

Norditropin® cartridge
Somatropin (rDNA origin)
injection 15 mg/1.5 mL

NDC 0169-7770-11

For use only with NordiPen® 15

delivery system.

Rx only. Prior to use, keep refrigerated

(2-8°C/36-46°F). Do not freeze. Avoid

direct light.

For

information

contact:

(01) 103 0169 7770 113

Novo Nordisk Inc.

Princeton, NJ 08540 1-888-NOVO-444

Manufactured by:

Novo Nordisk A/S

Expiry date/Control:
8-2072-31-201-5

Norditropin® cartridge
Somatotropin (rDNA origin)
injection 5 mg/1.5 mL

NDC 0169-7768-11

For use only with NordiPen® 5
delivery system.

Rx only. Prior to use, keep refrigerated
(2-8°C/36-46°F). Do not freeze. Avoid
direct light.

For
information
contact:

(01) 103 0169 7768 110

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8-2070-31-201-5

NORDIpen® 5

Somatropin Delivery System
Instructions For Use



Introduction

Dear NordiPen® 5 User:

Congratulations! You have selected an accurate, discreet, convenient and comfortable way to deliver from 0.05 to 1.25 mg of somatropin with the NordiPen 5 somatropin delivery system. This booklet includes everything you need to know about using the NordiPen 5. Read it carefully before using your NordiPen 5 for the first time.

The NordiPen 5 is designed for use with:

- Norditropin® cartridges [somatropin (rDNA origin) injection] 5 mg/1.5 mL
- NovoFine® disposable needles

Customer service and satisfaction are our top concern.

If you have any questions about your NordiPen 5 somatropin delivery system, please call Novo Nordisk Inc. at 1-888-NOVO-444.

Thank you for choosing the NordiPen 5 somatropin delivery system.

(See **Important Things to Know** and **Important Notes** on pages 26-27).

Open this flap for a drawing of the NordiPen 5 delivery system.



NordiPen® 5 Somatropin Delivery System



Pen cap

Cartridge holder



Residual
scale

Residual
scale
window

Barrel



Piston rod

Reset
mechanism

Dosage selector
Push button

Dosage
indicator
window

LOT number

NovoFine® Disposable Needle



Outer
needle
cap



Inner
needle
cap



Needle



Protective
tab

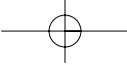
Front rubber
stopper

Color-coded label
band

Color-coded threaded
plastic cap

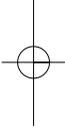
Rear
rubber
stopper

**Need Help?
Call 1-888-NOVO-444**



NordiPen® 5

Novo Nordisk

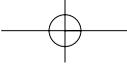


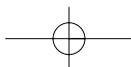
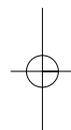
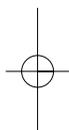
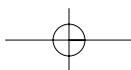
***To be sure you get the right dose, the color of the delivery system must match the color of the carton, label band, and threaded plastic cap of the Norditropin cartridge.
For the 5 mg/1.5 mL cartridge, the color of the NordiPen 5 delivery system and these items is orange.**

Do not use any other cartridges in this pen.

If your doctor prescribes Norditropin cartridges 10 mg/1.5 mL or 15 mg/1.5 mL you will need to use a blue NordiPen 10 (for a blue 10 mg/1.5 mL cartridge) or a green NordiPen 15 (for a green 15 mg/1.5 mL cartridge).

Norditropin®, NordiPen® and NovoFine® are trademarks of Novo Nordisk A/S.



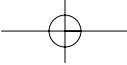


**Welcome to Your NordiPen 5
Somatropin Delivery System**



Norditropin cartridges must be used with their similar color NordiPen delivery system.

Cartridges must not be inserted into pens with a different color.



How to use this booklet

This booklet gives you step-by-step instructions for using the NordiPen 5.

Begin by reviewing the photo of the parts of the NordiPen 5, Norditropin cartridge 5 mg/1.5 mL and NovoFine disposable needle.

The inside front cover opens out so you have a handy reference while you read the rest of the booklet.

Most pages contain a photo with numbered instructions. **Important additional information is given below the instructions.**

Read the text carefully and look at the photos to make sure that you understand each step well.

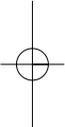
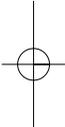


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Section 1: Preparing the NordiPen 5



Remove the pen cap:

- 1 Remove the NordiPen 5 from the case.
- 2 Gently twist the pen cap until the cap separates from the cartridge holder.
- 3 Pull the pen cap straight up to remove it.
- 4 If you already have a Norditropin cartridge in your NordiPen, go to section 3 - Attaching the NovoFine Disposable Needle.

Need Help?
Call 1-888-NOVO-444

If you use Norditropin cartridges 10 mg/1.5 mL (blue) or 15 mg/1.5 mL (green) you **must** use a NordiPen 10 (blue) or NordiPen 15 (green) delivery system to get the proper dose.

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Preparing the NordiPen 5

Section 1 (cont.)



Separate the cartridge holder from the barrel:

- 5 Unscrew and remove the cartridge holder from the barrel.



Make sure the dosage indicator window shows zero:

- 6 Press the push button all the way in until zero (0.00) appears in the window. The zero should be lined up with the "mg" marker next to the dosage indicator window.

Preparing the NordiPen 5

Section 1 (cont.)

The end of the piston rod should be flat against the end of the reset mechanism before you insert each new Norditropin cartridge 5 mg/1.5 mL. The piston rod should not stick out.



If the piston rod sticks out:

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

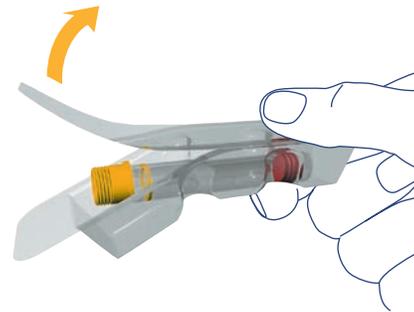
Need Help?
Call 1-888-NOVO-444

Never reset the piston rod until it is time to remove the used Norditropin cartridge 5 mg/1.5 mL and insert a new one.

If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks. Then call our toll free number (1-888-NOVO-444) so that we may review your operating technique with you.

Section 2: Inserting the Norditropin Cartridge 5 mg/1.5 mL

- 1 To remove the Norditropin cartridge 5 mg/1.5 mL from its wrapper, peel the plastic tab away from the packaging. Before use, check that the Norditropin cartridge 5 mg/1.5 mL is full and intact. If not, do not use it.



Each Norditropin cartridge 5 mg/1.5 mL contains a total of 5 mg of somatropin. Make sure you are using the correct cartridge. The color of the threaded plastic cap and the label band of the cartridge should match the orange color of the NordiPen 5 cartridge holder.

Each Norditropin cartridge 5 mg/1.5 mL is for single-person use only. DO NOT use the same cartridge for more than one person, even though you attach a new disposable needle for each injection. This will prevent the spread of disease.

Use only a new Norditropin cartridge 5 mg/1.5 mL when loading the NordiPen 5.

Never load a partially filled cartridge.

Never try to refill a used Norditropin cartridge 5 mg/1.5 mL.

Inserting the Norditropin Cartridge 5 mg/1.5 mL

Section 2 (cont.)

Insert the Norditropin cartridge 5 mg/1.5 mL:

- 2 Hold the cartridge holder so the wider opening is up.



- 3 Drop the Norditropin cartridge 5 mg/1.5 mL into the cartridge holder, threaded plastic cap first.

The threaded plastic cap of the Norditropin cartridge 5 mg/1.5 mL surrounds the end of the cartridge, like the cap on a bottle. In the center is the front rubber stopper. The rear rubber stopper is at the other end of the Norditropin cartridge 5 mg/1.5 mL.

Inserting the Norditropin Cartridge 5 mg/1.5 mL

Section 2 (cont.)

Re-attach the cartridge holder:

- 4 Screw the barrel into the cartridge holder completely until it is tight.

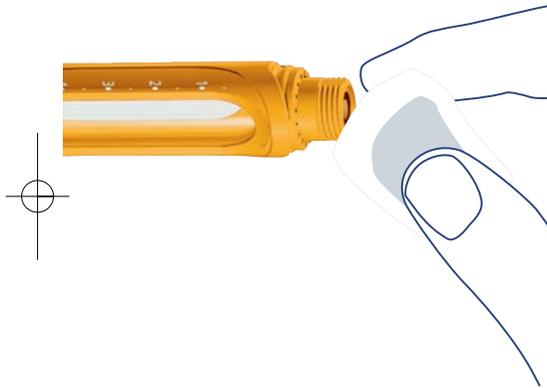


Need Help?
Call 1-888-NOVO-444

You can see the cartridge in the residual scale window. For your convenience, the cartridge holder has a scale with marks showing about how much somatropin is left in the Norditropin cartridge 5 mg/1.5 mL.

Section 3: Attaching the NovoFine Disposable Needle

- 1 Wipe the front rubber stopper on the threaded plastic cap with an alcohol swab.



