

Innovo®

Instruction Manual

Read this carefully before
you use Innovo®

Making insulin
easy to live with

Innovo®

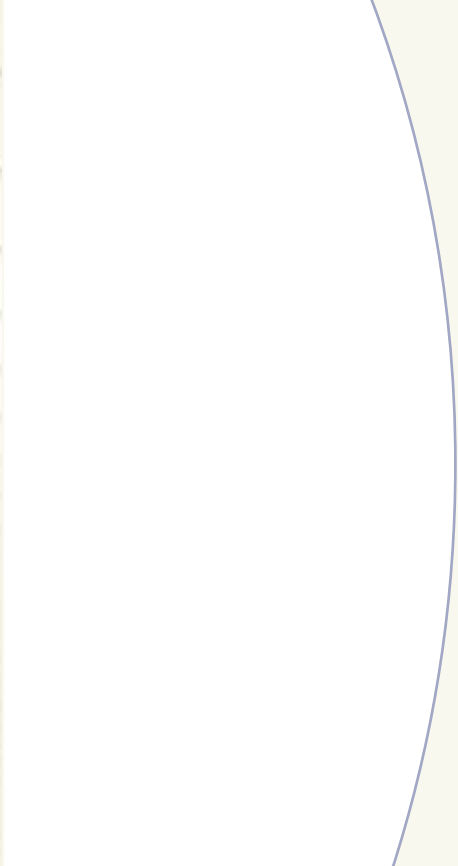


Notex Tryk & Design

Order no. 510620

Innovo® Eng. Neutral

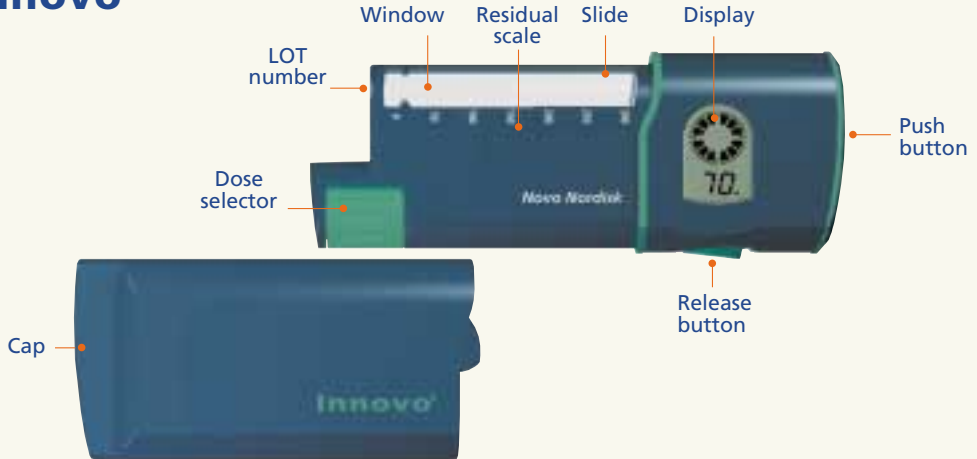
4. proof 02-11-07



Look at the diagram inside this cover for the names of the different parts of Innovo®.

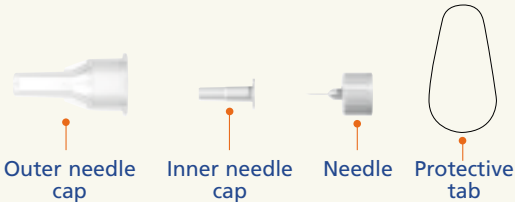
You can unfold the diagram to help you while you follow the instructions.

Innovo®

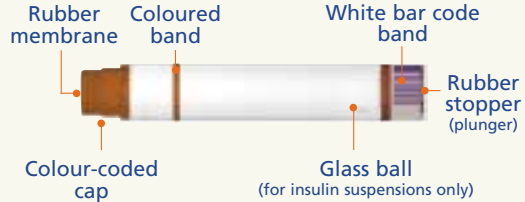


NovoFine®

6 mm or 8 mm **S**



Penfill® 3 ml



Innovo®

Novo Nordisk A/S
2880 Bagsvaerd
Denmark



If Innovo® has been dropped or knocked, you must carry out a function check (see page 23).

