

# NovoPen<sup>®</sup> 3 PenMate<sup>®</sup>

## Instruction Manual

For use with the following NovoPen<sup>®</sup> insulin delivery devices:

NovoPen<sup>®</sup> 3,  
NovoPen<sup>®</sup> 3 Demi,  
or NovoPen<sup>®</sup> Junior

Read this carefully before you use NovoPen<sup>®</sup> 3 PenMate<sup>®</sup> with NovoPen<sup>®</sup> 3, NovoPen<sup>®</sup> 3 Demi, or NovoPen<sup>®</sup> Junior



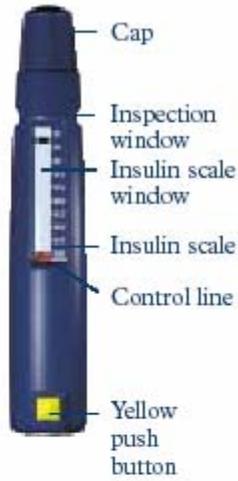
Look at the diagram



### NovoPen® 3 Insulin Delivery Device

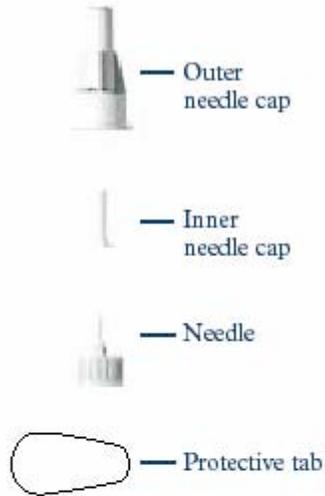


### NovoPen® 3 PenMate®



### NovoFine® Disposable Needle

(For single-use only. Discard immediately after use.)



### PenFill® Holder



### Mechanical Section



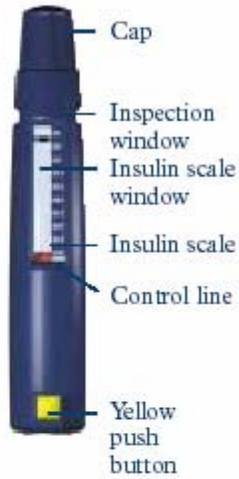
### PenFill®



### NovoPen® 3 Insulin Delivery Device



### NovoPen® 3 PenMate®



### PenFill® Holder



### Mechanical Section



### Mechanical Section



## INTRODUCTION

NovoPen<sup>®</sup> 3 PenMate<sup>®</sup> helps to give an injection without seeing a needle and is designed for use with the following Novo Nordisk 3 mL PenFill<sup>®</sup> cartridge compatible insulin delivery devices: NovoPen<sup>®</sup> 3, NovoPen<sup>®</sup> 3 Demi, or NovoPen<sup>®</sup> Junior (hereafter referred to as “NovoPen devices”). When the NovoPen 3 PenMate is used with one of the NovoPen devices mentioned above, it is called “NovoPen 3 PenMate system”. With NovoPen 3 PenMate system, you don’t see a needle when you give an injection.

**If you use NovoPen 3 PenMate with NovoPen 3, you can dial doses from 2 to 70 units in one unit steps.**

**If you use NovoPen 3 PenMate with NovoPen 3 Demi or NovoPen Junior, you can dial doses from 1 to 35 units in half (½) unit steps.**

NovoPen 3 PenMate should only be used in combination with the following products that are compatible and recommended by Novo Nordisk.

NovoPen 3 PenMate system is designed to be used with:

- NovoPen 3
- NovoPen 3 Demi
- NovoPen Junior
- Novo Nordisk 3 mL PenFill insulin cartridges (PenFill cartridges)
- NovoFine<sup>®</sup> disposable needles

**NovoFine disposable needles are for single-use only.**

NovoPen 3 PenMate system design allows you to use the same recommended injection technique as the NovoPen devices.

This booklet contains instructions for using, storing and cleaning NovoPen 3 PenMate system. Please read the instructions carefully. You should read these instructions even if you have used NovoPen devices, or NovoPen devices with the NovoPen 3 PenMate before. The two previous pages provide illustrations of NovoPen 3 and the NovoPen 3 PenMate. The diagrams in this booklet are shown using NovoPen 3 and NovoPen 3 PenMate. NovoPen 3 Demi and NovoPen Junior are different versions of NovoPen 3, but the NovoPen devices all work with NovoPen 3 PenMate in the same way.

Always check that the PenFill cartridge you use contains the correct type of insulin.

If you use more than one type of insulin in PenFill cartridges, you should use a separate NovoPen 3 PenMate system for each type of insulin to avoid giving an injection with the wrong type of insulin.

If you have any questions about your NovoPen 3 PenMate, NovoPen 3 PenMate system, or your NovoPen devices, please call Novo Nordisk Inc. at 1-800-727-6500.

Please complete and return the NovoPen 3 PenMate Warranty Card for full warranty protection.

## HOW TO USE THIS BOOKLET

### **This booklet gives you step-by-step instructions for using NovoPen 3 PenMate system.**

Begin by reviewing the illustration of the parts of the NovoPen devices, NovoPen 3 PenMate, Novo Nordisk 3 mL PenFill insulin cartridge, and NovoFine disposable needle. The inside front cover opens out while you read the rest of the booklet. Most pages contain a diagram (using NovoPen 3 and NovoPen 3 PenMate) on the right with numbered instructions to the left of the diagram.

### **Important additional information is given below the diagram.**

We suggest that you **read the text and look at the diagrams** to make sure that you understand each step thoroughly.

Also included is an illustration showing a side-by-side comparison of the NovoPen devices and the NovoPen 3 PenMate. This illustration allows you to see which part of the NovoPen devices the NovoPen 3 PenMate replaces.

### **The main differences between the NovoPen devices and the NovoPen 3 PenMate system are as follows:**

- The PenFill cartridge holder and the Pen cap of the NovoPen devices are replaced by the NovoPen 3 PenMate.
- With the NovoPen 3 PenMate system, you do not see a needle when you give an injection.

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

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## SECTION 1

## Assembly of the NovoPen 3 PenMate system

### Assembly of the NovoPen 3 PenMate system

- 1 Take the NovoPen 3 out of its case by pressing the top of the Pen cap, or take NovoPen 3 Demi or NovoPen Junior out of the soft carrying case.



- 2 Gently twist the Pen cap until it separates from the barrel.
- 3 Pull the Pen cap straight up to remove it.



- 4 Unscrew and remove the PenFill holder from the barrel.

You will not use the Pen cap and PenFill holder with the NovoPen 3 PenMate system but you should store them in case you want to use the NovoPen device without the NovoPen 3 PenMate in the future.



## SECTION 1 (cont.)

5 Press the push button all the way in until you see zero (0) in the dose indicator window. The zero should be lined up with the stripe next to the dose indicator window.