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You must wipe the front rubber stopper with an alcohol swab before each injection, even if you are using the same Norditropin cartridge 5 mg/1.5 mL.

Attaching the NovoFine Disposable Needle

Section 3 (cont.)

- 2 Remove the protective tab from the NovoFine disposable needle.
- 3 Screw the NovoFine disposable needle firmly onto the cartridge holder until it is tight.



Need Help?
Call 1-888-NOVO-444

Never place a NovoFine disposable needle on your NordiPen 5 until you are ready to do an air shot and give an injection. If the NovoFine disposable needle is "left on" the NordiPen 5, some liquid may leak out of the Norditropin cartridge 5 mg/1.5 mL.

Section 4: Doing an Air Shot

To prevent the injection of air and make certain somatropin is delivered, **you must do an air shot before each injection.**

Before starting the air shot procedure, the dosage indicator window must show zero (0.00).



Set the NordiPen 5 for the air shot:

- 1 Turn the dosage selector until 0.05 mg in the window lines up with the "mg" marker next to the dosage indicator window.

Need Help?
Call 1-888-NOVO-444

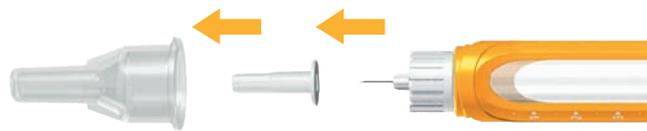
If you dial more than 0.05 mg, DO NOT turn the dial back to zero (0.00). If you do, the extra somatropin will squirt out of the needle. You may complete the air shot with the number of mg you have dialed or refer to page 17 for instructions on how to reset the dose to zero.

Doing an Air Shot

Section 4 (cont.)

Uncap the NovoFine disposable needle:

- 2 Pull off the outer needle cap and set aside.
- 3 Pull off the inner needle cap and discard.





Doing an Air Shot

Section 4 (cont.)

- 4 Hold the NordiPen 5 with the NovoFine disposable needle pointing upward.
- 5 Tap the cartridge holder with your finger a few times to raise any air bubbles that may be present to the top of the cartridge.

Doing an Air Shot

Section 4 (cont.)

Do the air shot:

- 6 Press the push button all the way in. Somatropin should appear at the needle tip.

If no somatropin appears, repeat the following steps, until somatropin appears:

- a. Make sure the NovoFine disposable needle is securely attached.
- b. Dial 0.05 mg.
- c. Tap the cartridge holder with your finger.
- d. Press the push button all the way in.

There still may be an air bubble in the Norditropin cartridge 5 mg/1.5 mL after this step but it will not be injected.

Need Help?
Call 1-888-NOVO-444

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



Section 5: Giving the Injection

Be sure to do an air shot before giving an injection (see pages 12-15).

Select the dose:

- 1 Check that the dosage selector is set to zero. If not, follow the instructions on the next page. Turn the dosage selector until you see the correct number of mg in the dosage indicator window. **DO NOT use the clicking sounds as a guide for selecting your dose.**



The NordiPen 5 can deliver from 0.05 to 1.25 mg of somatropin, in 0.05 mg increments.

If you dial more than your dose, DO NOT turn the dial back to zero (0.00). If you do, the extra somatropin will squirt out of the needle. For instructions on how to reset the dose to zero (0.00) so you can start again, see the next page.

Giving the Injection

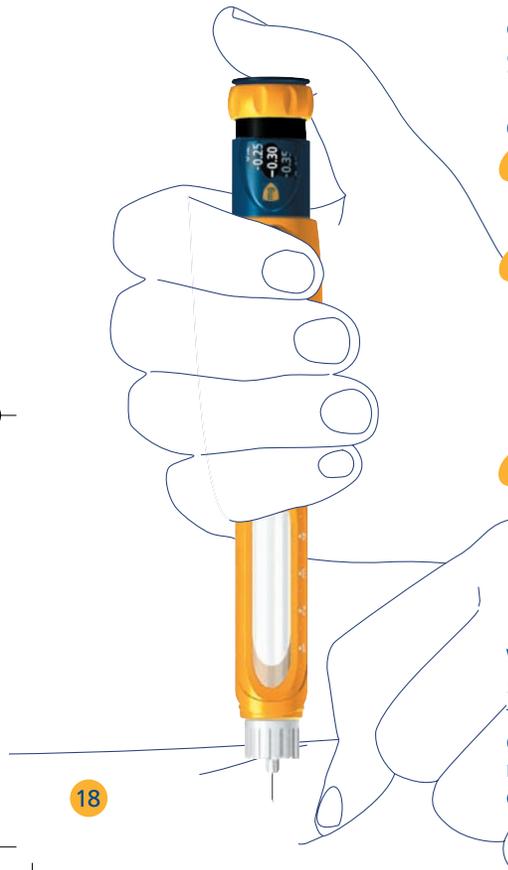
Section 5 (cont.)

To reset to zero (0.00) if you set the wrong dose:

- a. Hold the cartridge holder with your thumb and forefinger.
- b. Hold the barrel between your thumb and middle finger.
- c. Pull the cartridge holder away from the barrel as far as it will go (arrow #1).
- d. Press the push button against a hard surface as shown to reset the dose to zero (0.00).
- e. Release your grip and the cartridge holder will slide back into place.
- f. Check the dosage indicator window to make sure you have reset it all the way to zero (0.00). If you have not, repeat steps a through f.

Need Help?
Call 1-888-NOVO-444





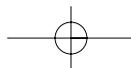
Giving the Injection

Section 5 (cont.)

Give the injection:

- 2 Insert the NovoFine disposable needle in the correct site on the body (Use the injection technique recommended by your health care professional).
- 3 Press the push button **as far as it will go** to deliver the somatropin. Do not force it. To ensure that all the somatropin is injected keep the NovoFine disposable needle in the skin for a least 6 seconds after injection with your thumb on the push button. Keep the push button fully pushed in until after the NovoFine disposable needle has been removed from the skin.
- 4 **Check the dosage indicator window to make sure it shows zero (0.00). If zero does not appear, you did not receive the full dose. See the instructions on the next page.**

When you get near the end of a Norditropin cartridge 5 mg/1.5 mL, you may need to give yourself two injections to receive your full dose. If, after giving an injection, zero does not appear in the dosage indicator window, you did not receive your full dose. See the next page for instructions on how to get the remaining part of your dose.



Giving the Injection

Section 5 (cont.)

If the dosage indicator window does not show zero, there were not enough mg of somatropin in the Norditropin cartridge 5 mg/1.5 mL for you to receive the full dose. The dosage indicator window shows the number of mg that you did not receive.

For example, if you dial 0.60 mg and there are only 0.40 mg left in the Norditropin cartridge 5 mg/1.5 mL, after the injection the number in the dosage indicator window will be 0.20 mg ($0.60 - 0.40 = 0.20$).

To get the remaining part of your dose:

- a. Note the number of mg in the dosage indicator window.
- b. Remove the NovoFine disposable needle from the NordiPen 5 (see Section 6).
- c. Remove the empty Norditropin cartridge 5 mg/1.5 mL (see Section 7).
- d. Insert a new Norditropin cartridge 5 mg/1.5 mL (see Section 2).
- e. Attach a NovoFine disposable needle (see Section 3).
- f. Do an air shot (see Section 4).
- g. Dial the number of mg noted in step a.
- h. Give the injection.

Need Help?
Call 1-888-NOVO-444

Section 6: Removing the NovoFine Disposable Needle

Remove the NovoFine disposable needle:

- 1 Carefully replace the outer needle cap.
- 2 Follow the instructions you received for removal and disposal of needles to prevent the risk of needle injury. Hold the cartridge holder firmly while you unscrew the NovoFine disposable needle.
- 3 Place the NovoFine disposable needle in a puncture-resistant disposal container. Used 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.

The NovoFine disposable needle must be removed immediately after each injection.

If the NovoFine disposable needle is not removed, some liquid may leak out of the Norditropin cartridge 5 mg/1.5 mL.

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



Removing the NovoFine Disposable Needle

Section 6: (cont.)

Replace the pen cap:

- 4 Gently slide the pen cap onto the cartridge holder.
- 5 Turn the pen cap until the cap secures onto the cartridge holder.



Need Help?
Call 1-888-NOVO-444

Section 7: Removing the Norditropin Cartridge 5 mg/1.5 mL

You will need to remove the Norditropin cartridge 5 mg/1.5 mL when the cartridge is empty.

Remove the barrel:

- 1 Remove the pen cap.
- 2 Hold the NordiPen 5 with the dosage indicator window at the top.
- 3 Unscrew the barrel from the cartridge holder.



Removing the Norditropin Cartridge 5 mg/1.5 mL

Section 7 (cont.)

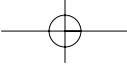
Remove the Norditropin cartridge 5 mg/1.5 mL:

- 4 Tip the cartridge holder until the Norditropin cartridge 5 mg/1.5 mL drops out.
- 5 Press the push button all the way in until zero (0.00) appears in the window.
- 6 Turn the end of the reset mechanism in a clockwise direction until the piston rod is no longer sticking out (refer to figure on page 6).
- 7 To insert a new Norditropin cartridge 5 mg/1.5 mL please refer to section 2.

