

NovoPen[®] 4

User Manual

Read this manual carefully before
you use your NovoPen[®] 4



Introduction

Thank you for choosing NovoPen® 4, the insulin pen designed to simplify insulin therapy. This manual contains instructions for using, storing, and cleaning your NovoPen® 4.

NovoPen® 4 is available in silver and coloured versions, which allows you to have a different colour NovoPen® 4 for each type of insulin you use.

NovoPen® 4 is easy to use. It can deliver doses from 1 to 60 units, in increments of 1 unit.

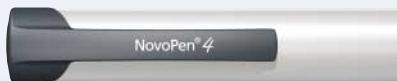
NovoPen® 4 is designed to be used with Penfill® 3 ml insulin cartridges and NovoFine® 6 mm **S** and 8 mm **S** disposable needles.

You should read the instructions in this manual even if you have used NovoPen® 4 or other Novo Nordisk delivery systems before.

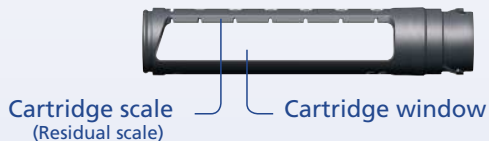


Inside this cover you will find a diagram with the names of the different parts of NovoPen® 4. Leave it unfolded when following the instructions in this manual. ►

Pen cap



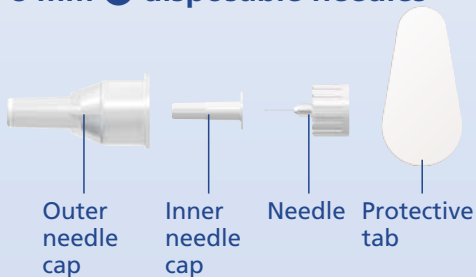
Penfill® cartridge holder



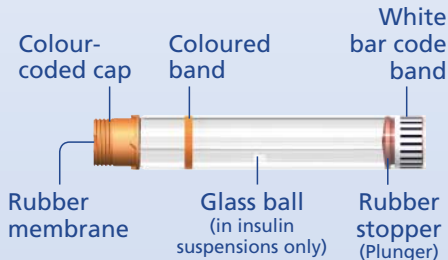
Mechanical part




NovoFine® 6 mm **S** and 8 mm **S** disposable needles



Penfill® 3 ml insulin cartridge (example)



NovoPen® 4 should only be used in combination with compatible products that allow the pen to function safely and effectively. NovoPen® 4 is designed to be used with Penfill® 3 ml insulin cartridges (referred to in this manual as Penfill® cartridges) and NovoFine® disposable needles. NovoPen®, Penfill®, NovoFine® and  are trademarks owned by Novo Nordisk A/S.

The CE-mark on a medical device indicates that the product conforms with the provisions in the EC Directive for Medical Devices 93/42/EEC. NovoPen® 4 fulfils the specification limits for dose accuracy according to ISO 11608-1 Pen-Injectors for Medical use, Part 1: Requirements and test methods.



Read this important information before you start using your NovoPen® 4

- NovoPen® 4 is not recommended for the blind or visually impaired, without the assistance of a sighted individual trained to use the device.
- If you are treated with more than one type of insulin in cartridges, you must use a different device for each type of insulin.
- In case your NovoPen® 4 is lost or damaged, always carry an extra insulin delivery device and extra insulin of the same type(s) you use.
- To minimise the risk of transmission of infectious diseases, your NovoPen® 4, your Penfill® cartridges and your NovoFine® disposable needles should be used only by you.
- Keep your NovoPen® 4, Penfill® cartridges and NovoFine® needles out of reach of others, especially children.

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4 Getting started | Preparing your NovoPen® 4



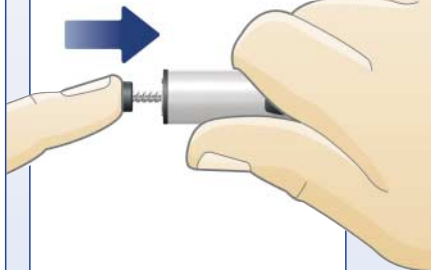
Preparing your NovoPen® 4

- 1** Pull off the cap.
- 2** Screw NovoPen® 4 apart.



