

NovoPen® 3 PenMate®

Instruction Manual

Read this carefully before you use PenMate® and NovoPen® 3.



Introduction

PenMate® is an accessory designed to be used with NovoPen® 3. PenMate® helps you to insert the needle and to make injections quickly and easily. With NovoPen® 3 and PenMate® you can dial doses in units of one from 2-70 units.

PenMate® is designed to be used with:

- NovoPen® 3
- Penfill® 3 ml
- NovoFine® needles with a length of up to 8 mm.

This booklet contains instructions for using, storing and cleaning PenMate® in combination with NovoPen® 3. Please follow them carefully. You should read these instructions even if you have used NovoPen® 3, or NovoPen® 3 in combination with PenMate® before.

Always check that the Penfill® you use contains the correct type of insulin.

If you are treated with more than one type of insulin in Penfill®, you should use a separate PenMate® and NovoPen® 3 for each type of insulin.

Look at the diagram

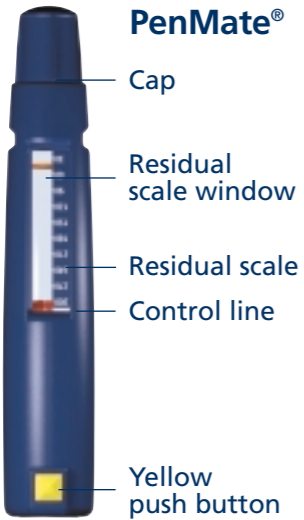


NovoPen® 3



Cap

PenMate®



- Cap
- Residual scale window
- Residual scale
- Control line
- Yellow push button

NovoFine®



- Outer needle cap
- Inner needle cap
- Needle
- Protective tab

NovoPen® 3 PenMate®

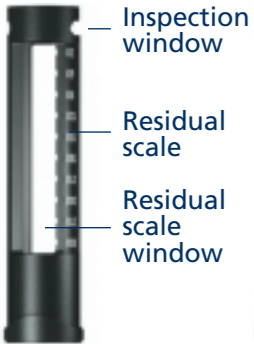
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Mechanical section



- Piston rod
- Return mechanism
- Dosage indicator window
- LOT number
- Dosage selector
- Push button

Penfill® holder



- Inspection window
- Residual scale
- Residual scale window

Penfill®



- Rubber membrane
- Colour-coded cap
- Coloured band
- Glass ball (for insulin suspensions only)
- White bar code band
- Rubber stopper (plunger)

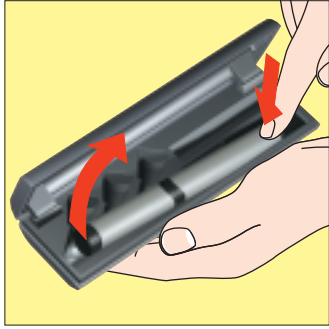
PenMate® is a needle insertion accessory designed for use with NovoPen® 3 insulin pen. PenMate® should only be used in combination with products that are compatible therewith and allow the device to function safely and effectively. Penfill® cartridges, NovoPen® 3 insulin pen and NovoFine® needles with a length of up to 8 mm are designed to be used with PenMate®. NovoPen®, Penfill®, NovoFine® and PenMate® 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® 3 PenMate® fulfills the specification limits for dose accuracy according to ISO/DIS 11608-1.2 Pen-Injectors for Medical use, Part 1: Requirements and test methods.

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← Look at the diagram inside the front cover for the names of the different parts of NovoPen® 3 and PenMate®. You can unfold the diagram to help you while you follow the instructions.

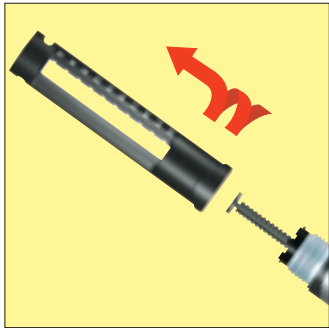


Assembly

- 1 Take NovoPen® 3 out of its case by pressing the top of the cap.