Innovo® insulin doser should only be used in combination with products that are compatible therewith and allow Innovo® to function safely and effectively.

Penfill® 3 ml cartridges and NovoFine® needles are designed to be used with Innovo® insulin doser.

Innovo®, 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. Innovo® fulfils the specification limits for dose accuracy according to ISO 11608-1 Pen-Injectors for Medical use, Part 1: Requirements and test methods.

Contents

Page 2 Introduction

4 Getting started

10 Priming Innovo®

12 Choosing your dose

14 Making the injection

16 Checking your previous injection

18 Subsequent injections

20 What to do when Penfill® is nearly empty

22 Changing Penfill®

23 Function check

24 What do I do if...?

28 How to store and look after your Innovo® insulin doser

30 Display information

 32 Important information

Introduction

Thank you for choosing Innovo®, the insulin doser designed to make insulin therapy easier to live with.

This manual contains instructions for using, storing, and cleaning your Innovo®. Here are some of the unique features Innovo® has to offer:

Easy to carry. Innovo® is short and compact, making it easy to carry in your pocket or purse.

Easy to inject. Innovo® is designed to fit perfectly in your hand, and is ideal for making quick and discreet injections.

Easy to read. The display on Innovo® is large and clear, making it easy to read the dose of insulin dialled and delivered.

Easy to remember. Innovo® has a built-in memory function, displaying your previous dose of insulin and the time passed since your last delivery.

Easy to dial. Innovo® is accurate to use, and can easily be dialled to deliver doses from 1 to 70 units, in steps of 1 unit.

Easy to change dose. The insulin dose can easily be changed without wasting insulin simply by dialling up or down.

Easy to change Penfill®. Innovo® is specially designed for the easy changing of Penfill® 3 ml cartridges and NovoFine® needles with a length of up to 8 mm. (Be sure to look for the **S** on the NovoFine® packaging when selecting needles).

Easy reminders. Innovo® has a battery that lasts for about 5 years from manufacturing date when used at a rate of four daily injections

(including priming). After this time, the display flashes to tell you that Innovo® will expire.

Be sure to replace Innovo® within 30 days. The battery cannot be changed. This is to guarantee quality and safety at all times.

Thank you for choosing Innovo®. It is important that you follow the instructions carefully to make insulin therapy as easy to live with as possible.

Getting started

Pull off the cap. Put the cap to one side and keep it. You will need to replace the cap after your injection.



The very first time the cap is pulled off, the display stays blank until the slide is opened.

GETTING STARTED

Make sure that the push button is pressed completely in. Otherwise the slide will be locked.

Open the slide in the direction of the arrow shown below.

The display now shows 0.



GETTING STARTED

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 Innovo® by pushing it slightly backwards as shown. The end with the rubber stopper goes in first.



GETTING STARTED

Make sure that the colour-coded cap fits firmly into place.



GETTING STARTED

Close the slide completely. The release button is locked until the slide has been closed.

Keep the slide closed until Penfill® is empty.



GETTING STARTED

Take the protective tab off a NovoFine® needle and screw the needle tightly onto the colour-coded cap.

Pull off the outer and inner needle caps.

Do not bend or damage the needle before use.



Priming Innovo®



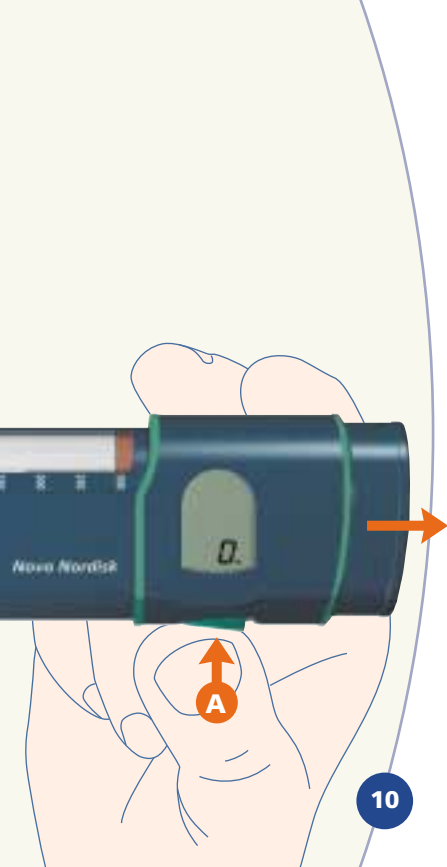
Always prime your Innovo® to ensure the insulin flow:

- before each injection
- after changing Penfill®
- after changing the needle
- after opening and closing the slide.