Need Help?
Call 1-888-NOVO-444

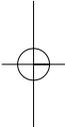
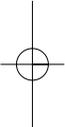
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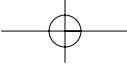




Storage

Guidelines for storing the NordiPen 5 and Norditropin cartridges 5 mg/1.5 mL:

- Keep the NordiPen 5 (with the Norditropin cartridge 5 mg/1.5 mL inside) **EITHER** refrigerated (2-8°C/36-46°F) for 4 weeks **OR** store not above 25°C (77°F) for 3 weeks. Do not freeze. Norditropin **MUST NOT BE INJECTED** if the solution is cloudy or contains particulate matter. Use it only if it is clear and colorless.
 - Store the NordiPen 5 **without** the NovoFine disposable needle attached and **with** the pen cap in position.
 - For information on storing Norditropin cartridges 5 mg/1.5 mL, see the leaflet that comes in the Norditropin cartridge 5 mg/1.5 mL box.
- 
- 



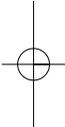
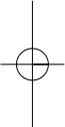
Maintenance

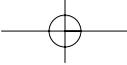
Guidelines for maintaining the NordiPen 5.

Be sure to:

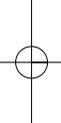
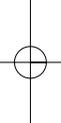
- 1 Clean the NordiPen 5 by wiping with a soft cloth moistened with a mild detergent.
- 2 Protect the NordiPen 5 from dust, dirt, and moisture when not in its case.

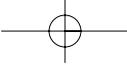
Make certain you:

- 1 **Do not** soak the NordiPen 5 in alcohol, wash it in soap and water, or lubricate it, since this may cause damage.
 - 2 **Do not** expose the NordiPen 5 to excessive pressure or blows.
 - 3 **Do not** drop the NordiPen 5.
- 
- 



Important Things to Know

- Norditropin cartridges must be used with their corresponding color-coded NordiPen delivery system. Cartridges must not be inserted into pens with a different color code.
 - The NordiPen 5 is not recommended for people who are blind or who have trouble seeing unless they have the help of a sighted individual trained to use the NordiPen 5.
 - Use only a new Norditropin cartridge 5 mg/1.5 mL when loading the NordiPen 5. Never load the NordiPen 5 with a partially filled Norditropin cartridge 5 mg/1.5 mL.
 - Keep the NordiPen 5, Norditropin cartridges 5 mg/1.5 mL, and NovoFine disposable needles out of the reach of children.
 - Keep the NordiPen 5 **EITHER** refrigerated (2-8°C/36-46°F) for 4 weeks **OR** store not above 25°C (77°F) for 3 weeks. Do not freeze.
 - The NordiPen 5 is designed for use with Norditropin cartridges 5 mg/1.5 mL and NovoFine disposable needles. Novo Nordisk is not responsible for any consequences arising from the use of the NordiPen 5 with products that are not recommended by Novo Nordisk.
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- 



Important Notes

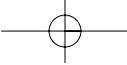
The following is a review of some important information about the use and care of your NordiPen 5.

Before each injection, be certain:

- 
- 1 The NordiPen 5 contains the correct cartridge. The color of the threaded plastic cap and the label band of the cartridge should match the orange color of the NordiPen 5 cartridge holder.
 - 2 To always do the air shot with the NovoFine disposable needle pointing upward.

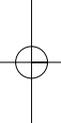
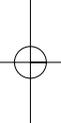
Be sure to:

- 
- 1 Check the dosage indicator window after each injection to make sure you have received your full dose.
 - 2 Remove the NovoFine disposable needle immediately after each injection.
 - 3 Select your dose only by using the number in the dosage indicator window.



Important Notes (cont.)

Make certain you:

- 1 Do not** place a NovoFine disposable needle on the NordiPen 5 until you are ready to do an air shot and give an injection.
Remove the needle immediately after each injection. If the NovoFine disposable needle is not removed, some liquid may leak out of the Norditropin cartridge 5 mg/1.5 mL.
 - 2 Do not** use the clicking sound to set your dose.
 - 3 Do not** try to refill a Norditropin cartridge 5 mg/1.5 mL.
 - 4 Do not** use the same Norditropin cartridge 5 mg/1.5 mL for more than one person, even though you attach a new NovoFine disposable needle for each injection. This will prevent the spread of disease. Each Norditropin cartridge 5 mg/1.5 mL is for single-person use only.
- 
- 

What to do if...

The dosage indicator window does not show zero after the injection:

- 1 You did not receive your full dose.**
Follow the steps on page 19 to get the remaining part of your dose.

No somatropin appears when you do the air shot:

- 1 The piston rod is not far enough down the cartridge holder to reach the rear rubber stopper.**

Repeat the air shot (pp. 12-15).

- 2 The NovoFine disposable needle may not be securely attached.**

- Put the plastic outer cap back on the NovoFine disposable needle.
- Turn the plastic outer cap in a clockwise direction to tighten the NovoFine disposable needle.

- 3 The NovoFine disposable needle may be blocked.**

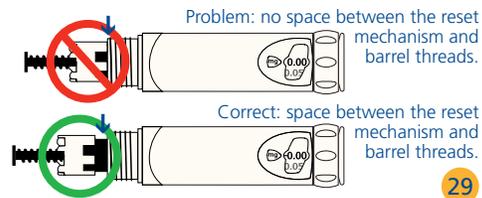
Change the NovoFine disposable needle (pp. 10-11) and continue the air shot (pp. 12-15).

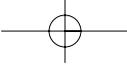
The piston rod is sticking out too far to attach the cartridge holder to the barrel:

- 1 You must screw the piston rod back into the barrel. Never try to push it in or you can damage the mechanism.**

The push button will not return to zero or the piston rod will not turn back into the reset mechanism:

- 1 The reset mechanism may be locked in the position shown in the upper of the diagrams below. This is usually due to improper technique. Gently turn the reset mechanism side to side until it unlocks as shown in the bottom diagram, then call our toll free number (1-888-NOVO-444) so that we may review your operating technique with you.**



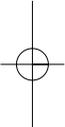
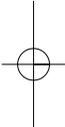


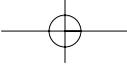
Warranty

Should your NordiPen 5 be defective in materials or workmanship within two (2) years of use, Novo Nordisk Inc. will replace it at no charge if you mail the defective unit, postage prepaid to:

**Novo Nordisk Inc.
Product Safety
100 College Road West
Princeton, NJ 08540**

**Licensed under U.S. Patent No. 5,626,566.
Designed and intended for use with Norditropin
cartridges and NovoFine disposable needles.**

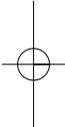
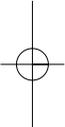


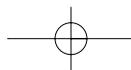
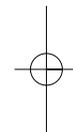
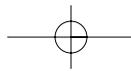


Warranty (cont.)

No other warranty is made with respect to NordiPen 5.

This 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 NordiPen 5 with products other than Norditropin cartridges 5 mg/1.5 mL and NovoFine disposable needles.
 - The use of the NordiPen 5 not in accordance with the instructions in this booklet.
 - Physical damage to the NordiPen 5 caused by neglect, misuse, unauthorized repair, accident, or other breakage.



CE
0088

For assistance or further information, write to:
Novo Nordisk Inc.
Drug Information
100 College Road West
Princeton, NJ 08540
Visit www.norditropin-us.com
Or call: 1-888-NOVO-444

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Novo Nordisk Inc.
Princeton, NJ 08540

8-4226-31-002-3

NORDI pen[®] 15

Somatropin Delivery System
Instructions For Use



Introduction

Dear NordiPen® 15 User:

Congratulations! You have selected an accurate, discreet, convenient and comfortable way to deliver from 0.1 to 4.0 mg of somatropin with the NordiPen 15 somatropin delivery system. This booklet includes everything you need to know about using the NordiPen 15. Read it carefully before using your NordiPen 15 for the first time.

The NordiPen 15 is designed for use with:

- Norditropin® cartridges [somatropin (rDNA origin) injection] 15 mg/1.5 mL
- NovoFine® disposable needles

Customer service and satisfaction are our top concern.

If you have any questions about your NordiPen 15 somatropin delivery system, please call Novo Nordisk Inc. at 1-888-NOVO-444.

Thank you for choosing the NordiPen 15 somatropin delivery system.

(See **Important Things to Know** and **Important Notes** on pages 26-27).

Open this flap for a drawing of the NordiPen 15 delivery system.