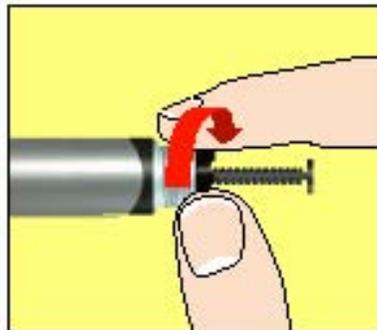


6 The end of the piston rod should be flat against the end of the reset mechanism before inserting a new 3 mL PenFill cartridge. The piston rod should not be sticking out.



**If the piston rod is sticking out:**

Turn the end of the reset mechanism in a clockwise direction until the piston rod is no longer sticking out. Never push the piston rod back in.



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Call 1-800-727-6500

You should never reset the piston rod until it is time to remove the empty PenFill cartridge and insert a new 3 mL PenFill cartridge.

If the reset mechanism locks, it is usually due to improper technique. Gently turn the reset mechanism side to side until it unlocks. Then call the toll free number 1-800-727-6500 so we may go over your technique with you.



## SECTION 1 (cont.)

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- 7 To remove the PenFill cartridge from its wrapper, push the PenFill cartridge through the foil side of the packaging.

Before use, check that the new PenFill cartridge does not have puncture holes in the rubber stopper. If the rubber stopper has holes in it, do not use the cartridge.

- 8 If you use a suspension insulin (white and cloudy), such as Novolin<sup>®</sup> N, Novolin<sup>®</sup> 70/30, or NovoLog<sup>®</sup> Mix 70/30, make sure to mix the insulin in the cartridge before use. You will find instructions in the 3 mL PenFill cartridge “Information For The Patient” leaflet on how to prepare the insulin.

**Once the PenFill cartridge is punctured (in use), it should be stored at room temperature below 86° F (30° C).** Stored at this temperature, the in-use PenFill cartridge can be used for the amount of days listed in the 3 mL PenFill cartridge “Information For The Patient” leaflet for the type of insulin you are using.

If you use more than one type of insulin in PenFill cartridges, use a separate NovoPen 3 PenMate system for each type of insulin to avoid giving an injection with the wrong type of insulin.

## SECTION 1 (cont.)

- 9 Take NovoPen 3 PenMate out of its case.  
Pull off the cap and put it to one side.

- 10 Put the PenFill cartridge into the NovoPen 3 PenMate. The threaded plastic cap goes in first. If you use a suspension insulin (white and cloudy), make sure to mix the insulin in the cartridge before you put it into the NovoPen 3 PenMate. You will find the instructions in the 3 mL PenFill cartridge "Information For The Patient" leaflet on how to mix the insulin.



- 11 Tightly screw the barrel of the NovoPen device into the NovoPen 3 PenMate and you have NovoPen 3 PenMate system.  
Make sure that the dose indicator window on the mechanical section is aligned with the yellow push button on NovoPen 3 PenMate.

Each 3 mL PenFill cartridge contains 300 units of insulin. Make sure you are using the correct type of insulin. The name of the insulin is on the glass part of the PenFill cartridge.

PenFill cartridge is for single-person use only. **DO NOT SHARE** the PenFill cartridge with anyone else even if you attach a new disposable needle for each injection. Sharing the PenFill cartridge can spread disease.

**Use only a new 3 mL PenFill cartridge when loading the NovoPen 3 PenMate. Never load a partially filled PenFill cartridge. Never try to refill a used PenFill cartridge.**

## SECTION 1 (cont.)

- 12 Clean the front rubber stopper on the PenFill cartridge with an alcohol swab.

You must wipe the front rubber stopper with an alcohol swab before each injection, even if you are using the same PenFill cartridge.



- 13 Remove the protective tab from the NovoFine disposable needle.

Screw the NovoFine disposable needle firmly onto the threaded plastic cap of the PenFill cartridge until it is tight.

Pull off the outer and inner needle caps.

**For users of a suspension insulin (white and cloudy), always remix the insulin in the PenFill cartridge before each injection.**

You will find instructions on how to remix the suspension insulin in the PenFill cartridge in the 3 mL PenFill cartridge "Information For The Patient" leaflet.

Never place a NovoFine disposable needle on your NovoPen 3 PenMate system until you are ready to do an air shot and give an injection. If the NovoFine needle is left on, some insulin may leak out from the PenFill cartridge. This may cause a change in the concentration (strength) of a suspension insulin (white and cloudy).



## SECTION 2

## Air shot before each injection

### Air shot before each injection

14 Small amounts of air may be present in the needle and/or PenFill cartridge. To avoid injecting air bubbles and to make sure of correct dosing, **you must perform an air shot before each injection.**

- Check that the dial-a-dose selector is set to zero.
- Dial 2 units.
- Hold the NovoPen 3 PenMate system with the NovoFine needle pointing up and tap gently near the window of NovoPen 3 PenMate with your finger a few times.
- Press the push button at the end of the barrel all the way in.

A drop of insulin should appear at the needle tip.

If no insulin appears, repeat the above steps until a drop of insulin appears. There may still be some small air bubble(s) in the PenFill cartridge after this, but they will not affect your dose and they will not be injected.



**If you dialed more than 2 units, DO NOT turn the dial-a-dose selector back to zero (0).** If you do, the extra insulin will squirt out of the needle. You may complete the air shot with the number of units you have dialed or refer to the instructions on how to reset the dose to zero in Section 3 “Choosing your dose”, step 17.

## SECTION 3

## Choosing your dose

### Choosing your dose

15 NovoPen 3 PenMate system has an insulin scale with marks showing the approximate number of units left in the PenFill cartridge. Always check that there is enough insulin left in the 3 mL PenFill cartridge for the injection.

Grip the barrel of the NovoPen device and the NovoPen 3 PenMate and firmly pull in opposite directions until you hear a click.



**Important: Do not pull the dial-a-dose selector.**

Make sure that the dial-a-dose selector is set to zero. If zero does not appear, follow the instructions in step 17.



16 Dial the number of units you need to inject.

With the NovoPen 3, the odd numbers (1, 3, 5, 7 ...) are shown as long lines between the even numbers. With the NovoPen 3 Demi and NovoPen Junior, half units (1.5, 2.5, 3.5 ...) are shown as long lines between the whole numbers.

**Do NOT use the clicking sound as a guide for selecting your dose.**

The NovoPen 3 PenMate system can deliver from 2 to 70 units of insulin in one unit increments if you use NovoPen 3 and from 1 to 35 units of insulin in half ( $\frac{1}{2}$ ) unit increments if you use NovoPen 3 Demi and NovoPen Junior. **If you dialed more than your dose, do NOT turn the dial back to zero (0).** If you do, the

extra insulin will squirt out of the needle. For instructions on how to reset the dose to zero (0), see step 17.

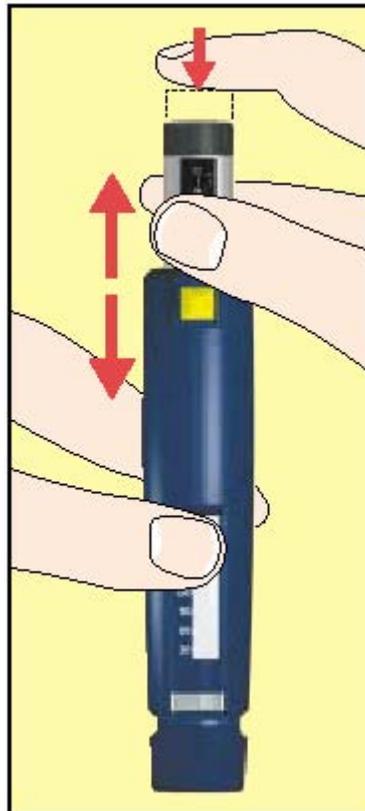
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### SECTION 3 (cont.)