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 your Innovo®

- Make sure that a needle is mounted, the push button is pressed completely in, and the slide is closed. If the slide is not closed, the release button will be locked.
- Press the release button **A**. You will see that the push button jumps out.





- Dial 1 unit **B**.

When inserting a new Penfill®, start with 8 units.

After opening and closing the slide you will need to dial a larger number of units, depending on the amount of insulin left in Penfill®.

- Hold Innovo® with the needle upwards and tap the slide gently with your finger a few times **C**.
- Press the push button completely in until it locks **D**.
- A drop of insulin should appear at the needle tip.
- If not, repeat the procedure dialling 1 unit until a drop of insulin appears.



Choosing your dose



Make sure that a needle is mounted and that the push button is pressed completely in.

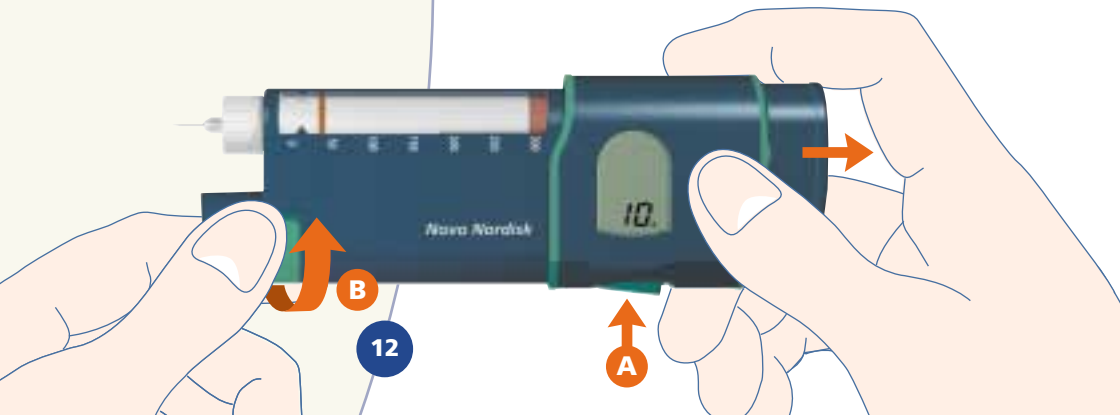


Press the release button **A** and the push button will jump out. The display will show 0.



Dial the number of units you need by turning the dose selector at a steady speed **B**. In this example a dose of 10 units has been dialled.

The number of units you have dialled is shown in the display. You cannot use the clicks as you dial to determine the dose.



Changing a dose

If you accidentally dial a larger dose than you need, dial back to the correct number of units. The dose dialled can be changed until you press the push button.

Cancelling a dose


If you want to cancel a chosen dose, dial back to zero and press the push button completely in. Your last delivered dose (or priming) and the time passed since its delivery will reappear on the display.



Making the injection

Follow the injection technique demonstrated by your doctor or nurse.

To inject, press the push button completely in until it locks. You will probably feel that it becomes a little harder to press at the end.* This is normal.

 Do not change the dose after you have pressed the push button.

With all insulin injection devices the needle should be left under the skin for at least 6 seconds to ensure that the full insulin dose has been delivered. Innovo® helps you to do this by providing a built-in timer.



When the push button is pressed completely in, the segments turn on two by two telling you to leave the needle under your skin.



When the circle appears, the full insulin dose has been delivered and you can withdraw the needle.

MAKING THE INJECTION

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

Put the outer needle cap on and unscrew the needle. Discard it carefully.

Always replace the cap after using Innovo®.