NordiPen® 15 Somatropin Delivery System



Pen cap

Cartridge holder



Residual
scale

Residual
scale
window

Barrel



Piston rod

Reset
mechanism

Dosage
indicator
window

Dosage selector
Push button

LOT number

NovoFine® Disposable Needle



Outer
needle
cap

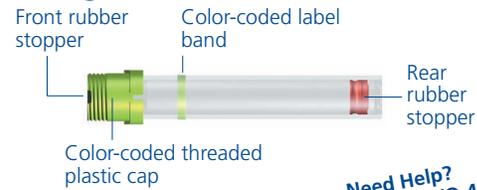
Inner
needle
cap

Needle



Protective
tab

Norditropin® Cartridge 15 mg/1.5 mL*



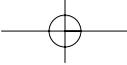
Front rubber
stopper

Color-coded label
band

Rear
rubber
stopper

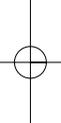
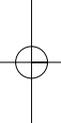
Color-coded threaded
plastic cap

**Need Help?
Call 1-888-NOVO-444**



NordiPen® 15

Novo Nordisk

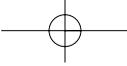


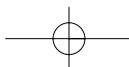
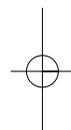
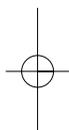
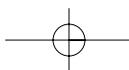
***To be sure you get the right dose, the color of the delivery system must match the color of the carton, label band, and threaded plastic cap of the Norditropin cartridge.
For the 15 mg/1.5 mL cartridge, the color of the NordiPen 15 delivery system and these items is green.**

Do not use any other cartridges in this pen.

If your doctor prescribes Norditropin cartridges 5 mg/1.5 mL or 10 mg/1.5 mL you will need to use an orange NordiPen 5 (for an orange 5 mg/1.5 mL cartridge) or a blue NordiPen 10 (for a blue 10 mg/1.5 mL cartridge).

Norditropin®, NordiPen® and NovoFine® are trademarks of Novo Nordisk A/S.



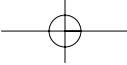


**Welcome to Your NordiPen 15
Somatropin Delivery System**



Norditropin cartridges must be used with their similar color NordiPen delivery system.

Cartridges must not be inserted into pens with a different color.



How to use this booklet

This booklet gives you step-by-step instructions for using the NordiPen 15.

Begin by reviewing the photo of the parts of the NordiPen 15, Norditropin cartridge 15 mg/1.5 mL and NovoFine disposable needle.

The inside front cover opens out so you have a handy reference while you read the rest of the booklet.

Most pages contain a photo with numbered instructions. **Important additional information is given below the instructions.**

Read the text carefully and look at the photos to make sure that you understand each step well.

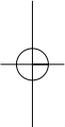
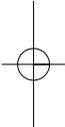


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Section 1: Preparing the NordiPen 15



Remove the pen cap:

- 1 Remove the NordiPen 15 from the case.
- 2 Gently twist the pen cap until the cap separates from the cartridge holder.
- 3 Pull the pen cap straight up to remove it.
- 4 If you already have a Norditropin cartridge in your NordiPen, go to section 3 - Attaching the NovoFine Disposable Needle.

Need Help?
Call 1-888-NOVO-444

If you use Norditropin cartridges 5 mg/1.5 mL (orange) or 10 mg/1.5 mL (blue) you **must** use a NordiPen 5 (orange) or NordiPen 10 (blue) delivery system to get the proper dose.

4

Preparing the NordiPen 15

Section 1 (cont.)



Separate the cartridge holder from the barrel:

- 5 Unscrew and remove the cartridge holder from the barrel.



Make sure the dosage indicator window shows zero:

- 6 Press the push button all the way in until zero (0.0) appears in the window. The zero should be lined up with the "mg" marker next to the dosage indicator window.

Preparing the NordiPen 15

Section 1 (cont.)

The end of the piston rod should be flat against the end of the reset mechanism before you insert each new Norditropin cartridge 15 mg/1.5 mL. The piston rod should not stick out.



If the piston rod sticks out:

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

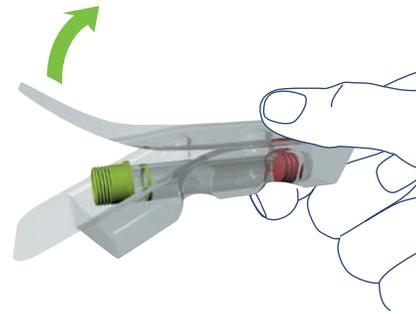
Need Help?
Call 1-888-NOVO-444

Never reset the piston rod until it is time to remove the used Norditropin cartridge 15 mg/1.5 mL and insert a new one.

If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks. Then call our toll free number (1-888-NOVO-444) so that we may review your operating technique with you.

Section 2: Inserting the Norditropin Cartridge 15 mg/1.5 mL

- 1 To remove the Norditropin cartridge 15 mg/1.5 mL from its wrapper, peel the plastic tab away from the packaging. Before use, check that the Norditropin cartridge 15 mg/1.5 mL is full and intact. If not, do not use it.



Each Norditropin cartridge 15 mg/1.5 mL contains a total of 15 mg of somatropin. Make sure you are using the correct cartridge. The color of the threaded plastic cap and the label band of the cartridge should match the green color of the NordiPen 15 cartridge holder.

Each Norditropin cartridge 15 mg/1.5 mL is for single-person use only. DO NOT use the same cartridge for more than one person, even though you attach a new disposable needle for each injection. This will prevent the spread of disease.

Use only a new Norditropin cartridge 15 mg/1.5 mL when loading the NordiPen 15.

Never load a partially filled cartridge.

Never try to refill a used Norditropin cartridge 15 mg/1.5 mL.

Inserting the Norditropin Cartridge 15 mg/1.5 mL

Section 2 (cont.)

Insert the Norditropin cartridge 15 mg/1.5 mL:

- 2 Hold the cartridge holder so the wider opening is up.



- 3 Drop the Norditropin cartridge 15 mg/1.5 mL into the cartridge holder, threaded plastic cap first.

The threaded plastic cap of the Norditropin cartridge 15 mg/1.5 mL surrounds the end of the cartridge, like the cap on a bottle. In the center is the front rubber stopper. The rear rubber stopper is at the other end of the Norditropin cartridge 15 mg/1.5 mL.

Inserting the Norditropin Cartridge 15 mg/1.5 mL

Section 2 (cont.)

Re-attach the cartridge holder:

- 4 Screw the barrel into the cartridge holder completely until it is tight.



Need Help?
Call 1-888-NOVO-444

You can see the cartridge in the residual scale window. For your convenience, the cartridge holder has a scale with marks showing about how much somatropin is left in the Norditropin cartridge 15 mg/1.5 mL.

Section 3: Attaching the NovoFine Disposable Needle

- 1 Wipe the front rubber stopper on the threaded plastic cap with an alcohol swab.



10

You must wipe the front rubber stopper with an alcohol swab before each injection, even if you are using the same Norditropin cartridge 15 mg/1.5 mL.

Attaching the NovoFine Disposable Needle

Section 3 (cont.)

- 2 Remove the protective tab from the NovoFine disposable needle.
- 3 Screw the NovoFine disposable needle firmly onto the cartridge holder until it is tight.



Need Help?
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Never place a NovoFine disposable needle on your NordiPen 15 until you are ready to do an air shot and give an injection.
If the NovoFine disposable needle is "left on" the NordiPen 15, some liquid may leak out of the Norditropin cartridge 15 mg/1.5 mL.

Section 4: Doing an Air Shot

To prevent the injection of air and make certain somatropin is delivered, **you must do an air shot before each injection.**

Before starting the air shot procedure, the dosage indicator window must show zero (0.0).



Set the NordiPen 15 for the air shot:

- 1 Turn the dosage selector until the first long line between zero and 0.2 mg (equal to 0.1 mg) in the window lines up with the "mg" marker next to the dosage indicator window.

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Call 1-888-NOVO-444

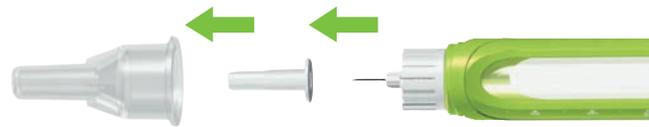
If you dial more than 0.1 mg, DO NOT turn the dial back to zero (0.0). If you do, the extra somatropin will squirt out of the needle. You may complete the air shot with the number of mg you have dialed or refer to page 17 for instructions on how to reset the dose to zero.

Doing an Air Shot

Section 4 (cont.)

Uncap the NovoFine disposable needle:

- 2 Pull off the outer needle cap and set aside.
- 3 Pull off the inner needle cap and discard.





Doing an Air Shot

Section 4 (cont.)

- 4 Hold the NordiPen 15 with the NovoFine disposable needle pointing upward.
- 5 Tap the cartridge holder with your finger a few times to raise any air bubbles that may be present to the top of the cartridge.

Doing an Air Shot

Section 4 (cont.)

Do the air shot:

- 6 Press the push button all the way in. Somatropin should appear at the needle tip.

If no somatropin appears, repeat the following steps, until somatropin appears:

- a. Make sure the NovoFine disposable needle is securely attached.
- b. Dial 0.1 mg.
- c. Tap the cartridge holder with your finger.
- d. Press the push button all the way in.

There still may be an air bubble in the Norditropin cartridge 15 mg/1.5 mL after this step but it will not be injected.

Need Help?
Call 1-888-NOVO-444

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



Section 5: Giving the Injection

Be sure to do an air shot before giving an injection (see pages 12-15).