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17 If you dialed a larger dose than you need, you need to reset your NovoPen 3 PenMate system to zero by following the instructions below:

- a. Pull the barrel of the NovoPen device and the NovoPen 3 PenMate in opposite directions and keep hold of them (see diagram).
- b. Press the push button on the barrel of the NovoPen device with your finger or gently press the push button against a hard surface. The zero should now be lined up with the stripe next to the dose indicator window.
- c. Release your grip and the barrel section will slide back into place.
- d. You can now dial the correct units of insulin.



## SECTION 4

## Giving the injection

### Giving the injection

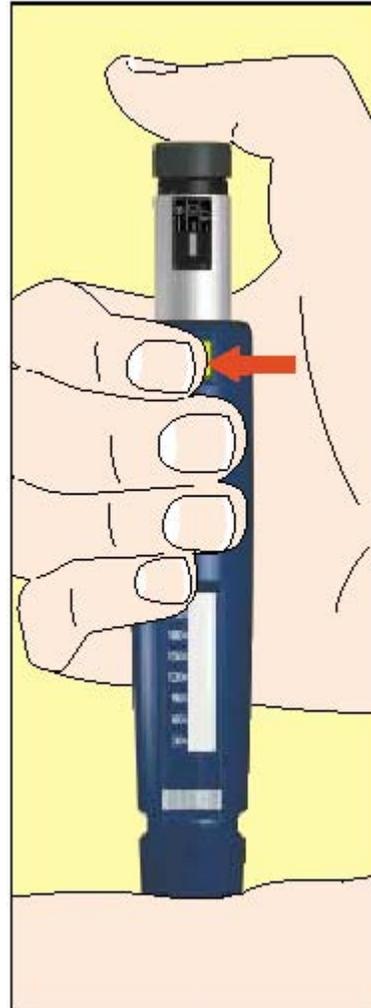
18 After the air shot is done, check the dose indicator window to make sure you have chosen the correct number of units for your dose.

Hold the NovoPen 3 PenMate system at the correct site on the body for an injection. Use the injection technique recommended by your health care professional. If you use a suspension insulin (white and cloudy), remix the insulin before injecting. See the 3 mL PenFill cartridge “Information For The Patient” leaflet for instructions on remixing. Make sure the insulin in the PenFill cartridge looks uniformly white and cloudy before you inject.

The PenMate is designed with a cut-away on one side. This cut-away allows injections at various angles other than 90°.

When you press the yellow push-button on the NovoPen 3 PenMate system with your finger

(see arrow in diagram), the needle will enter the skin.



## SECTION 4 (cont.)

- 19 To inject your dose, press the push button on the barrel of the NovoPen device **as far as it will go** to inject the insulin. **Do not force it** (see arrow in diagram).

To make sure that all of the insulin is injected, keep the NovoFine needle in the skin for several seconds after the injection with your thumb on the push button. Keep the push button fully depressed for 6 seconds before removing the needle from the injection site. **Do not rub the injection area.**

If there is not enough insulin in the 3 mL PenFill cartridge for the whole dose, you will be able to see the number of units you still need to inject in the dose indicator window. You must always check the dose indicator window after you have given an injection.

**Important: Never turn the dial-a-dose selector to inject the insulin.**

When you press the push button, the piston rod presses against the rear rubber stopper of the PenFill cartridge. This moves the rear rubber stopper and pushes the correct amount of insulin out through the needle.



## SECTION 4 (cont.)

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After the injection, check the dose indicator window to make sure it shows zero (0). If it does not show zero, you did not receive your full dose.

For example: If you dial **25** units and there are only **20** units in the PenFill cartridge, the number **5** will appear in the dose indicator window following the injection ( $25-20=5$ ). This means you only received 20 units and need to inject 5 more units. If this happens, proceed with the following steps to get your remaining units of insulin dose:

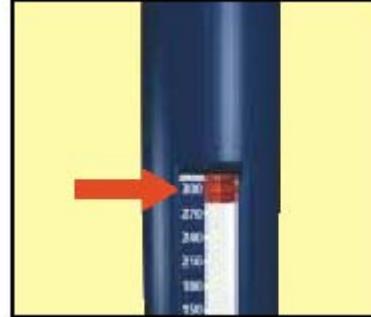
- a. Note the number of units in the dose indicator window.
- b. Remove the NovoFine needle (see step 20).
- c. Unscrew the barrel of the NovoPen device from the NovoPen 3 PenMate system.
- d. Remove the empty PenFill cartridge (see steps 26 and 27).
- e. Insert a new 3 mL PenFill cartridge (see steps 5 to 10).
- f. Screw the barrel of the NovoPen 3 device into the NovoPen 3 PenMate (see step 11).
- g. Attach a new NovoFine needle (see steps 12 and 13).
- h. Do an air shot (see step 14).
- i. Dial the number of units you still need to inject from the above step (a).
- j. Give the injection.

## SECTION 4 (cont.)

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**To make sure that the insulin has been injected, do the following:**

- Check that you can see the control line (solid white line) at the top of the insulin scale (above the number 300).
- Check to see if your skin is wet where you gave the injection.



If you cannot see the control line after the injection or your skin is wet, you did not receive your full dose of insulin and need to do a mechanical function check. See steps 21 and 22 to perform a mechanical function check of NovoPen 3 PenMate system.

If you suspect that your NovoPen 3 PenMate is not working properly, call Novo Nordisk at 1-800-727-6500 so we can review your injection technique with you.

Call 1-800-727-6500 *or your health care professional if you have any questions.*

## SECTION 4 (cont.)

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20 Immediately after the injection, place an outer needle cap on the needle and carefully remove the needle. Hold the NovoPen 3 PenMate system firmly while you unscrew the NovoFine disposable needle. Used NovoFine disposable needles should be placed in sharps containers (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.

Health care professionals, relatives and other care givers should also follow the instructions for removing the needle to eliminate the risk of unintended needle stick.

**The NovoFine disposable needle must be removed right after each injection by placing an outer needle cap on the needle and turn counter-clockwise.** After the NovoFine disposable needle is removed, put the NovoPen 3 PenMate cap back on. If the NovoFine disposable needle is not removed, some insulin may leak out of the PenFill cartridge. This may cause a change in the concentration (strength) of a suspension insulin (white and cloudy). For information on how to throw away needle containers properly, contact your local trash company.