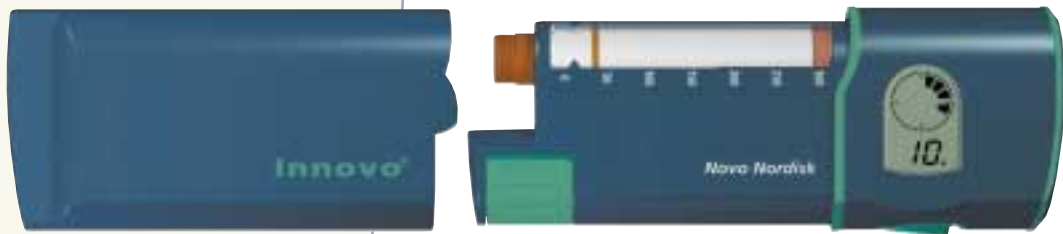
*Thin needles reduce pain, but you may need to press the push button firmly when injecting your insulin. NovoFine® needles, made using thin-wall technology, minimise the amount of pressure needed.



Checking your previous injection

Pull off the cap.

After the display test, your previous dose (or priming) and the time passed since delivery can be seen on the display. Each timer segment represents 1 hour.



CHECKING YOUR PREVIOUS INJECTION



For example, if 4 segments are displayed, more than 4 hours have passed since the previous injection.



If 12 segments are displayed, more than 12 hours have passed. In this example the display tells you that a dose of 10 units were delivered more than 12 hours ago.

If the last thing you did before replacing the cap was to dial a dose, this dose will appear on the display.

Always replace the cap after using Innovo®.



Subsequent injections

Pull off the cap.



When the cap is pulled off, all the display symbols are turned on telling you that the display is fully functioning.



Your previous dose (or priming) and the time passed since delivery then appear on the display.

SUBSEQUENT INJECTIONS

Check that Innovo® contains the type of insulin you want to inject.


If Penfill® contains a soluble insulin, follow the instructions from page 9 in this manual.

If Innovo® contains an insulin suspension (cloudy insulin), you must resuspend the insulin as described in the Penfill® leaflet.

Then carry on as shown from page 9 and inject shortly after resuspending the insulin suspension.

What to do when Penfill® is nearly empty

Do not try to inject an insulin suspension (cloudy insulin) if the rubber stopper is below the arrow marks on the slide as shown in the picture. The glass ball must have adequate space to resuspend the insulin.

Innovo® will not let you dial a larger dose than that remaining in Penfill®.  Do not force the dose selector to turn; instead change Penfill®.

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

- change Penfill® and inject the whole dose at once,
or
- inject the remaining insulin and insert a new Penfill® cartridge for the rest of your dose.



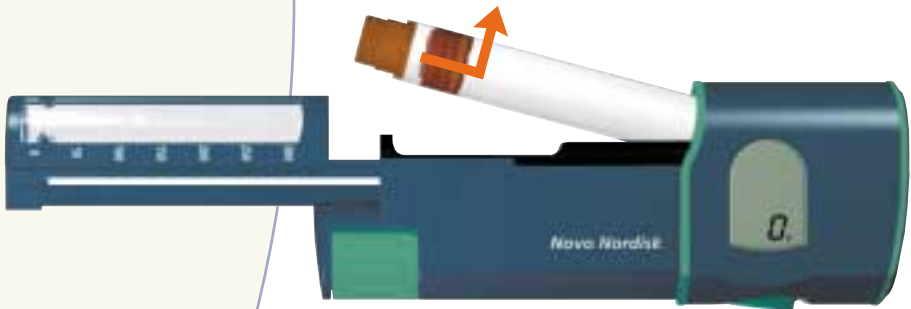
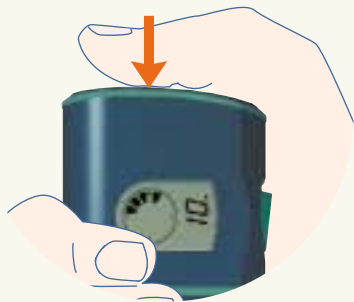
Change Penfill® as described on page 22.
Then prime Innovo® as described on
page 10-11.

Dial the remaining number of units to
complete your dose.
Inject, making sure that you have now
injected your full dose.

If you have changed Penfill® so your total
dose was divided into two doses, note that
Innovo® will only remember the second of
the two doses given.

Changing Penfill®

- Make sure that the push button is pressed completely in.
- Unscrew the needle.
- Open the slide.
- Take out the used Penfill® cartridge.
- Take a new Penfill® cartridge and continue as described from page 6.