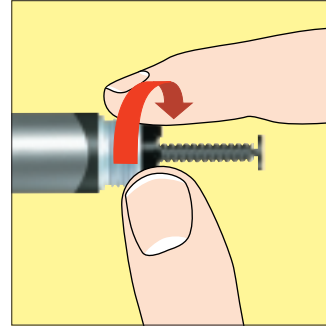


- 2 Twist and pull off the cap. Put the cap to the side.



- 3 Unscrew the Penfill® holder.

You will not use the cap and Penfill® holder with PenMate® but you should store them in the case if you may want to use NovoPen® 3 without PenMate® in the future.



- 4 Then turn the return mechanism to the right until the piston rod is completely inside it. Never push the piston rod back.

Important:

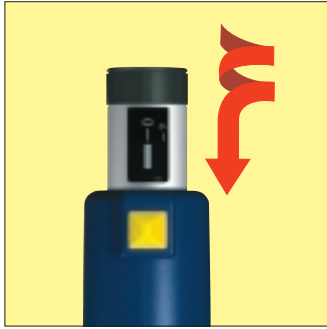
Always reset the piston rod before inserting a new Penfill®. Never load a partially filled Penfill®.



- 5 In the Penfill® leaflet you will find instructions on how to:

- check that Penfill® is intact (e.g. no fissures).
- resuspend the insulin, if Penfill® contains an insulin suspension (cloudy insulin).

Put Penfill® into PenMate®. The colour-coded cap goes in first.



- 6** Screw the mechanical section of NovoPen® 3 and PenMate® tightly together.

Make sure that the dosage indicator window on the mechanical section is level with the yellow push button on PenMate®.



- 7** Take the protective tab off a NovoFine® needle and screw the needle tightly onto PenMate®.

Pull off the outer and inner needle caps.

Do not bend or damage the needle before use.



Priming NovoPen® 3 PenMate®

- 8** Always prime NovoPen® 3 PenMate® to ensure the insulin flow before each injection.

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

How to prime NovoPen® 3 PenMate®:

Check that the dosage selector is set at zero.

Dial 2 units.

Hold NovoPen® 3 PenMate® with the needle upwards and tap gently near to the window of PenMate® with your finger a few times.

Press the push button right in.

A drop of insulin should appear at the needle tip.

If not, repeat the procedure until a drop of insulin appears. There may still be some air in Penfill® after this, but you will not inject it.



Choosing your dose

- 9** Check that the dosage selector is set at zero. If not, press the push button right in.

PenMate® has a residual scale with marks showing the approximate number of units left in Penfill®. Always check that there is enough insulin left for the injection.

To activate grip the mechanical section of NovoPen® 3 and PenMate® firmly and pull in opposite directions until you hear a click.

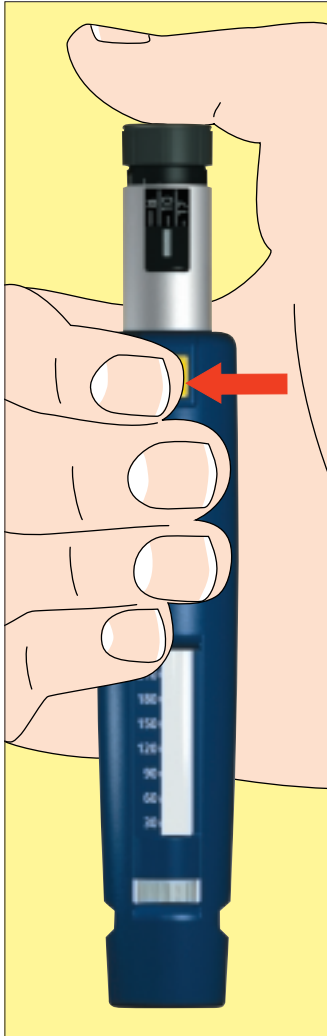
Important: Do not pull the dosage selector.



- 10** Dial the number of units you need to inject.
The odd numbers are shown as full lines between the even numbers.