- 3** Return the piston rod, if it is not already returned, by pressing the piston rod head in until it stops and looks like illustration A.

The piston rod head will not come out unless the cartridge holder – with a cartridge inserted – is attached.

3**A**

6 Getting started | Preparing your NovoPen® 4

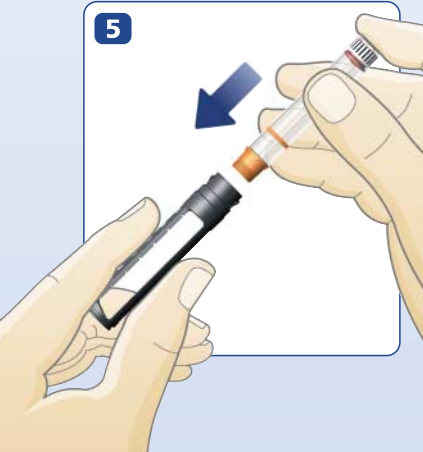
4



Colour-coding (example)



5



- 4 Take a new Penfill® cartridge. **Always make sure that you are using the correct type of insulin.**

On the cartridge there is a colour-coded cap and a label with a coloured band. Each colour is associated with a unique type of insulin and the displayed colour is an example only.

Check that the cartridge is intact, e.g. no fissures. See the leaflet in the Penfill® cartridge pack on how to do this.

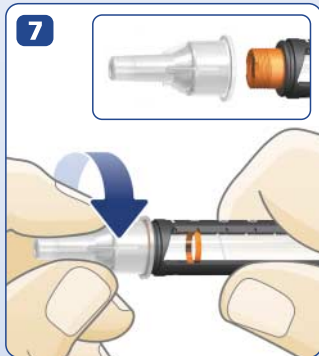
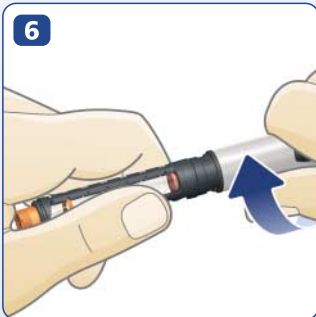
- 5 Insert the Penfill® cartridge into the cartridge holder. The colour-coded cap end goes in first.

- 6** Screw NovoPen® 4 together.

Before each injection, inspect the cartridge

If it contains an insulin suspension (cloudy looking insulin) you must always mix (resuspend) it. Please, refer to the leaflet in the Penfill® pack to see how to do this.

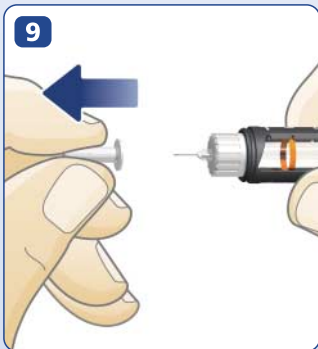
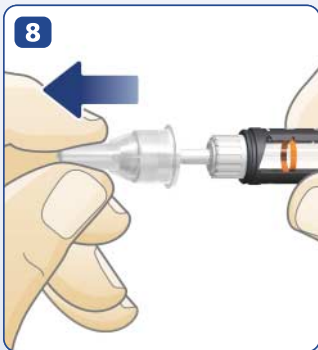
- 7** Take a NovoFine® disposable needle and remove the protective tab. Screw the needle tightly onto the colour-coded cap.



Always use a new needle

Always use a new NovoFine® disposable needle for each injection. This has several benefits, including minimising the risk of painful injection and incorrect insulin delivery.

8 Getting started | Preparing your NovoPen® 4



- 8** Pull off the outer needle cap and **keep it**. You will need it to safely remove and dispose of the used needle.
- 9** Carefully remove the inner needle cap and **dispose of it**. A droplet of insulin may appear at the needle tip. This is normal.



Risk of needle injuries

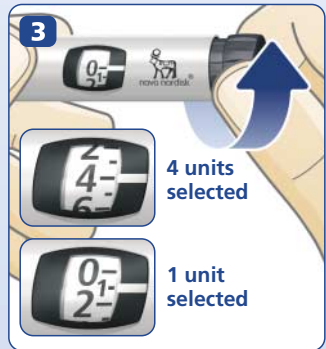
Do not bend or damage the needle before use. To minimise the risk of unintended needle penetration and transmission of infectious diseases, **never** replace the inner needle cap once removed.