Select the dose:

- 1 Check that the dosage selector is set to zero. If not, follow the instructions on the next page. Turn the dosage selector until you see the correct number of mg in the dosage indicator window. **DO NOT use the clicking sounds as a guide for selecting your dose.**



The NordiPen 15 can deliver from 0.1 to 4.0 mg of somatropin, in 0.1 mg increments.

If you dial more than your dose, DO NOT turn the dial back to zero (0.0). If you do, the extra somatropin will squirt out of the needle. For instructions on how to reset the dose to zero (0.0) so you can start again, see the next page.

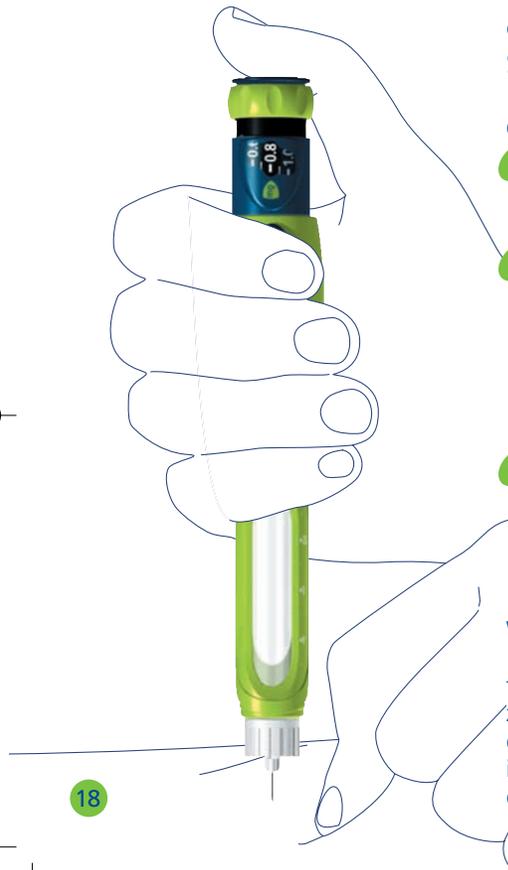
Section 5 (cont.)

To reset to zero (0.0) if you set the wrong dose:

- a. Hold the cartridge holder with your thumb and forefinger.
- b. Hold the barrel between your thumb and middle finger.
- c. Pull the cartridge holder away from the barrel as far as it will go (arrow #1).
- d. Press the push button against a hard surface as shown to reset the dose to zero (0.0).
- e. Release your grip and the cartridge holder will slide back into place.
- f. Check the dosage indicator window to make sure you have reset it all the way to zero (0.0). If you have not, repeat steps a through f.

Need Help?
Call 1-888-NOVO-444





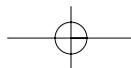
Giving the Injection

Section 5 (cont.)

Give the injection:

- 2 Insert the NovoFine disposable needle in the correct site on the body (Use the injection technique recommended by your health care professional).
- 3 Press the push button **as far as it will go** to deliver the somatropin. Do not force it. To ensure that all the somatropin is injected keep the NovoFine disposable needle in the skin for at least 6 seconds after injection with your thumb on the push button. Keep the push button fully pushed in until after the NovoFine disposable needle has been removed from the skin.
- 4 **Check the dosage indicator window to make sure it shows zero (0.0). If zero does not appear, you did not receive the full dose. See the instructions on the next page.**

When you get near the end of a Norditropin cartridge 15 mg/1.5 mL, you may need to give yourself two injections to receive your full dose. If, after giving an injection, zero does not appear in the dosage indicator window, you did not receive your full dose. See the next page for instructions on how to get the remaining part of your dose.



Giving the Injection

Section 5 (cont.)

If the dosage indicator window does not show zero, there were not enough mg of somatropin in the Norditropin cartridge 15 mg/1.5 mL for you to receive the full dose. The dosage indicator window shows the number of mg that you did not receive.

For example, if you dial 0.6 mg and there are only 0.4 mg left in the Norditropin cartridge 15 mg/1.5 mL, after the injection the number in the dosage indicator window will be 0.2 mg ($0.6 - 0.4 = 0.2$).

To get the remaining part of your dose:

- a. Note the number of mg in the dosage indicator window.
- b. Remove the NovoFine disposable needle from the NordiPen 15 (see Section 6).
- c. Remove the empty Norditropin cartridge 15 mg/1.5 mL (see Section 7).
- d. Insert a new Norditropin cartridge 15 mg/1.5 mL (see Section 2).
- e. Attach a NovoFine disposable needle (see Section 3).
- f. Do an air shot (see Section 4).
- g. Dial the number of mg noted in step a.
- h. Give the injection.

Need Help?
Call 1-888-NOVO-444

Section 6: Removing the NovoFine Disposable Needle

Remove the NovoFine disposable needle:

- 1 Carefully replace the outer needle cap.
- 2 Follow the instructions you received for removal and disposal of needles to prevent the risk of needle injury. Hold the cartridge holder firmly while you unscrew the NovoFine disposable needle.
- 3 Place the NovoFine disposable needle in a puncture-resistant disposal container. Used 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.



The NovoFine disposable needle must be removed immediately after each injection.

If the NovoFine disposable needle is not removed, some liquid may leak out of the Norditropin cartridge 15 mg/1.5 mL.

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

Removing the NovoFine Disposable Needle

Section 6: (cont.)

Replace the pen cap:

- 4 Gently slide the pen cap onto the cartridge holder.
- 5 Turn the pen cap until the cap secures onto the cartridge holder.



Need Help?
Call 1-888-NOVO-444

Section 7: Removing the Norditropin Cartridge 15 mg/1.5 mL

You will need to remove the Norditropin cartridge 15 mg/1.5 mL when the cartridge is empty.

Remove the barrel:

- 1 Remove the pen cap.
- 2 Hold the NordiPen 15 with the dosage indicator window at the top.
- 3 Unscrew the barrel from the cartridge holder.



Removing the Norditropin Cartridge 15 mg/1.5 mL

Section 7 (cont.)

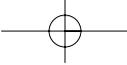
Remove the Norditropin cartridge 15 mg/1.5 mL:

- 4 Tip the cartridge holder until the Norditropin cartridge 15 mg/1.5 mL drops out.
- 5 Press the push button all the way in until zero (0.0) appears in the window.
- 6 Turn the end of the reset mechanism in a clockwise direction until the piston rod is no longer sticking out (refer to figure on page 6).
- 7 To insert a new Norditropin cartridge 15 mg/1.5 mL please refer to section 2.

Need Help?
Call 1-888-NOVO-444

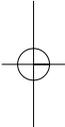
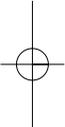
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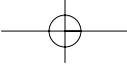




Storage

Guidelines for storing the NordiPen 15 and Norditropin cartridges 15 mg/1.5 mL:

- Keep the NordiPen 15 (with the Norditropin cartridge 15 mg/1.5 mL inside) refrigerated (2-8°C/36-46°F). Do not freeze. Norditropin **MUST NOT BE INJECTED** if the solution is cloudy or contains particulate matter. Use it only if it is clear and colorless.
 - Store the NordiPen 15 **without** the NovoFine disposable needle attached and **with** the pen cap in position.
 - For information on storing Norditropin cartridges 15 mg/1.5 mL, see the leaflet that comes in the Norditropin cartridge 15 mg/1.5 mL box.
- 
- 



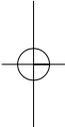
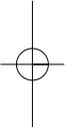
Maintenance

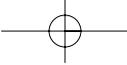
Guidelines for maintaining the NordiPen 15.

Be sure to:

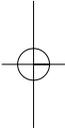
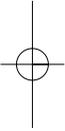
- 1 Clean the NordiPen 15 by wiping with a soft cloth moistened with a mild detergent.
- 2 Protect the NordiPen 15 from dust, dirt, and moisture when not in its case.

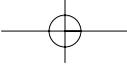
Make certain you:

- 1 **Do not** soak the NordiPen 15 in alcohol, wash it in soap and water, or lubricate it, since this may cause damage.
 - 2 **Do not** expose the NordiPen 15 to excessive pressure or blows.
 - 3 **Do not** drop the NordiPen 15.
- 
- 



Important Things to Know

- Norditropin cartridges must be used with their corresponding color-coded NordiPen delivery system. Cartridges must not be inserted into pens with a different color code.
 - The NordiPen 15 is not recommended for people who are blind or who have trouble seeing unless they have the help of a sighted individual trained to use the NordiPen 15.
 - Use only a new Norditropin cartridge 15 mg/1.5 mL when loading the NordiPen 15. Never load the NordiPen 15 with a partially filled Norditropin cartridge 15 mg/1.5 mL.
 - Keep the NordiPen 15, Norditropin cartridges 15 mg/1.5 mL, and NovoFine disposable needles out of the reach of children.
 - Keep the NordiPen 15 refrigerated (2-8°C/36-46°F). Do not freeze.
 - The NordiPen 15 is designed for use with Norditropin cartridges 15 mg/1.5 mL and NovoFine disposable needles. Novo Nordisk is not responsible for any consequences arising from the use of the NordiPen 15 with products that are not recommended by Novo Nordisk.
- 
- 



Important Notes

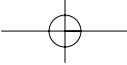
The following is a review of some important information about the use and care of your NordiPen 15.