## SECTION 5 Mechanical function check of NovoPen 3 PenMate system

### Mechanical function check of NovoPen 3 PenMate system

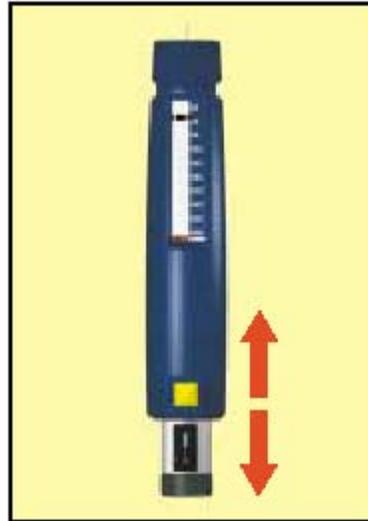
- 21 Hold the NovoPen 3 PenMate system with the needle pointing up.
- Grip the barrel of the NovoPen device and the NovoPen 3 PenMate and firmly pull in opposite directions until you hear a click. If you do not hear a click, contact Customer Relations at the toll free number 1-800-727-6500. Never use a NovoPen 3 PenMate unless you are sure that it is working properly.

**Important: Do not pull the dial-a-dose selector.**

Make sure that the dial-a-dose selector is set to zero (0). If not, press the push button all the way in.



- 22 Push the yellow push button and the needle should appear. You should now be able to see the needle and the control line. If you cannot see the needle, do not use the NovoPen 3 PenMate system. Never use the NovoPen 3 PenMate system unless you are sure that it is working properly.

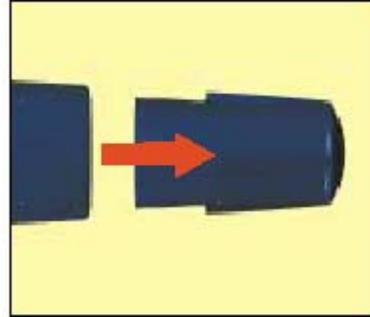


## SECTION 6

## For subsequent injections

### For subsequent injections

- 23 Remove the NovoPen 3 PenMate cap. **Check that the needle has been removed since your last injection.** Make sure that NovoPen 3 PenMate system contains the correct type of insulin for an injection. If your NovoPen 3 PenMate system contains a solution insulin (clear) follow steps 12 to 20.
- 24 If your NovoPen 3 PenMate system contains a suspension insulin (white and cloudy), see the 3 mL PenFill cartridge "Information For The Patient" leaflet on how to remix the insulin.  
Then continue as shown in steps 12 to 20 and inject immediately.



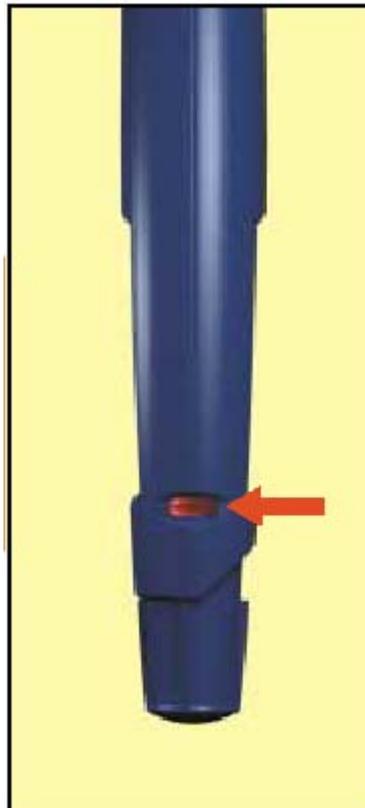
## SECTION 7 What to do if the 3 mL PenFill cartridge is nearly empty

### What to do if the 3 mL PenFill cartridge is nearly empty

**25 If you use a suspension insulin (white and cloudy),** do not inject if you can see the rubber piston in the small inspection window. At least 12 units of insulin must be in the PenFill cartridge for adequate mixing with the glass ball.

With the NovoPen 3 PenMate system, it is possible to select a dose that is larger than the number of units left in the PenFill cartridge. If there is not enough insulin in the PenFill cartridge for the whole dose, you will be able to see the number of units you still need to inject in the dose indicator window after the injection.

To get the remaining units of your dose, refer to Section 4 “Giving the injection”, Page 14, a through j.



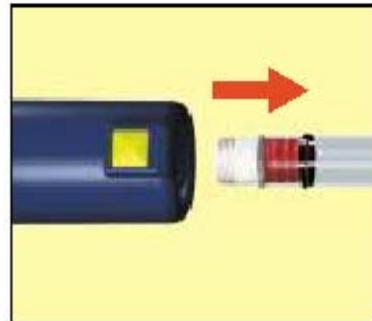
When you get near to the end of a PenFill cartridge, you may need to give yourself two injections to receive your full dose. Always check the dose indicator window after giving an injection. If zero (0) does not show in the dose indicator window, you did not receive your full dose. See Section 4 “Giving the injection” on page 14 for instructions on how to get the remaining units of your dose.

## SECTION 8

## Changing 3 mL PenFill cartridge

### Changing 3 mL PenFill cartridge:

- 26 a. Unscrew the barrel of the NovoPen device from the NovoPen 3 PenMate system.
  - b. Press the push button of the NovoPen device to set the dose indicator back to zero (0).
  - c. Make sure that the piston rod is not sticking out. If the piston rod is sticking out, reset the piston rod by gently turning the end of the reset mechanism in a clockwise direction until the piston rod is no longer sticking out. **Never push the piston rod back in.**
- 
- 27 Take out the empty PenFill cartridge. Take a new 3 mL PenFill cartridge and continue as described in steps 7 and 8.



Need Help?  
Call 1-800-727-6500

## SECTION 9

## Function check

### Function check

28 If you think your NovoPen 3 PenMate system is not working properly, follow this procedure:

- a. Make sure that the barrel of the NovoPen device and NovoPen 3 PenMate are screwed together tightly and that the dose indicator window on the barrel is aligned with the yellow push button on the NovoPen 3 PenMate.
- b. Screw on a new NovoFine needle as described in steps 12 and 13.
- c. Do an air shot to remove air bubbles as described in step 14.
- d. **DO NOT replace the inner needle cap.** Put the outer needle cap over the needle.
- e. Dispense 20 units into the outer needle cap.

The insulin should fill the lower part of the outer needle cap. If the pen has delivered too much or too little insulin, repeat the test. If it happens again, do not use the NovoPen device. Contact Novo Nordisk Inc. at the toll free number 1-800-727-6500.

**DO NOT** try to repair a NovoPen device or a NovoPen 3 PenMate.

Never use a NovoPen device or NovoPen 3 PenMate unless you are sure that they are working properly.



## IMPORTANT

- Keep the NovoPen 3 PenMate system away from areas where temperatures may get too hot or too cold such as in a car or in a refrigerator.
- Once the PenFill cartridge is punctured (in use) inside the NovoPen 3 PenMate system, it should be kept at room temperature (below 86°F [30°C]) for the length of time stated in the storage information section of the “Information For The Patient” leaflet supplied with the 3 mL PenFill cartridges.
- Make sure that the piston rod is not sticking out before you screw together the barrel of the NovoPen device and the NovoPen 3 PenMate. (see steps 5 to 6).
- Always screw the mechanical section of the NovoPen device and NovoPen 3 PenMate tightly together.
- Before each injection, make sure that you are using the correct type of insulin PenFill cartridge.
- Always clear air bubbles with the needle pointing up before each injection (see step 14).
- With NovoPen 3 PenMate system, it is possible to select a dose which is larger than the number of units left in the 3 mL PenFill cartridge. Before you inject, always check on the insulin scale window that there is enough insulin left in the PenFill cartridge for your dose.