Checking the insulin flow (priming)

Always check the insulin flow before each injection.

- 1** Make sure that a NovoFine® disposable needle is attached.
- 2** Pull out the dose button, if it is not already pulled out.
- 3** Turn the dose button to select:
 - **4 units with a new Penfill® cartridge.**
4 units are selected when the number 4 lines up with the dose indicator.
 - **1 unit with a cartridge already in use.**
1 unit is selected when the number 1 lines up with the dose indicator.

1 increment is equal to 1 unit.



10 Checking the insulin flow (priming)

4



4

Hold your NovoPen® 4 with the needle facing upwards.

Tap the Penfill® cartridge holder gently with your finger a few times to raise any air bubbles to the top of the cartridge.

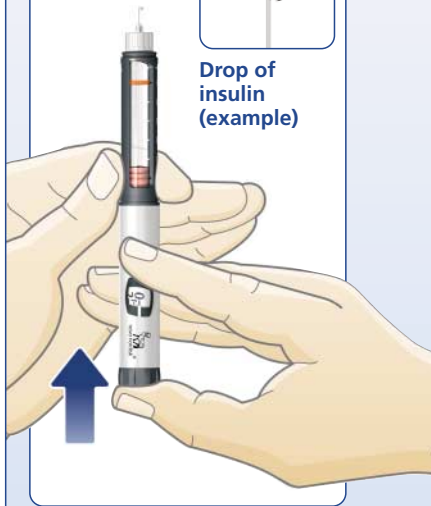
- 5** Press the dose button completely in, until you hear or feel a click. The display will return to 0. A drop of insulin **must** appear at the needle tip.

If this is not the case, repeat steps 2 to 5 until a drop of insulin appears at the needle tip.

5



Drop of insulin
(example)



Risk of incorrect dose

It is very important that insulin appears at the needle tip before you make your injection. Otherwise you will not receive your full insulin dose.

12 Selecting your dose



Selecting your dose

- 1** Pull out the dose button, if it is not already pulled out.
- 2** Select the number of units you need to inject by turning the dose button until your required dose lines up with the dose indicator. The odd units are shown as lines only. Remember that 60 units is the maximum dose you can deliver in one injection.

If you select a different dose than you need, simply turn the dose button until the correct dose lines up with the dose indicator.


If you need more than 60 units you must divide your dose into two injections. Inject the 60 units first and then make a new injection with the remaining number of units needed to complete your dose.

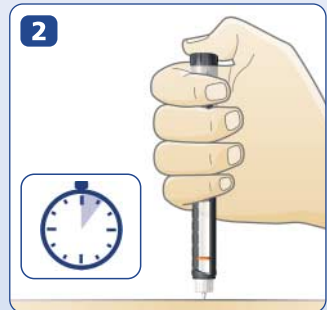
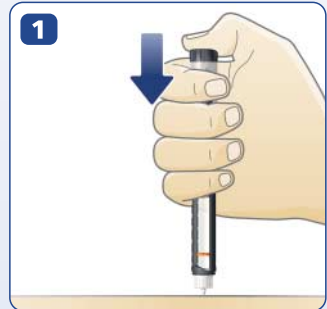
Making your injection

Follow the injection technique demonstrated by your health care professional.

- 1** To inject, **press** the dose button completely in, until you hear or feel a click.
- 2** Leave the NovoFine® needle under the skin for **at least 6 seconds**.

This ensures that the selected insulin dose is delivered.

 **Risk of no insulin delivery**
Always **press** the dose button to inject the insulin. **Turning** the dose button will **not** inject insulin.



14 Making your injection

3



- 3 Withdraw the needle. You have completed your injection and the selected insulin dose has been delivered. The display will show 0.

After you have withdrawn the needle, a few droplets of insulin may appear at the needle tip. This is normal and has no effect on the dose delivered.



Risk of needle injuries

Health care professionals, relatives and other caregivers should follow general safety measures for removal and disposal of needles in order to minimise the risk of unintended needle penetration and transmission of infectious diseases.

- 4** Immediately after the injection:
- Carefully replace the outer needle cap onto the needle.

Do not replace the inner needle cap before unscrewing the needle.