Before each injection, be certain:

- 
- 1 The NordiPen 15 contains the correct cartridge. The color of the threaded plastic cap and the label band of the cartridge should match the green color of the NordiPen 15 cartridge holder.
 - 2 To always do the air shot with the NovoFine disposable needle pointing upward.

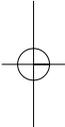
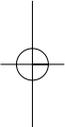
Be sure to:

- 
- 1 Check the dosage indicator window after each injection to make sure you have received your full dose.
 - 2 Remove the NovoFine disposable needle immediately after each injection.
 - 3 Select your dose only by using the number in the dosage indicator window.



Important Notes (cont.)

Make certain you:

- 1 Do not** place a NovoFine disposable needle on the NordiPen 15 until you are ready to do an air shot and give an injection.
Remove the needle immediately after each injection.
If the NovoFine disposable needle is not removed, some liquid may leak out of the Norditropin cartridge 15 mg/1.5 mL.
 - 2 Do not** use the clicking sound to set your dose.
 - 3 Do not** try to refill a Norditropin cartridge 15 mg/1.5 mL.
 - 4 Do not** use the same Norditropin cartridge 15 mg/1.5 mL for more than one person, even though you attach a new NovoFine disposable needle for each injection. This will prevent the spread of disease. Each Norditropin cartridge 15 mg/1.5 mL is for single-person use only.
- 
- 

What to do if...

The dosage indicator window does not show zero after the injection:

- 1 You did not receive your full dose.**
Follow the steps on page 19 to get the remaining part of your dose.

No somatropin appears when you do the air shot:

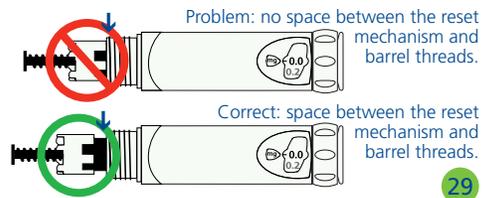
- 1 The piston rod is not far enough down the cartridge holder to reach the rear rubber stopper.**
Repeat the air shot (pp. 12-15).
- 2 The NovoFine disposable needle may not be securely attached.**
 - Put the plastic outer cap back on the NovoFine disposable needle.
 - Turn the plastic outer cap in a clockwise direction to tighten the NovoFine disposable needle.
- 3 The NovoFine disposable needle may be blocked.**
Change the NovoFine disposable needle (pp. 10-11) and continue the air shot (pp. 12-15).

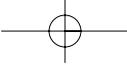
The piston rod is sticking out too far to attach the cartridge holder to the barrel:

- 1 You must screw the piston rod back into the barrel. Never try to push it in or you can damage the mechanism.**

The push button will not return to zero or the piston rod will not turn back into the reset mechanism:

- 1 The reset mechanism may be locked in the position shown in the upper of the diagrams below. This is usually due to improper technique. Gently turn the reset mechanism side to side until it unlocks as shown in the bottom diagram, then call our toll free number (1-888-NOVO-444) so that we may review your operating technique with you.**



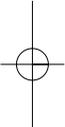
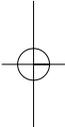


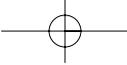
Warranty

Should your NordiPen 15 be defective in materials or workmanship within two (2) years of use, Novo Nordisk Inc. will replace it at no charge if you mail the defective unit, postage prepaid to:

**Novo Nordisk Inc.
Product Safety
100 College Road West
Princeton, NJ 08540**

**Licensed under U.S. Patent No. 5,626,566.
Designed and intended for use with Norditropin
cartridges and NovoFine disposable needles.**

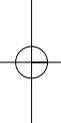
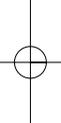


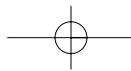
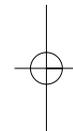
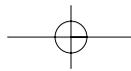


Warranty (cont.)

No other warranty is made with respect to NordiPen 15.

This 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 NordiPen 15 with products other than Norditropin cartridges 15 mg/1.5 mL and NovoFine disposable needles.
 - The use of the NordiPen 15 not in accordance with the instructions in this booklet.
 - Physical damage to the NordiPen 15 caused by neglect, misuse, unauthorized repair, accident, or other breakage.



CE
0088

For assistance or further information, write to:
Novo Nordisk Inc.
Drug Information
100 College Road West
Princeton, NJ 08540
Visit www.norditropin-us.com
or call: 1-888-NOVO-444

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Princeton, NJ 08540

8-4228-31-002-4

NORDI
penmate[®]

Auto-insertion accessory for
NordiPen[®] somatropin
delivery system
Instruction manual



Introduction

Dear NordiPenMate® User:

The NordiPenMate® is an auto-insertion accessory designed to be used with the NordiPen® delivery system. The NordiPenMate helps you to insert the needle and to give injections quickly and easily.

This booklet includes everything you need to know about using the NordiPenMate. Read it carefully before using your NordiPenMate for the first time.

The NordiPenMate is designed for use with:

- NordiPen delivery system
- Norditropin® cartridges (somatropin [rDNA origin] injection)
- NovoFine® disposable needles

Customer service and satisfaction are our top concern. If you have any questions about your NordiPenMate or your NordiPen somatropin delivery system, please call Novo Nordisk Inc. at 1-888-NOVO-444.

Thank you for choosing the NordiPenMate.

(See **Important Things to Know** and **Important Notes** on pages 24-25)

Open this flap for a drawing of the NordiPenMate and NordiPen.



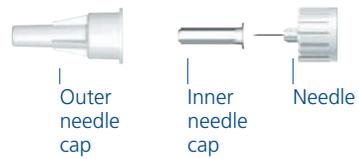
NordiPenMate®



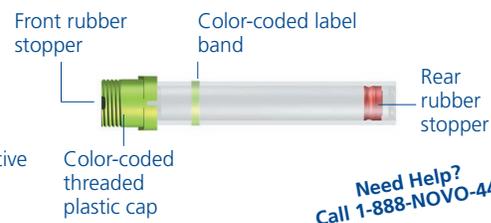
Barrel (NordiPen®)



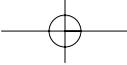
NovoFine® Disposable Needle



Norditropin® Cartridge*

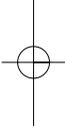


**Need Help?
Call 1-888-NOVO-444**



NordiPenMate®

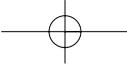
Novo Nordisk

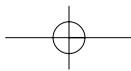
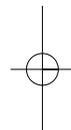
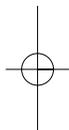
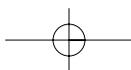


***To be sure you get the right dose, the color of the delivery system must match the color of the carton, label band and threaded plastic cap of the Norditropin cartridge. For example, for the 15 mg/1.5 mL cartridge, the color of the NordiPen 15 delivery system and these items is green. If your doctor prescribes Norditropin cartridges 5 mg/1.5 mL or 10 mg/1.5 mL you will need to use an orange NordiPen 5 (for an orange 5 mg/1.5 mL cartridge) or a blue NordiPen 10 (for a blue 10 mg/1.5 mL cartridge).**

Norditropin cartridges, NordiPen delivery systems and NovoFine® disposable needles are designed to be used with NordiPenMate.

Norditropin®, NordiPen®, NordiPenMate® and NovoFine® are trademarks owned by Novo Nordisk A/S.



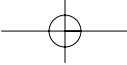


Welcome to Your NordiPenMate
Auto-insertion accessory for
NordiPen somatropin
delivery system



Norditropin cartridges must be used
with their similar color NordiPen
delivery system.

Cartridges must not be inserted into
pens with a different color.



How to use this booklet

This booklet gives you step-by-step instruction for using the NordiPenMate in combination with the NordiPen. A NordiPen 15 delivery system is used to show the correct use of the NordiPenMate. The NordiPen delivery system is also available for 5 mg cartridges (orange) and 10 mg cartridges (blue).

Begin by reviewing the photo of the parts of the NordiPenMate, NordiPen, Norditropin cartridge and NovoFine disposable needle. The inside front cover opens out so you have a handy reference while you read the rest of the booklet.

Most pages contain a photo with numbered instructions. **Important additional information is given below the instructions.**

Read the text carefully and look at the photos to make sure that you understand each step well.

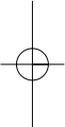
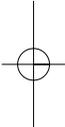


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Section 1: Assembling Your NordiPenMate



Remove the pen cap:

- 1 Remove the NordiPen from the case.
- 2 Gently twist the pen cap until the cap separates from the cartridge holder.
- 3 Pull the pen cap straight up to remove it.

Need Help?
Call 1-888-NOVO-444

Assembling Your NordiPenMate

Section 1 (cont.)



Separate the cartridge holder from the barrel:

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

Note: You will not use the cap and cartridge holder with NordiPenMate, but you should store them in case you need to use NordiPen without NordiPenMate in the future.



Make sure the dosage indicator window shows zero:

- 5 Press the push button all the way in until zero (0.00 or 0.0) appears in the window. The zero should be lined up with the "mg" marker next to the dosage indicator window.