After the injection, always make sure that the dose indicator window is back to zero (0). If not, you did not receive your full dose of insulin. See step 25.

- Do not use the insulin scale on the NovoPen 3 PenMate system to measure the amount of insulin to be injected.
- Before an injection, always check the dose indicator window to make sure you have dialed the correct number of units.
- After an injection, make sure that NovoPen 3 PenMate system delivered your full dose by making sure that the control line is at the top of the insulin scale and that the insulin has been injected (see page 15).”
- **Take the needle off NovoPen 3 PenMate system right after each injection by carefully replacing the outer needle cap on the needle and turn counter-clockwise** . If you do not remove the needle, temperature changes may cause

insulin to leak out of the needle. With a suspension insulin (white and cloudy), this may change the concentration (strength) of the insulin.

22

**IMPORTANT (cont.)**

- Do not inject a suspension insulin (white and cloudy) if the rear rubber stopper can be seen in the small inspection window.
- Always keep a spare insulin delivery device available in case the NovoPen 3 PenMate system you are using is lost or damaged.
- Keep NovoPen 3 PenMate, NovoPen 3 PenMate system, NovoPen device, PenFill cartridges, and NovoFine disposable needles out of the reach of children.
- Your NovoPen device, NovoPen 3 PenMate, or NovoPen 3 PenMate system should not be shared with anyone else even if you attach a new NovoFine needle for each injection.
- NovoPen 3 PenMate system is not recommended for blind or visually impaired patients, without the assistance of a sighted individual trained to use it.
- If you use more than one type of insulin in Novo Nordisk 3 mL PenFill cartridge, use a separate NovoPen 3 PenMate system for each type of insulin to avoid giving an injection with a wrong type of insulin.
- The American Diabetes Association recommends that insulin should be self-administered. The proper age for self administration of insulin should be decided by the adult caregiver.
- Use only a new 3 mL PenFill cartridge when loading the NovoPen 3 PenMate system. Never load the NovoPen 3 PenMate system with a partially filled PenFill cartridge.
- The NovoPen 3 PenMate system is designed for use with Novo Nordisk 3 mL PenFill cartridges, NovoFine single-use disposable needles, and NovoPen devices.

Novo Nordisk is not responsible for any consequences arising from the use of the NovoPen 3 PenMate with products that are not recommended by Novo Nordisk.

## IMPORTANT (cont.)

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### Guidelines for storing the NovoPen 3 PenMate:

- **Store the NovoPen 3 PenMate system (with the PenFill cartridge inside) at room temperature (below 86°F [30°C]). DO NOT store** the NovoPen 3 PenMate system in a refrigerator or areas where there may be extreme temperatures or moisture, such as in a car. Once the PenFill cartridge is punctured (in use) inside the NovoPen 3 PenMate system, NovoPen 3 PenMate system should be kept at room temperature below 86°F (30°C). Stored at this temperature, the PenFill cartridge can be used for the amount of days listed in the 3 mL PenFill cartridge “Information For The Patient” leaflet for the type of insulin you are using.
- Store the NovoPen 3 PenMate system **without** the NovoFine needle attached and **with** the NovoPen 3 PenMate cap placed in its position. Leaving the needle on the NovoPen 3 PenMate system can cause the insulin to leak. This may change the concentration (strength) of a suspension insulin (white and cloudy).
- For information on storing PenFill cartridges, see the “Information For The Patient” leaflet that comes in the PenFill cartridge box.
- The expiration date on the PenFill cartridge is for unused cartridges when stored in the refrigerator.

## WHAT TO DO IF ...

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Here are the answers to some questions you might have when using your NovoPen 3 PenMate system.

---

**No insulin appears when I try to clear the air bubbles.**

- Check that your NovoPen 3 PenMate system was put together correctly when you changed the PenFill cartridge.
  - Make sure that the piston rod is not sticking out.
  - Make sure that the barrel of the NovoPen device and the NovoPen 3 PenMate are screwed tightly together. (see steps 5 and 25).
- 

**No insulin appears when I try to clear the air bubbles and the push button will not go in.**

- The needle may be blocked. Change the needle and repeat air shots until insulin appears at the needle tip.
  - Check if the PenFill cartridge is empty.
- 

**The push button will not depress during the injection.**

- Do not try to force the push button down.
  - Check if the PenFill cartridge is empty. If there was not enough insulin in the PenFill cartridge for the full dose, you will see the number of units you still need to inject in the dose indicator window. Make a note of this. Change the PenFill cartridge and continue as described in step 26.
-

## WHAT TO DO IF ... (cont.)

---

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

- The reset mechanism may be locked. Gently twist the reset mechanism from side to side until it unlocks. See the diagram in step 6. Then you can press the push button back to zero. Never turn the dial-a-dose selector back.

---

**I cannot get the piston rod back inside the reset mechanism when I change the PenFill cartridge.**

- The reset mechanism may be locked. Gently twist the reset mechanism from side to side until it unlocks. Then turn the reset mechanism to the right until the piston rod is completely inside it. See the diagram in step 6.

---

**I think the needle has not entered the skin.**

- Check that you can see the control line at the top of the insulin scale.
- Check if your skin is wet at the injection site. Carry out the mechanical function check of the NovoPen 3 PenMate system as described in steps 21 and 22.

---

**I think my NovoPen 3, NovoPen 3 Demi, NovoPen Junior, or my NovoPen 3 PenMate is not working properly.**

- Do the function check as described in step 28. Make sure that the lower part of the outer needle cap is filled with 20 units of insulin.
- Do the mechanical function check of the NovoPen 3 PenMate system as described in steps 21 and 22. Make sure that the control line is visible when the NovoPen 3 PenMate system is released. Never use a NovoPen device or NovoPen 3 PenMate unless you are sure that they are working properly.

## MAINTENANCE

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### **How to store and look after your NovoPen 3 PenMate system**

NovoPen 3 PenMate system should be handled with care. Avoid situations where your NovoPen 3 PenMate system can be damaged. Do not drop the device. Do not expose the device to excessive pressure or blows. Keep it in the case whenever possible.

You can put PenFill cartridges in NovoPen 3 PenMate system or carry them with you as spares. Please read the "Information For The Patient" leaflet supplied with the PenFill cartridges for details on how to store the cartridges and how long to keep them.

You can clean your NovoPen 3 PenMate system by wiping it with a cotton swab moistened with ethyl or isopropyl alcohol.

Your NovoPen devices and your NovoPen 3 PenMate are sturdy products but could still get damaged. So handle them with care and protect them against dust and dirt when they are not in a case.

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

NovoPen 3 PenMate system must only be used in the way described in this booklet. The manufacturer will not be responsible for any problems you have with the device if you have not followed this booklet. If you find your NovoPen 3 PenMate system faulty, Novo Nordisk will replace it if:

You call Novo Nordisk Inc. at the toll free number 1-800-727-6500 within three years of getting it.