- Hold the cartridge holder and unscrew the needle. Dispose of the needle properly as instructed by your health care professional.
- Always firmly replace the pen cap after use.

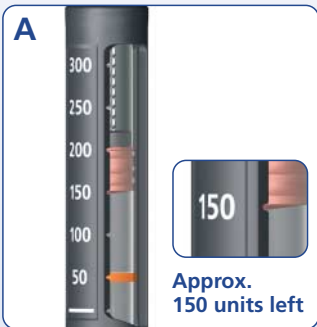


Risk of incorrect insulin delivery

Always remove the used needle immediately after each injection. If you do not remove it, temperature changes may cause liquid to leak out of the needle. With an insulin suspension (cloudy looking insulin) this may change the concentration of the insulin, leading to inaccurate dosing.



16 Changing the Penfill® cartridge | When the cartridge is nearly empty



When the cartridge is nearly empty

The cartridge scale on the Penfill® cartridge holder shows the **approximate** number of insulin units left in the cartridge as in illustration A. **Do not use the cartridge scale to measure the amount of insulin to be injected.**

If the cartridge contains less than 60 units, the **exact** number of units left can be read in the display. To do this, pull out the dose button, if it is not already pulled out, and turn it until it stops. The number of units left will line up with the dose indicator as in illustration B. If the dose indicator is positioned between two lines, adjust to the lower of the two.

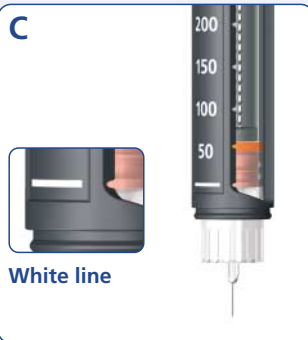


Risk of damaging your NovoPen® 4

Do not force the dose button to turn as this can damage your NovoPen® 4.

Insulin suspension (cloudy looking insulin):

Do not try to inject an insulin suspension (cloudy looking insulin) if the rubber piston is below the white line on the cartridge holder as in illustration C. The glass ball inside the cartridge must have enough space to mix the insulin.



18 Changing the Penfill® cartridge | When the cartridge is nearly empty

If you need more insulin than the amount left in the Penfill® cartridge, you can either:

Divide your dose into two injections:

- Inject the insulin left in the cartridge, making a note of the number of units you inject.
- Replace the used cartridge with a new one as described on the next page.
- Check the insulin flow (prime) as described on pages 9 to 11.
- Select and inject the number of units still needed to complete your dose.

or

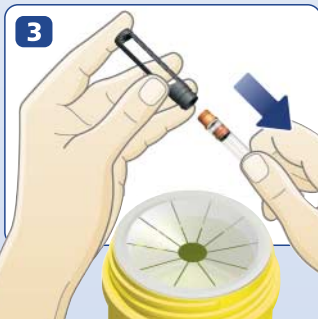
Inject the full dose with a new Penfill® cartridge:

- Remove the used cartridge and replace it with a new one as described on the next page.
- Check the insulin flow (prime) as described on pages 9 to 11.
- Select and inject the full dose.

Replacing a used cartridge

- 1** Unscrew the NovoFine® disposable needle and dispose of it properly as instructed by your health care professional.
- 2** Screw NovoPen® 4 apart.
- 3** Take out the cartridge to be replaced and dispose of it properly.

To prepare for a new injection continue as described on pages 5 to 8.



What to do if...

Here are the answers to some questions you might ask when using your NovoPen® 4.

Question

Answer

No insulin appears at the needle tip when I check the insulin flow (prime).

The needle may be blocked.

- Screw on a new needle and check the insulin flow (prime) until insulin appears at the needle tip (see pages 9 to 11).

I want to change the selected dose before injection.

- Turn the dose button until the number of units you need lines up with the dose indicator.

Question

The dose button stops during the injection, before 0 lines up with the dose indicator.

Answer**The needle may be blocked.**

You did not receive the selected dose of insulin. To complete your dose you must inject the remaining number of units as described below:

- Check the display. The number that lines up with the dose indicator is the number of units that you need to inject to complete your dose. Make a note of this number.
- Turn the dose button until 0 lines up with the dose indicator.
- Screw on a new needle and check the insulin flow (prime) as described on pages 9 to 11.
- Select the number of units you need to complete your dose. This is the number that you made a note of. Inject as described on pages 13 to 15.