Function check

If you think that Innovo® is not working properly, follow this procedure.

- Screw on a new NovoFine® needle as described on page 9.
- Prime Innovo® as described on page 10-11.
- Put the outer needle cap over the needle.
- Dispense 20 units into the outer needle cap.

The insulin should fill the lower part of the outer needle cap. If Innovo® has released too much or too little insulin, repeat the test. If it happens again, do not use your Innovo®. Contact your supplier. Do not try to repair a faulty Innovo®.



What do I do if...?

Here are the answers to some questions you might ask when using your Innovo[®] insulin doser.

Display

The display does not respond when I turn the dose selector.

Press the release button so that the push button jumps out before a dose can be dialled.

The display shows a minus sign.

The dose selector has been dialled below 0. Dial forward until the display shows the correct number of units.

The display is off.

If the display goes off, press the release button, and the push button will jump out. Press the push button completely in, and the display should reappear. If the display does not reappear, open and close the slide. Prime Innovo[®] as described on page 10. If the display remains off, Innovo[®] is not working. Do not use Innovo[®] but contact your supplier to get a new Innovo[®].

Priming

No insulin appears when I try to prime Innovo[®].

The needle may be blocked. Change the needle and prime Innovo[®] until insulin appears at the needle tip.

Check that the push button is pressed completely in and locked. Open the slide and make sure that Penfill® is inserted correctly. If Penfill® is damaged or empty, change it. Check that the slide is closed, and prime Innovo® until insulin appears at the needle tip.

No insulin appears when I prime Innovo® and the push button will not go in.

The needle may be blocked. Change the needle and prime Innovo® until insulin appears at the needle tip. To open the slide, dial back to zero and press the push button completely in until it locks. Then change Penfill® as described on page 22.

Choosing the dose

I cannot release the push button.

Make sure that the slide is closed completely. The release button is locked until the slide is closed.

I want to cancel or change the dialled dose.

Dial back to zero and press the push button completely in. Your last dose and the time passed since delivery will reappear on the display. You can increase, decrease or cancel the dialled dose until you press the push button.

Do not change the dose after you have pressed the push button.

Insulin is delivered when I turn the dose selector.

You have dialled the maximum dose of 70 units and then carried on dialling. If you need to inject a dose of insulin larger than 70 units, you must divide the dose into amounts equal to or less than 70 units.

Injection

The push button blocks during the injection.

Do not try to force the push button in.

The needle may be blocked. Change the needle and prime Innovo® as described on page 10.

Check if Penfill® is damaged. Dial back to zero and press the push button completely in until it locks. Then open the slide and change Penfill® as described on page 22. Prime Innovo® until insulin appears at the needle tip.

Please observe that part of the insulin dose may have been injected.

If the push button still cannot be pressed completely in, contact your supplier.

Changing Penfill®

I cannot open the slide.

Put on a new needle. Press the push button completely in until it locks. Remove the needle and open the slide. If the slide still cannot be opened, contact your supplier.

Do not try to force the slide open.

Function check

I do not think that my Innovo® is working properly.

Carry out the function check described on page 23. Make sure that the lower part of the outer needle cap is filled with 20 units of insulin.

Never use your Innovo® unless you are sure that it is working properly.

How to store and look after your Innovo[®] insulin doser

Your Innovo[®] insulin doser is designed to work accurately and safely. It should be handled with care. Avoid situations where your Innovo[®] insulin doser can be damaged. Always replace the cap after using Innovo[®].

Please read the leaflet in the Penfill[®] pack. This will tell you how to store the cartridges and how long to keep them.

Storage and handling

- Do not expose Innovo[®] Insulin Doser to temperatures below minus 25°C.
- With Penfill[®] inserted, store Innovo[®] at room temperature (up to 25°C).
- Your Innovo[®] is tough but can still be damaged. Handle it with care and protect it against direct sunlight, water, dust and dirt.

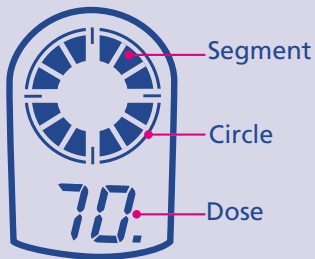
Cleaning

- Clean off dirt and dust with a dry, soft brush.
- You can clean your Innovo® by wiping it with cotton wool moistened with ethyl or isopropyl alcohol.
- Do not soak Innovo® in alcohol, wash it or lubricate it. This may damage the mechanism.