## WARRANTY

---

Should your NovoPen 3 PenMate device be defective in materials or workmanship within three (3) years of purchase, Novo Nordisk Inc. will replace it at no charge if you contact Novo Nordisk Inc. at 1-800-727-6500 with a description of the problem. Arrangements will be made for you to return the defective NovoPen 3 PenMate along with the sales receipt or other proof of purchase to Novo Nordisk Inc.

Protected by U.S. Patents No. 5,980,491 and other Patents Pending. Designed and recommended for use with Novo Nordisk 3 mL PenFill insulin cartridges and NovoPen devices.

No other warranty is made with respect to NovoPen 3 PenMate. The mechanical section of the NovoPen devices is covered by its own separate warranty, which is described in its instruction manual. Warranty will be invalid and Novo Nordisk A/S, Novo Nordisk Inc., Bristol-Myers Squibb Co., Nipro Medical Industries Ltd., and Bang &

Olufsen A/S cannot be held responsible in the case of defects or damages arising from:

- The use of the NovoPen 3 PenMate with products other than NovoPen devices, Novo Nordisk 3 mL PenFill cartridges, or NovoFine single-use disposable needles.
- The use of the NovoPen 3 PenMate not in accordance with the instructions in this booklet.
- Physical damage to the NovoPen 3 PenMate caused by neglect, misuse, unauthorized repair, accident, or other breakage.

Use of the NovoPen 3 PenMate does not extend the warranty of the NovoPen devices.

NovoPen<sup>®</sup>, Novo Nordisk<sup>®</sup>, PenMate<sup>®</sup>, PenFill<sup>®</sup>, NovoFine<sup>®</sup>, Novolin<sup>®</sup> and NovoLog<sup>®</sup> are registered trademarks owned by Novo Nordisk A/S.

For assistance or further information, write to:

**Novo Nordisk Inc.  
Customer Relations  
100 College Road West  
Princeton, NJ 08540  
Or call: 1-800-727-6500**

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***Novo Nordisk Inc.***  
Princeton, NJ 08540-7810  
[www.novonordisk-us.com](http://www.novonordisk-us.com)

8-4241-31-001-2 5/17/05 Draft



NNPI submission date: 5/17/05

1  
2  
3 **R HUMAN**

---

4  
5 Information for the patient

6  
7 *Novolin® R PenFill®*

8  
9 Regular, Human Insulin Injection  
10 (recombinant DNA origin)  
11 3 mL Disposable Cartridge  
12 (300 units per cartridge)

13  
14 **100** units/mL (U-100)

15  
16 Please read this leaflet carefully before using this product.  
17 Please note the special directions under PREPARING THE INJECTION.  
18 Novolin® R PenFill® 3 mL is designed for use with Novo Nordisk 3 mL PenFill® cartridge  
19 compatible insulin delivery devices, with or without the addition of a NovoPen® 3  
20 PenMate®, and NovoFine® disposable needles.  
21 PenFill® cartridge is for single person use only. See IMPORTANT NOTES section.

22  
23 **WARNING**

24 **ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER**  
25 **MEDICAL SUPERVISION. CHANGES IN PURITY, STRENGTH, BRAND**  
26 **(MANUFACTURER), TYPE (REGULAR, NPH, LENTE®, ETC.), SPECIES (BEEF,**  
27 **PORK, BEEF-PORK, HUMAN), AND/OR METHOD OF MANUFACTURE**  
28 **(RECOMBINANT DNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE**  
29 **NEED FOR A CHANGE IN DOSAGE.**

30 **SPECIAL CARE SHOULD BE TAKEN WHEN THE TRANSFER IS FROM A**  
31 **STANDARD BEEF OR MIXED SPECIES INSULIN TO A PURIFIED PORK OR**  
32 **HUMAN INSULIN. IF A DOSAGE ADJUSTMENT IS NEEDED, IT WILL USUALLY**  
33 **BECOME APPARENT EITHER IN THE FIRST FEW DAYS OR OVER A PERIOD OF**  
34 **SEVERAL WEEKS. ANY CHANGE IN TREATMENT SHOULD BE CAREFULLY**  
35 **MONITORED.**

36 **PLEASE READ THE SECTIONS "INSULIN REACTION AND SHOCK" AND**  
37 **"DIABETIC KETOACIDOSIS AND COMA" FOR SYMPTOMS OF HYPOGLYCEMIA**  
38 **(LOW BLOOD GLUCOSE) AND HYPERGLYCEMIA (HIGH BLOOD GLUCOSE).**

39  
40 **INSULIN USE IN DIABETES**

41 Your physician has explained that you have diabetes and that your treatment involves  
42 injections of insulin or insulin therapy combined with an oral antidiabetic medicine.  
43 Insulin is normally produced by the pancreas, a gland that lies behind the stomach.  
44 Without insulin, glucose (a simple sugar made from digested food) is trapped in the  
45 bloodstream and cannot enter the cells of the body. Some patients who don't make  
46 enough of their own insulin, or who cannot use the insulin they do make properly, must  
47 take insulin by injection in order to control their blood glucose levels.

48 Each case of diabetes is different and requires direct and continued medical  
49 supervision. Your physician has told you the type, strength and amount of insulin you  
50 should use and the time(s) at which you should inject it, and has also discussed with  
51 you a diet and exercise schedule. You should contact your physician if you experience  
52 any difficulties or if you have questions.

53

#### 54 **TYPES OF INSULINS**

55 Standard and purified animal insulins as well as human insulins are available. Standard  
56 and purified insulins differ in their degree of purification and content of noninsulin  
57 material. Standard and purified insulins also vary in species source; they may be of  
58 beef, pork, or mixed beef and pork origin. Human insulin is identical in structure to the  
59 insulin produced by the human pancreas, and thus differs from animal insulins. Insulins  
60 vary in time of action; see PRODUCT DESCRIPTION for additional information. Your  
61 physician has prescribed the insulin that is right for you; be sure you have purchased  
62 the correct insulin and check it carefully before you use it.

63

#### 64 **PRODUCT DESCRIPTION**

65 This package contains five (5) Novolin<sup>®</sup> R PenFill<sup>®</sup> 3 mL cartridges. Novolin R is  
66 commonly known as Regular, Human Insulin Injection (recombinant DNA origin). The  
67 concentration of this product is 100 units of insulin per milliliter. It is a clear, colorless  
68 solution which has a short duration of action. The effect of Novolin R begins  
69 approximately ½ hour after injection. The effect is maximal between 2½ and 5 hours  
70 and ends approximately 8 hours after injection.

71 The time course of action of any insulin may vary considerably in different individuals, or  
72 at different times in the same individual. Because of this variation, the time periods  
73 listed here should be considered as general guidance only.

74 This human insulin (recombinant DNA origin) is structurally identical to the insulin  
75 produced by the human pancreas. This human insulin is produced by recombinant  
76 DNA technology utilizing *Saccharomyces cerevisiae* (bakers' yeast) as the production  
77 organism.