If you are not sure whether you received the selected dose, you must observe your blood glucose level.

22 What to do if...

Question

I turn the dose button but my NovoPen® 4 does not release any insulin.

Answer

This is normal.

- **Always press** the dose button to inject the insulin. **Turning** the dose button will **not** inject insulin.

When selecting a dose, the dose button will not turn at all.

You have not pulled out the dose button before turning it.

- Pull out the dose button and then turn it to select the required number of units.

or

The Penfill® cartridge is empty.

- Insert a new cartridge and check the insulin flow (prime) as described on pages 9 to 11.
- Select the required number of units and inject as described on pages 13 to 15.

Question

When selecting a dose the dose button stops before I have selected the required number of units.

Answer

Either, you are trying to select more units of insulin than there are left in the cartridge **or** you are trying to select a dose larger than 60 units.

- If you need more than the number of units left in the cartridge, follow the instructions on page 18.
- If you need more than 60 units you must divide your dose into two injections (see pages 9 to 15).

Do not force the dose button to turn. If the problem is not related to the reasons described above, your NovoPen® 4 might be faulty. Do not use it. Contact your supplier.

Question

My NovoPen® 4 has been dropped or knocked.

or

I am not sure that my NovoPen® 4 is working properly.



Answer

You must carry out a function check by following the instructions below:

- Check that the Penfill® cartridge is intact, e.g. no fissures (see the leaflet in the Penfill® cartridge pack).
- Make sure that NovoPen® 4 is screwed properly together.
- Screw on a new NovoFine® disposable needle (see page 8).
- Check the insulin flow (prime) (see pages 9 to 11).
- Put the outer needle cap onto the needle.
- Make sure that the inner needle cap is removed from the needle.
- Select 20 units. Dispense the insulin into the outer needle cap by pressing the dose button completely in, until you hear or feel a click. The insulin should fill the lower part of the outer needle cap, as illustrated.

If your NovoPen® 4 has released too much or too little insulin, repeat the function check. If it still releases too much or too little insulin, do not use your NovoPen® 4. Contact your supplier.

Caring for your NovoPen® 4

Storage and handling

NovoPen® 4 is designed to work accurately and safely. It is sturdy but could still be damaged.

- Handle your NovoPen® 4 with care, do not drop it and avoid knocking it against hard surfaces.
- Always remove the needle and replace the pen cap after use.
- Protect your NovoPen® 4 against direct sunlight, water, dust and dirt.
- When a Penfill® cartridge is inserted, store your NovoPen® 4 at room temperature (up to 25°C). Please read the leaflet in the Penfill® pack. This will tell you how to store the Penfill® cartridges and how long to keep them.

- Keep your NovoPen® 4 in the case supplied whenever possible.

In the case you can also keep:

- an extra NovoPen® 4
- an extra Penfill® cartridge (in its blister pack)
- extra NovoFine® disposable needles



26 Caring for your NovoPen® 4

Cleaning and maintenance

NovoPen® 4 does not require any maintenance except cleaning.

- You can clean your NovoPen® 4 by wiping it with cotton wool moistened with a mild detergent. Do not put your NovoPen® 4 in water, as this may damage it.
- Clean off dirt and dust with a dry soft brush.

Warranty

- Do not try to repair a faulty NovoPen® 4.
- Do not lubricate NovoPen® 4.
- NovoPen® 4 must only be used according to the instructions provided in this manual. The manufacturer cannot be held responsible for any problems with NovoPen® 4 if these instructions have not been followed.

If you find that your NovoPen® 4 is faulty, Novo Nordisk will replace it if you return NovoPen® 4 to your supplier for inspection within 3 years of receiving it and you enclose the receipt you were given when you received NovoPen® 4.

If you need the LOT number of your NovoPen® 4 it is located on the mechanical part as illustrated in the diagram inside the cover.

Disposing of NovoPen® 4

If NovoPen® 4 is to be disposed of, do so in a safe and environmentally correct way:

- Remove and dispose of the needle and the cartridge as instructed by your health care professional.
- Dispose of your NovoPen® 4 as prescribed by your local authorities.

NovoPen® 4 does not contain substances harmful to the environment.