Assembling Your NordiPenMate

Section 1 (cont.)

The end of the piston rod should be flat against the end of the reset mechanism before you insert each new Norditropin cartridge. The piston rod should not stick out.



If the piston rod sticks out:

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

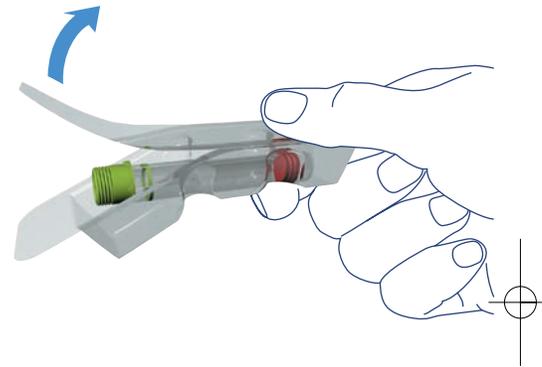
Need Help?
Call 1-888-NOVO-444

Never reset the piston rod until it is time to remove the used Norditropin cartridge and insert a new one.

If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks. Then call our toll free number (1-888-NOVO-444) so that we may review your operating technique with you.

Section 2: Inserting the Norditropin Cartridge

- 1 To remove the Norditropin cartridge from its wrapper, peel the plastic tab away from the packaging. Before use, check that the Norditropin cartridge is full and intact. If not, do not use it.



Make sure you are using the correct cartridge. The color of the threaded plastic cap and the label band of the cartridge should match the color of the NordiPen dosage selector.

Each Norditropin cartridge is for single-person use only. DO NOT use the same cartridge for more than one person, even though you attach a new disposable needle for each injection. This will prevent the spread of disease.

Use only a new Norditropin cartridge when loading the NordiPenMate.

Never load a partially filled cartridge.

Never try to refill a used Norditropin cartridge.

Inserting the Norditropin Cartridge

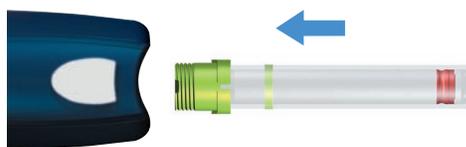
Section 2 (cont.)

Take your NordiPenMate out of its carton. Pull off the pen cap and put it to one side.

- 2 Insert the cartridge into NordiPenMate, threaded plastic cap first.
- 3 Screw the barrel of NordiPen and NordiPenMate tightly together.
- 4 Wipe the front rubber stopper on the threaded plastic cap of the cartridge with an alcohol swab.

Note:

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



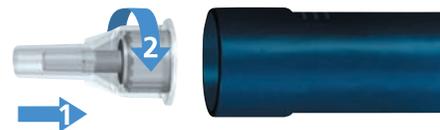
Inserting the Norditropin Cartridge

Section 2 (cont.)

- 5 Take the protective tab off a NovoFine disposable needle. Screw the needle tightly onto the threaded cap of the cartridge. Pull off the outer and inner needle caps. Put the outer needle cap aside for use later.

Note:

Never place a NovoFine disposable needle on your NordiPenMate until you are ready to do an air shot and give an injection. If the NovoFine disposable needle is "left on" the NordiPenMate, some liquid may leak out of the Norditropin cartridge.



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Call 1-888-NOVO-444

Section 3: Doing an Air Shot

To prevent the injection of air and make certain somatropin is delivered, **you must do an air shot before each injection.**

Before starting the air shot procedure, the dosage indicator window must show zero (0.00 or 0.0).

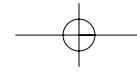
1 Set the NordiPenMate for the air shot:

Turn the dosage selector to 0.05 mg when using a NordiPen 5 or 0.1 mg when using a NordiPen 10 and NordiPen 15.

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Call 1-888-NOVO-444

If you dial more than 0.05 mg when using a NordiPen 5 or 0.1 mg when using a NordiPen 10 and NordiPen 15, DO NOT turn the dial back to zero (0.00 or 0.0). If you do, the extra somatropin will squirt out of the needle. You may complete the air shot with the number of mg you have dialed or refer to page 14 for instructions on how to reset the dose to zero.





Doing an Air Shot

Section 3 (cont.)

- 2 Hold the NordiPenMate with the NovoFine disposable needle pointing upward.
- 3 Tap the NordiPenMate with your finger a few times to raise any air bubbles that may be present to the top of the cartridge.



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Doing an Air Shot

Section 3 (cont.)

Do the air shot:

- 4 Press the push button all the way in.
Somatropin should appear at the needle tip.

If no somatropin appears, repeat the following steps, until the somatropin appears:

- a. Make sure the NovoFine disposable needle is securely attached.
- b. Dial 0.05 mg when using a NordiPen 5 or 0.1 mg when using a NordiPen 10 and NordiPen 15.
- c. Tap the NordiPenMate with your finger.
- d. Press the push button all the way in.
There still may be an air bubble in the Norditropin cartridge after this step but it will not be injected.

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Call 1-888-NOVO-444

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

Section 4: Giving the Injection

- 1 To activate NordiPenMate, grip the barrel and NordiPenMate firmly and pull in opposite directions until you hear a click.

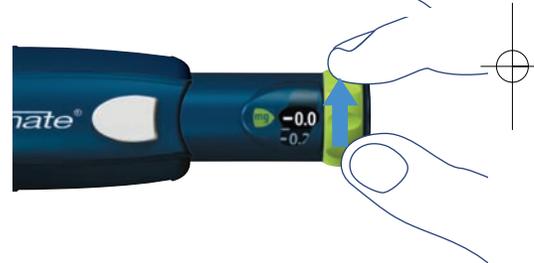
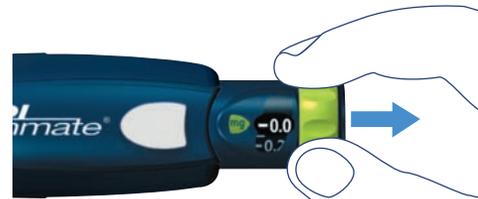
Important:

Do not pull the dosage selector.

- 2 Check that the dosage selector is set to zero. If not, reset the dosage selector (see page 14). Dial the number of mg you need to inject.

Do not use the clicking sounds as a guide for selecting dose.

If you dial more than your dose, DO NOT turn the dial back to zero (0.00 or 0.0). See page 14 for instructions.



Need Help?
Call 1-888-NOVO-444



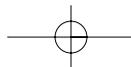
Giving the Injection

Section 4 (cont.)

To reset to zero (0.00 or 0.0) if you set the wrong dose:

- Hold the NordiPenMate with your thumb and forefinger.
- Hold the barrel between your thumb and middle finger.
- Pull the NordiPenMate away from the barrel as far as it will go (arrow #1).
- Press the push button against a hard surface as shown to reset the dose to zero (0.00 or 0.0).
- Release your grip and the NordiPenMate will slide back into place.
- Check the dosage indicator window to make sure you have reset it all the way to zero (0.00 or 0.0). If you have not, repeat steps a through f.

Need Help?
Call 1-888-NOVO-444

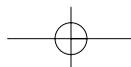
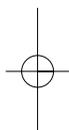


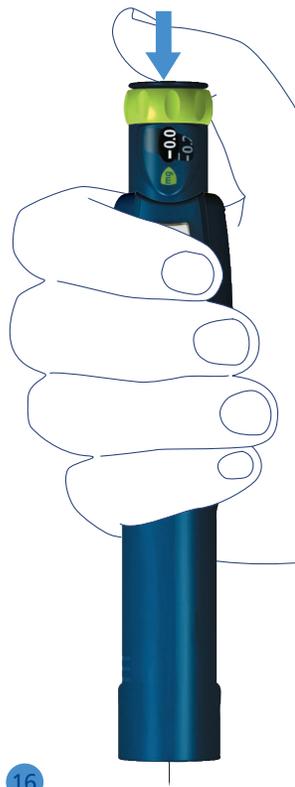
Giving the Injection

Section 4 (cont.)

Give the injection:

- 3 Hold NordiPenMate against your skin. Press the gray insertion button with your finger. The needle will automatically enter your skin (Use the injection technique recommended by your health care professional).





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Giving the Injection

Section 4 (cont.)

- 4 Press the push button **as far as it will go** to deliver the somatropin. Do not force it. To ensure that all of the somatropin is injected keep the NovoFine disposable needle in the skin for at least 6 seconds after injection with your thumb on the push button. Keep the push button fully pushed in until after the NovoFine disposable needle has been removed from the skin.

Giving the Injection

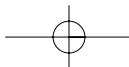
Section 4 (cont.)

- 5 After the injection make sure that NordiPenMate has released and that the somatropin has been injected. Check that the blue insertion control bar is completely hidden (as in picture 1).
- 6 **Check the dosage indicator window to make sure it shows zero (0.00 or 0.0). If zero does not appear, you did not receive the full dose. See the instructions on the next page.**

*Need Help?
Call 1-888-NOVO-444*

When you get near the end of a Norditropin cartridge, you may need to give yourself two injections to receive your full dose. If, after giving an injection, zero does not appear in the dosage indicator window, you did not receive your full dose. See the next page for instructions on how to get the remaining part of your dose.