78

#### 79 **INSULIN DELIVERY SYSTEMS**

80 These Novolin R PenFill 3 mL cartridges are designed for use with Novo Nordisk<sup>®</sup> 3 mL  
81 PenFill cartridge compatible insulin delivery devices, with or without the addition of a  
82 NovoPen<sup>®</sup> 3 PenMate<sup>®</sup>, and NovoFine<sup>®</sup> disposable needles.

83

#### 84 **STORAGE**

85 **Insulin should be stored in a cold (36° - 46°F [2° - 8°C]) place, preferably in a**  
86 **refrigerator, but not in the freezer. Do not let it freeze. Keep Novolin R PenFill**  
87 **cartridges in the carton so that they will stay clean and protected from light. The**  
88 **Novolin R PenFill cartridge that you are currently using should not be refrigerated**  
89 **but should be kept as cool as possible (below 86°F [30°C]) and away from direct**  
90 **heat and light. Unrefrigerated Novolin R PenFill cartridges must be discarded 28**  
91 **days after the first use, even if they still contain Novolin R insulin. Never use**  
92 **PenFill cartridges after the expiration date which is printed on the label and**  
93 **carton.**

94 Never use any Novolin R PenFill cartridge if the insulin becomes viscous (thickened) or  
95 cloudy; use it only if it is clear and colorless.

96

### 97 **IMPORTANT**

98 Failure to follow the antiseptic measures listed below may lead to infections at the  
99 injection site.

- 100 - Disposable needles are for single use; they should be used only once and destroyed.
- 101 - Clean your hands and the injection site with soap and water or with alcohol.
- 102 - Wipe the rubber stopper on the insulin cartridge with an alcohol swab.

103

### 104 **PREPARING THE INJECTION**

105 Never place a single-use disposable needle on your device until you are ready to give  
106 an injection, and remove the needle immediately after the injection. Follow the  
107 directions for use in the instruction manual for your insulin delivery device.

108 **PenFill cartridges may contain a small amount of air bubbles. To prevent an**  
109 **injection of air and to make certain a full dose of insulin is injected, an air shot**  
110 **must be done before each injection. Directions for performing an air shot are**  
111 **provided in your insulin delivery device instruction manual.**

112

### 113 **GIVING THE INJECTION**

- 114 1. The following areas are suitable for subcutaneous insulin injection: thighs, upper  
115 arms, buttocks, abdomen. Do not change areas without consulting your physician.  
116 The actual point of injection should be changed each time; injection sites should be  
117 about an inch apart.
- 118 2. The injection site should be clean and dry. Pinch up skin area to be injected and hold  
119 it firmly.
- 120 3. Hold the device like a pencil and push the needle quickly and firmly into the pinched-  
121 up area.
- 122 4. Release the skin and push the push-button all the way in to inject insulin beneath the  
123 skin. After the injection, the needle should remain under the skin for at least 6  
124 seconds. Keep the push button fully depressed until the needle is withdrawn from the  
125 skin. This will ensure that the full dose has been injected.
- 126 5. Do not inject into a muscle unless your physician has advised it. You should never  
127 inject insulin into a vein. Follow the directions for use of your insulin delivery device.
- 128 6. Remove the needle. If slight bleeding occurs, press lightly with a dry cotton swab for  
129 a few seconds - **do not rub.**

130 **Note: Use the injection technique recommended by your physician.**

131

### 132 **USAGE IN PREGNANCY**

133 It is particularly important to maintain good control of your diabetes during pregnancy  
134 and special attention must be paid to your diet, exercise and insulin regimens. If you  
135 are pregnant or nursing a baby, consult your physician or nurse educator.

136

### 137 **INSULIN REACTION AND SHOCK**

138 Insulin reaction (hypoglycemia) occurs when the blood glucose falls very low. This can  
139 happen if you take too much insulin, miss or delay a meal, exercise more than usual, or  
140 work too hard without eating, or become ill (especially with vomiting or fever).

141 Hypoglycemia can also happen if you combine insulin therapy and other medications  
142 that lower blood glucose, such as oral antidiabetic agents or other prescription and  
143 over-the-counter drugs. The first symptoms of an insulin reaction usually come on  
144 suddenly. They may include a cold sweat, fatigue, nervousness or shakiness, rapid  
145 heartbeat, or nausea. Personality change or confusion may also occur. If you drink or  
146 eat something right away (a glass of milk or orange juice, or several sugar candies), you  
147 can often stop the progression of symptoms. If symptoms persist, call your physician -  
148 an insulin reaction can lead to unconsciousness. If a reaction results in loss of  
149 consciousness, emergency medical care should be obtained immediately. If you have  
150 had repeated reactions or if an insulin reaction has led to a loss of consciousness,  
151 contact your physician. Severe hypoglycemia can result in temporary or permanent  
152 impairment of brain function and death.

153 **In certain cases, the nature and intensity of the warning symptoms of**  
154 **hypoglycemia may change. A few patients have reported that after being**  
155 **transferred to human insulin, the early warning symptoms of hypoglycemia were**  
156 **less pronounced than they had been with animal-source insulin.**  
157

158

### 158 **DIABETIC KETOACIDOSIS AND COMA**

159 Diabetic ketoacidosis may develop if your body has too little insulin. The most common  
160 causes are acute illness or infection or failure to take enough insulin by injection. If you  
161 are ill, you should check your urine for ketones. The symptoms of diabetic ketoacidosis  
162 usually come on gradually, over a period of hours or days, and include a drowsy feeling,  
163 flushed face, thirst and loss of appetite. Notify your physician right away if the urine test  
164 is positive for ketones (acetone) or if you have any of these symptoms. Fast, heavy  
165 breathing and rapid pulse are more severe symptoms and you should have medical  
166 attention right away. Severe, sustained hyperglycemia may result in diabetic coma and  
167 death.

168

### 169 **ADVERSE REACTIONS**

170 A few people with diabetes develop red, swollen and itchy skin where the insulin has  
171 been injected. This is called a "local reaction" and it may occur if the injection is not  
172 properly made, if the skin is sensitive to the cleansing solution, or if you are allergic to  
173 the insulin being used. If you have a local reaction, tell your physician.

174 Generalized insulin allergy occurs rarely, but when it does it may cause a serious  
175 reaction, including skin rash over the body, shortness of breath, fast pulse, sweating,  
176 and a drop in blood pressure. If any of these symptoms develop, you should seek  
177 emergency medical care.

178 If severe allergic reactions to insulin have occurred (i.e., generalized rash, swelling or  
179 breathing difficulties) you should be skin-tested with **each** new insulin preparation  
180 before it is used.

181

### 182 **IMPORTANT NOTES**

- 183 1. A change in the type, strength, species or purity of insulin could require a dosage  
184 adjustment. Any change in insulin should be made under medical supervision.
- 185 2. To avoid possible transmission of disease, PenFill cartridge should not be shared.