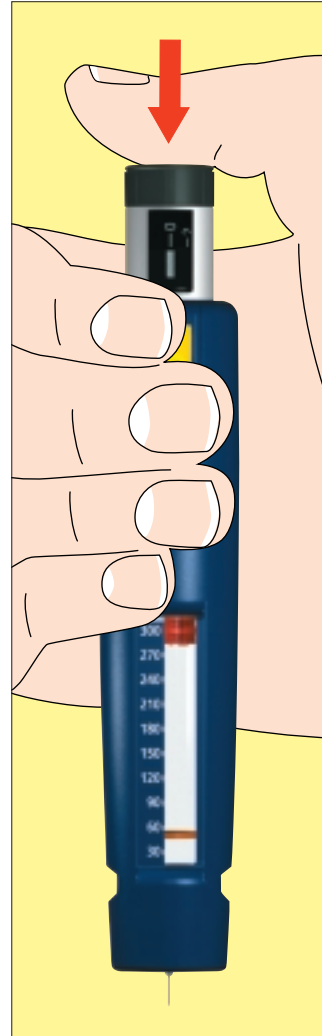
- 11** If you dial a larger dose than you need, pull the mechanical section of NovoPen® 3 and PenMate® apart, as shown in the picture **A**. While holding them apart, press the push button back to 0, against a hard surface and release your grip **B**. You can now dial the correct number of units.



Making the injection

- 12** Use the injection technique your doctor has shown you.

To insert the needle, hold PenMate® against your skin. Press the yellow push button with your finger. The needle will automatically enter your skin.



- 13** To inject, press the push button as far as it will go.

After injection the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle has been withdrawn from the skin.

If there is not enough insulin in Penfill® for the whole dose, you will be able to see the number of units you still need to inject in the dosage indicator window. You must always check this after you have made the injection.

Important: Never turn the dosage selector to inject the insulin.



14 After the injection make sure that PenMate® was released and that the insulin has been injected.

- Check that you can see the control line at the top of the residual scale.
- Also check if your skin is wet where you gave the injection.



Mechanical function check of PenMate®

15 If you cannot see the control line after the injection or your skin is wet, do the following check:

- Hold PenMate® with the needle pointing upwards.
- To activate grip the mechanical section of NovoPen® 3 and PenMate® firmly and pull in opposite directions until you hear a click.

Important: Do not pull the dosage selector.

Check that the dosage selector is set to zero. If not, press the push button right in.



16 Push the yellow push button to release PenMate®.

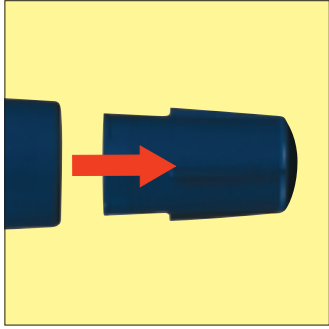
You should now be able to see the needle and the control line.

If you cannot see the needle, do not use PenMate®. Never use PenMate® unless you are sure that it is working properly.



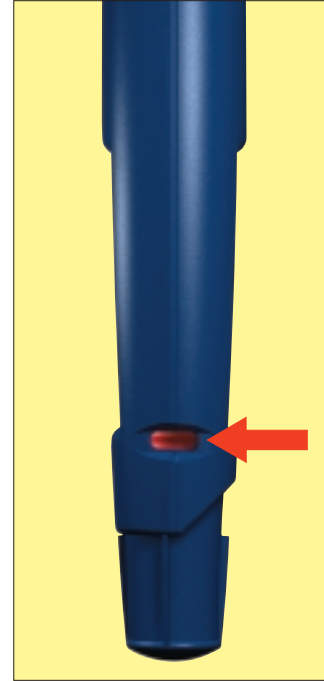
17 After the injection, put the outer needle cap on and unscrew the needle. Discard the needle carefully.

Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle penetration.



Following injections

- 18** Pull off the cap. Check that PenMate® contains the type of insulin you want to inject. If PenMate® does not contain an insulin suspension (cloudy insulin), follow points 7-12. Otherwise follow the instructions given in the package insert supplied with the insulin.