Remember

- Do not try to repair a faulty Innovo®.
- Innovo® must only be used according to the instructions in this manual. The manufacturer will not be held responsible for any equipment problems if you have not followed these instructions.
- If you find that Innovo® is faulty, Novo Nordisk will replace it if:
 - you return Innovo® to your supplier within 1 year of receiving it
 - you enclose any documents you were given when you received Innovo®
 - Novo Nordisk can inspect Innovo® and confirm that it is faulty.

Display Information



Display is off

The very first time the cap is pulled off, the display stays blank until the slide is opened.



If the display goes off, press the release button, and the push button will jump out. Press the push button completely in, and the display should reappear.

If the display does not reappear, open and close the slide. Prime Innovo® as described on page 10.

If the display remains off, Innovo® is not working. Do not use Innovo® but contact your supplier to get a new Innovo®.

Display test



When the cap is pulled off, all the display symbols are turned on, telling you that the display is fully functional.

Dialling a dose



The display shows the number of insulin units dialled.



During delivery

The segments turning on two by two tell you to leave the needle under the skin during injection.



After delivery

The display shows the number of insulin units delivered. The circle confirms that the delivery has been completed.



Previous injection

The display shows the number of insulin units delivered. The segments indicate the time passed since delivery. One segment represents 1 hour. In this example more than 4 hours have passed since Innovo[®] delivered the previous dose.



Flashing display

A flashing display indicates that the battery power is low. Be sure to replace your Innovo[®] within 30 days. The battery cannot be changed. Contact your supplier to get a new Innovo[®].



Minus sign

A minus sign on the display tells you that the dose selector has been dialled below 0. Dial forward until the display shows the number of units required.

Important information

- Always prime your Innovo® (as described on page 10-11) to ensure the insulin flow:
 - before each injection
 - after changing Penfill®
 - after changing the needle
 - after opening and closing the slide
- With a Penfill® in Innovo®, never press the push button unless a needle is mounted.
- Always make sure that the push button is pressed completely in and locks.
The display confirms completed delivery when the segments turn on two by two and then the circle appears.
- Do not change the dose after you have pressed the push button.
- On the Penfill® label there is a coloured band that is unique to the different types of insulin. When

Penfill® is inserted into Innovo®, the coloured band is visible through the slide. Before each injection make sure that you are using the right type of insulin.

- If you are treated with more than one type of insulin in Penfill® 3 ml cartridges, you should use two devices, one for each type of insulin.
- Do not use the residual scale to measure the amount of insulin to be injected.
- Take the needle off Innovo® 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.
- Do not initiate injection of an insulin suspension (cloudy insulin) if the rubber stopper is below the arrow marks on the slide.

- Your Innovo® insulin doser is designed to work accurately and safely. Innovo® has built-in safety features to ensure that the insulin dose injected is the dose that has been dialled. In the unlikely event of a malfunction your Innovo® doser will lock to prevent you from receiving a wrong dose.
- As a precautionary measure, always carry a spare insulin delivery device in case your Innovo® is lost or damaged.
- A flashing display tells you that battery power is low. Be sure to replace Innovo® within 30 days. The battery cannot be changed. This is to guarantee quality and safety at all times. Contact your supplier to get a new Innovo®.
- Innovo® is tough but could still be damaged. So handle it with care, do not drop it and avoid knocking it against hard surfaces. If Innovo® has been dropped or knocked, you must carry out a function check (see page 23).
- Never use your Innovo® unless you are sure that it is working properly.
- Always replace the cap after using Innovo®.
- Do not play with the dose selector or the push button as this can cause Innovo® to wear out.
- Keep Innovo®, Penfill® and NovoFine® out of the reach of children.
- Your Innovo® is for use by you alone. Do not allow anyone else to use it.
- 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.

CE
0088

© 2001 Novo Nordisk A/S
Revision date: October 2002
Novo Nordisk A/S
2880 Bagsvaerd, Denmark

8-4249-00-004-1