatures.
 - Always remove the needle and put the PenMate® cap back on after every use.
 - When Norditropin NordiFlex® is inserted in PenMate®, store it as described in the leaflet in your Norditropin NordiFlex® pack.
- Keep your PenMate® and your Norditropin NordiFlex® in the case supplied whenever possible. The expected lifetime of your PenMate® is 5 years of normal use. Inside the case you can also keep 3 extra disposable needles.



Cleaning and maintenance

PenMate® does not require any maintenance except cleaning.

- Do not try to wash, soak or lubricate your PenMate® or pen. If necessary, clean them with a mild detergent on a moistened cloth. Do not put your PenMate® in water, as this may damage it.
- Clean off dirt and dust with a dry soft brush.

Disposing of PenMate®

If PenMate® is to be disposed of, do so as advised by your local authorities.

NordiFlex PenMate® does not contain substances harmful to the environment.

22 Caring for your PenMate®

Warranty

- Do not try to repair a faulty PenMate®.
- Do not lubricate PenMate®.
- PenMate® must only be used according to the instructions provided in this user manual. The manufacturer cannot be held responsible for any problems with PenMate® if these instructions have not been followed.

If you find that your PenMate® is faulty, Novo Nordisk will replace it if you return it to your supplier for inspection within 5 years of receiving it and you enclose the receipt you were given when you received PenMate®.

If you need the LOT number of your PenMate®, it is located as illustrated in the diagram inside the cover.

For customers in the European Union; if your doctor and/or you believe you had a serious incident caused by using PenMate®, make sure to report it to Novo Nordisk and to your national authority.

PenMate® should only be used in combination with compatible products that allow it to function correctly.

Norditropin NordiFlex® and NordiFlex PenMate® are trademarks owned by Novo Nordisk Health Care AG, Switzerland.

PenMate®, NovoFine® and NovoTwist® are trademarks owned by Novo Nordisk AIS, Denmark.

The CE mark on a medical device indicates that the product conforms with the requirements in the Medical Device Regulations (EU) 2017/745.

Important information is clearly marked by the symbol below:

 **Important information**

Pay special attention to these notes as they are important for safe use of your pen or PenMate®.

 **Read this important information before you start using your PenMate®**

- If your PenMate® becomes lost or damaged, you can still use your Norditropin NordiFlex® without PenMate®.
- PenMate® is for single patient use only. Never share your PenMate®, your pen or your needles with anyone else. It might lead to cross-infection.
- Always keep your pen, PenMate® and needles out of sight and reach of children.
- Caregivers must be very careful when handling used needles – to reduce the risk of needle sticks and cross-infection.



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