What to do when Penfill® is nearly empty

- 19** Do not try to inject an insulin suspension (cloudy insulin) if you can see the rubber piston in the small inspection window. The glass ball must have adequate space to resuspend the insulin. It is possible to select a dose larger than the number of units left in Penfill®. However, if there is not enough insulin for the whole dose, you will be able to see the number of units you still need to inject in the dosage indicator window. Make a note of this number, change Penfill® (ref. point 20), prime (ref. point 8), dial the remaining dose and inject.

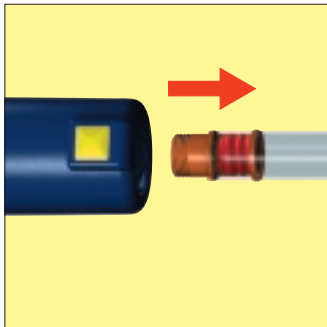


Changing Penfill®

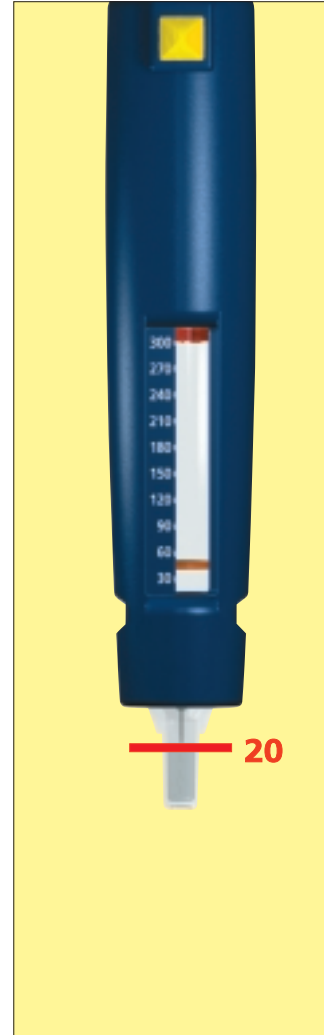
- 20** Unscrew PenMate® from the mechanical section of NovoPen® 3 and make sure that the return mechanism on NovoPen® 3 is out as far as it will go.

(Twist it gently from side to side if necessary).

Press the push button to set the dosage indicator to zero.



- 21** Take out the empty Penfill®. Take a new Penfill® and continue as described from point 4.



Function check

- 22** If you think that your NovoPen® 3 or PenMate® is not working properly, follow this procedure:

- Check that the mechanical section of NovoPen® 3 and PenMate® are screwed tightly together and the dosage indicator window on the mechanical section is level with the yellow push button on PenMate®.
- Screw on a new NovoFine® needle as described in point 7.
- Prime NovoPen® 3 PenMate® as described in point 8.
- Put the outer needle cap over the needle.
- Dispense 20 units into the needle cap.

The insulin should fill the lower part of the outer needle cap.

If the pen has cleared too much or too little insulin, repeat the test. If it happens again, do not use the pen. Contact your supplier.

Do not try to repair a faulty NovoPen® 3 or a faulty PenMate®.

Never use NovoPen® 3 and PenMate® unless you are sure that they are working properly.

Important notes

- NovoPen® 3 and PenMate® must be handled with care, do not drop them and avoid knocking them against hard surfaces.
- Protect NovoPen® 3 and PenMate® against dust and dirt when they are not in their case.
- Make sure that the piston rod is completely inside the return mechanism before you screw together the mechanical section of NovoPen® 3 and PenMate® (see point 4).
- Always screw the mechanical section of NovoPen® 3 and PenMate® tightly together.
- Always prime NovoPen® 3 PenMate® to expell air with the needle pointing upwards before each injection (see point 8).
- The coloured band on Penfill® tells you which type of insulin Penfill® contains. Before each injection make sure that you are using the right insulin preparation.
- Before injecting always check that there is enough insulin left for your dose. After the injection make sure that the dosage indicator window reads 0. If not, see point 19.
- Do not initiate injection of an insulin suspension (cloudy insulin) if the rubber piston can be seen in the small inspection window.
- Do not use the residual scale to measure the amount of insulin to be injected.
- After injecting make sure that PenMate® was released and that the insulin has been injected (see point 14).
- Take the needle off NovoPen® 3 PenMate® 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 insulin) this may change the concentration of the insulin.
- Keep NovoPen® 3 and PenMate®, Penfill® and NovoFine® out of reach of children.
- Your NovoPen® 3 and PenMate® are for use by one person only.