- 186 3. Before use, check that the PenFill cartridge is intact (e.g. no cracks). Do not use if  
187 any damage is visible, or if the part of the rubber piston that you see is wider than the  
188 white bar code band.
- 189 4. You may have learned how to test your urine or your blood for glucose. It is  
190 important to do these tests regularly and to record the results for review with your  
191 physician or nurse educator.
- 192 5. If you have an acute illness, especially with vomiting or fever, continue taking your  
193 insulin. If possible, stay on your regular diet. If you have trouble eating, drink fruit  
194 juices, regular soft drinks, or clear soups; if you can, eat small amounts of bland  
195 foods. Test your urine for glucose and ketones and, if possible, test your blood  
196 glucose. Note the results and contact your physician for possible insulin dose  
197 adjustment. If you have severe and prolonged vomiting, seek emergency medical  
198 care.
- 199 6. You should always carry identification which states that you have diabetes.
- 200 7. Always ask your physician or pharmacist before taking any drug.
- 201 8. Do not try to refill a PenFill cartridge.
- 202

203 **Always consult your physician if you have any questions about your condition or**  
204 **the use of insulin.**

205 Helpful information for people with diabetes is published by American Diabetes  
206 Association, 1660 Duke Street, Alexandria, VA 22314

207  
208 Date of issue:

209  
210 Protected by U.S. Patent No. 6,126,646 and Des. 347,894 and other U.S. Patents  
211 Pending, recommended for use with Novo Nordisk 3 mL PenFill cartridge compatible  
212 insulin delivery devices, with or without a NovoPen 3 PenMate, and Novo Nordisk pen  
213 needles.

214  
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216  
217 Novo Nordisk<sup>®</sup>, Novolin<sup>®</sup>, PenFill<sup>®</sup>, NovoPen<sup>®</sup>, PenMate<sup>®</sup>, NovoFine<sup>®</sup> and Lente<sup>®</sup> are  
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220 Novo Nordisk Inc.  
221 Princeton, NJ 08540  
222 Call 1-800-727-6500 for additional information

223  
224 [www.novonordisk-us.com](http://www.novonordisk-us.com)

225  
226 Manufactured by  
227 Novo Nordisk A/S  
228 DK-2880 Bagsvaerd, Denmark

Front Panel:

<p>List 185242 <b>NovoPen<sup>®</sup> 3 PenMate<sup>®</sup></b></p>	<p>Designed for use with Novo Nordisk 3 mL PenFill<sup>®</sup> cartridge compatible insulin delivery devices, PenFill<sup>®</sup> 3 mL cartridges and NovoFine<sup>®</sup> disposable needles</p>
<p><b>CONTAINS ONE NOVOPEN<sup>®</sup> 3 PENMATE<sup>®</sup></b></p>	
	<p><i><b>Novo Nordisk</b></i></p>

Side Panel:

<p><b>NovoPen<sup>®</sup> 3 PenMate<sup>®</sup></b> NovoPen<sup>®</sup> 3 PenMate<sup>®</sup> is specially designed for use with Novo Nordisk 3 ml PenFill<sup>®</sup> cartridge compatible insulin delivery devices, PenFill<sup>®</sup> 3 mL cartridges and NovoFine<sup>®</sup> needles with a length of up to 8 mm to allow the device to function safely and effectively.</p>	<p>Carrying Case Enclosed</p>	<p>Novo Nordisk delivery devices, NovoFine<sup>®</sup> disposable needles and 3 mL PenFill<sup>®</sup> insulin cartridges not included.</p>
--	-------------------------------	---

Back Panel:

<p>For information contact: <b>Novo Nordisk Inc.</b> Princeton, NJ 08540</p> <p>Manufactured in Denmark for: <b>Novo Nordisk A/S</b> 2880 Bagsvaerd, Denmark <a href="http://www.novonordisk-us.com">www.novonordisk-us.com</a></p> <p>BARCODE</p>	<p>Protected by U.S. Patent No. 5,980,491 and other Patents Pending.</p> <p>Designed and recommended for use with Novo Nordisk 3 mL PenFill<sup>®</sup> insulin cartridges and NovoPen<sup>®</sup> devices.</p> <p>Novo Nordisk<sup>®</sup>, NovoPen<sup>®</sup>, PenMate<sup>®</sup>, PenFill<sup>®</sup> and NovoFine<sup>®</sup> are registered trademarks of Novo Nordisk A/S.</p>
	<p>novo nordisk<sup>®</sup></p>

Side Panel:

<p><b>NovoPen<sup>®</sup> 3 PenMate<sup>®</sup></b> NovoPen<sup>®</sup> 3 PenMate<sup>®</sup> is specially designed for use with Novo Nordisk 3 mL PenFill<sup>®</sup> cartridges compatible insulin delivery devices, PenFill<sup>®</sup> 3 mL cartridges and NovoFine<sup>®</sup> needles with a length of up to 8 mm to allow the device to function safely and effectively.</p>	<p>LIST: 185242</p>
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End Flap:

List: 185242  
**NovoPen<sup>®</sup> 3 PenMate<sup>®</sup>**  
  
Batch:

End Flap:

List: 185242  
**NovoPen<sup>®</sup> 3 PenMate<sup>®</sup>**

NDA 19-938/S-037  
8-0199-31-201-X/12-7-04/DRAFT

**Novo Nordisk®**

NDC 0169-3473-18

Novolin® R PenFill®  
Regular,  
Human Insulin Injection  
(rDNA origin)

3mL 100 units/mL

For use with Novo Nordisk 3mL PenFill®  
cartridge compatible insulin delivery devices

For information contact: *BARCODE*  
Novo Nordisk Inc.  
Princeton, NJ 08540  
1-800-727-6500

8-0199-31- Exp.Date:  
201-X/12-7-04/DRAFT Control

NDC 0169-3473-18

# Novolin® **R** PenFill®

Regular,  
Human Insulin Injection  
(recombinant DNA origin)

**3 mL**

For use with Novo Nordisk 3 mL PenFill®  
cartridge compatible insulin delivery devices

Keep in a cold place  
Avoid freezing

**100 units/mL (U-100)**

**5x3 mL  
cartridges**

**Novo Nordisk™**  
List 347318

# Novolin® **R** PenFill®

**5x3 mL  
cartridges**  
100 units/mL

**Warning**

Any change of insulin should be made cautiously  
and only under medical supervision.

PenFill® cartridge is for single person use only.  
See package insert.

Contains metacresol 0.315% added  
during manufacture as a preservative.

Novolin®, PenFill®, PenMate®, and NovoPen®  
are trademarks owned by Novo Nordisk A/S.

Protected by U.S. Patent No. 6,126,646 and Des. 347,894  
and other U.S. Patents Pending. Recommended for use with Novo  
Nordisk 3 mL PenFill® cartridge compatible insulin delivery devices,  
with or without a NovoPen® 3 PenMate®, and NovoFine® disposable needles.

Novo Nordisk Inc.  
Princeton, NJ 08540  
Call 1-800-727-6500 for additional  
information  
[www.novonordisk-us.com](http://www.novonordisk-us.com)  
Manufactured by  
Novo Nordisk A/S  
DK-2880 Bagsvaerd, Denmark



Exp. date:  
Control:

**5x3 mL**  
cartridges  
100 units/mL

**Novolin® **R** PenFill®**

6 mm  
1 mm