What do I do if...

Here are the answers to some questions you might need to ask when using your NovoPen® 3 and PenMate®.

No insulin appears when I try to prime NovoPen® 3 PenMate®?

Check that your NovoPen® 3 and PenMate® were put together correctly when you changed Penfill®. Make sure that the piston rod is completely inside the return mechanism. Also make sure that the mechanical section of NovoPen® 3 and PenMate® are screwed tightly together (see points 4-6). Keep priming until a drop of insulin appears at the tip of the needle.

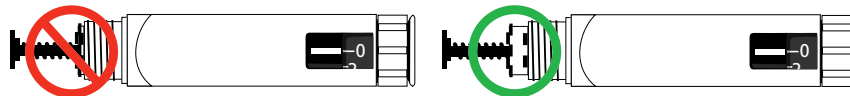
No insulin appears when I try to prime NovoPen® 3 PenMate® and the push button will not go in?

The needle may be blocked. Change the needle and prime until insulin appears at the needle tip.

Check if Penfill® is empty.

The push button blocks during the injection?

Do not try to force the push button down. Check if Penfill® is empty. If there was not enough insulin in Penfill® for the whole dose, you will see the number of units you still need to inject in the dosage indicator window. Make a note of this. Change Penfill® and continue as described from point 20.



I cannot press the push button back to zero before I return the piston rod?

The return mechanism may be locked. Gently twist the return mechanism from side to side until it comes out. See the picture above. Then you can press the push button back to zero. Never turn the dosage selector back. To ensure that the pen is still working properly carry out the function check described in point 22.

I cannot get the piston rod back inside the return mechanism when I change Penfill®?

The return mechanism may be locked. Gently twist the return mechanism from side to side until it comes out. Then turn the return mechanism to the right until the piston rod is completely inside it. See the picture above. Finally carry out the function check described in point 22

I think the needle has not entered the skin.

Check that you can see the control line at the top of the residual scale. Also check if your skin is wet at the injection site. Carry out the mechanical function check as described in points 15-16.

I think my NovoPen® 3 or my PenMate® is not working properly?

Carry out the function check described in point 22. Make sure that the lower part of the outer needle cap is filled with 20 units of insulin. Also carry out the mechanical function check as described in points 15-16. Make sure that the control line is visible when PenMate® is released.

Never use your NovoPen® 3 or your PenMate® unless you are sure that they are working properly.

How to store and look after your NovoPen® 3 and your PenMate®

Storage and maintenance

- Keep your NovoPen® 3 PenMate® in the case whenever possible.
- Please read the leaflet in the Penfill® pack for details of how to store the cartridges and how long to keep them.
- Do not lubricate NovoPen® 3 PenMate®.

Cleaning

- You can clean your NovoPen® 3 PenMate® by wiping it with cotton wool moistened with a mild detergent. Do not immerse NovoPen® 3 PenMate® in water. This may damage the mechanism. Clean off dirt and dust with a soft brush.

Remember

- Always have extra insulin of the same type(s) you use available for alternative administration in case your NovoPen® 3 or PenMate® gets lost or damaged.
- Do not try to repair a faulty NovoPen® 3 or PenMate®.
- NovoPen® 3 PenMate must only be used in the way described in this booklet. The manufacturer will not be responsible for any problems you have with the equipment if instructions are not followed.
- Novo Nordisk will replace a NovoPen® 3 PenMate® if:
 - you return NovoPen® 3 PenMate® to your supplier within a year of getting it,
 - you enclose any documents you were given when you got the pen and
 - Novo Nordisk can inspect NovoPen® 3 PenMate® and confirm that it is faulty.