Giving the Injection

Section 4 (cont.)

If the dosage indicator window does not show zero, there were not enough mg of somatropin in the Norditropin cartridge for you to receive the full dose. The dosage indicator window shows the number of mg that you did not receive. For example, if you dial 0.6 mg and there are only 0.4 mg left in the Norditropin cartridge, after the injection the number in the dosage indicator window will be 0.2 mg ($0.6 - 0.4 = 0.2$).

To get the remaining part of your dose:

- Note the number of mg in the dosage indicator window.
- Remove the NovoFine disposable needle from the NordiPenMate (see Section 5).
- Remove the empty Norditropin cartridge (see Section 6).
- Insert a new Norditropin cartridge (see Section 2).
- Attach a new NovoFine disposable needle (see Section 2, page 9).
- Do an air shot (see Section 3).
- Dial the number of mg noted in step a.
- Give the injection.

Need Help?
Call 1-888-NOVO-444

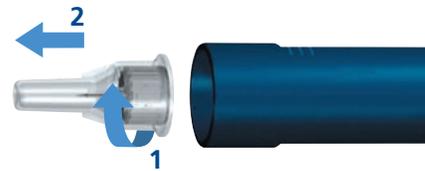
Section 5: Removing the NovoFine Disposable Needle

Remove the NovoFine disposable needle:

- 1 Carefully replace the outer needle cap.
- 2 Follow the instructions you received for removal and disposal of needles to prevent the risk of needle injury.
Hold the NordiPenMate firmly while you unscrew the NovoFine disposable needle.
- 3 Place the NovoFine disposable needle in a puncture-resistant disposal container. Used 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.
- 4 Replace the NordiPenMate cap.

The NovoFine disposable needle must be removed immediately after each injection. If the NovoFine disposable needle is not removed, some liquid may leak out of the Norditropin cartridge.

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



Section 6: Removing the Norditropin Cartridge

You will need to remove the Norditropin cartridge when the cartridge is empty.

Remove the barrel:

- 1 Remove the NordiPenMate cap.
- 2 Unscrew the barrel from the NordiPenMate.



Removing the Norditropin Cartridge

Section 6 (cont.)

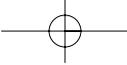
Remove the Norditropin cartridge:

- 3 Tip the NordiPenMate until the Norditropin cartridge drops out.
- 4 Press the push button all the way in until zero (0.00 or 0.0) appears in the dosage indicator window.
- 5 Turn the end of the reset mechanism in a clockwise direction until the piston rod is no longer sticking out (refer to figure on page 6).
- 6 To insert a new Norditropin cartridge please refer to section 2.

Need Help?
Call 1-888-NOVO-444

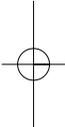
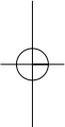
If the reset mechanism locks, it is usually due to improper technique. Gently turn the mechanism side to side until it unlocks and then call our toll free number (1-888-NOVO-444) so that we may review your operating technique with you.

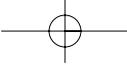




Storage

Guidelines for storing the NordiPenMate, NordiPen and Norditropin cartridges:

- When using a NordiPenMate with a NordiPen 5 or a NordiPen 10 (with the correct Norditropin cartridge inside) **EITHER** keep refrigerated (2-8°C/36-46°F) for 4 weeks **OR** store not above 25°C (77°F) for 3 weeks.
When using a NordiPenMate with a NordiPen 15 (with the correct Norditropin cartridge inside) keep refrigerated (2-8°C/36-46°F) for 4 weeks.
Do not freeze. Norditropin **MUST NOT BE INJECTED** if the solution is cloudy or contains particulate matter. Use it only if it is clear and colorless.
 - Store the NordiPenMate and NordiPen **without** the NovoFine disposable needle attached and **with** the NordiPenMate cap in position.
 - For information on storing Norditropin cartridges, see the leaflet that comes in the Norditropin cartridge box.
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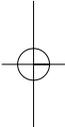


Maintenance

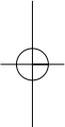
Guidelines for maintaining the NordiPenMate and NordiPen:

Be sure to:

- 1 Clean the NordiPenMate and NordiPen by wiping with a soft cloth moistened with a mild detergent.
- 2 Protect the NordiPenMate and NordiPen from dust, dirt, and moisture when not in its case.



Make certain that you:

- 1 **Do not** soak the NordiPenMate and/or NordiPen in alcohol, wash it in soap and water, or lubricate it, since this may cause damage.
 - 2 **Do not** expose the NordiPenMate and/or NordiPen to excessive pressure or blows.
 - 3 **Do not** drop the NordiPenMate and/or NordiPen.
- 

Important Things to Know

- Always screw the barrel of NordiPen and NordiPenMate tightly together.
- Norditropin cartridges must be used with their corresponding color-coded NordiPen delivery system.
Cartridges must not be inserted into pens with a different color code.
- The NordiPenMate and NordiPen are not recommended for people who are blind or who have trouble seeing unless they have a sighted individual trained to use the NordiPenMate and NordiPen.
- Use only a new Norditropin cartridge when loading the NordiPenMate and NordiPen.
Never load the NordiPenMate and NordiPen with a partially filled Norditropin cartridge.
- Keep the NordiPenMate, NordiPen, Norditropin cartridges and NovoFine disposable needles out of reach of children.
- When using a NordiPenMate with a NordiPen 5 or a NordiPen 10 **EITHER** keep refrigerated (2-8°C/36-46°F) for 4 weeks **OR** store not above 25°C (77°F) for 3 weeks.
When using a NordiPenMate with a NordiPen 15 keep refrigerated (2-8°C/36-46°F) for 4 weeks.
Do not freeze.
- The NordiPenMate and NordiPen are designed for use with Norditropin cartridges and NovoFine disposable needles.
Novo Nordisk is not responsible for any consequences arising from the use of the NordiPenMate and NordiPen with products that are not recommended by Novo Nordisk.

Important Notes

The following is a review of some important information about the use and care of your NordiPenMate and NordiPen.

Before each injection, be certain:

- 1 The NordiPenMate and NordiPen delivery system contain the correct cartridge. The color of the threaded plastic cap and the label band of the cartridge should match the color of the dosage selector.
- 2 To always do the air shot with the NovoFine disposable needle pointing upward.

Be sure to:

- 1 Check the dosage indicator window and blue insertion control bar after each injection to make sure you have received your full dose.
- 2 Remove the NovoFine disposable needle immediately after each injection.
- 3 Select your dose only by using the number in the dosage indicator window.

Make certain you:

- 1 **Do not** place a NovoFine disposable needle on the NordiPenMate or NordiPen until you are ready to do an air shot and give an injection. Remove the needle immediately after each injection. If the NovoFine disposable needle is not removed, some liquid may leak out of the Norditropin cartridge.
- 2 **Do not** use the clicking sound to set your dose.
- 3 **Do not** try to refill a Norditropin cartridge.
- 4 **Do not** use the same Norditropin cartridge for more than one person, even if you attach a new NovoFine disposable needle for each injection. This will prevent the spread of disease. Each Norditropin cartridge is for single-person use only.

What to do if...

The dosage indicator window does not show zero after the injection:

- 1 You did not receive your full dose.**
Follow the steps on page 18 to get the remaining part of your dose.

No somatropin appears when you do the air shot:

- 1 The piston rod is not far enough down the NordiPenMate to reach the rear rubber stopper.**
Repeat the air shot (pp. 10-12).
- 2 The NovoFine disposable needle may not be securely attached.**
 - Put the plastic outer cap back on the NovoFine disposable needle.
 - Turn the plastic outer cap in a clockwise direction to tighten the NovoFine disposable needle.

- 3 The NovoFine disposable needle may be blocked.**

Change the NovoFine disposable needle (p. 19 for removal, then p. 9 to replace the needle) and continue the air shot (pp. 10-12).

You think the needle has not entered the skin.

- 1 Check the blue insertion control bar is completely hidden.**
- 2 Check NordiPenMate for damage (that it is not broken or cracked) and that it works normally.**
- 3 Check that the needle is not bent.**

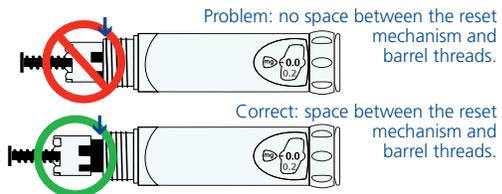
What to do if... (cont.)

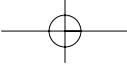
The piston rod is sticking out too far to attach the NordiPenMate to the barrel:

- 1 You must screw the piston rod back into the barrel (p. 6). Never try to push it in or you can damage the mechanism.

The push button will not return to zero or the piston rod will not turn back into the reset mechanism:

- 1 The reset mechanism may be locked in the position shown in the upper of the diagrams below. This is usually due to improper technique. Gently turn the reset mechanism side to side until it unlocks as shown in the bottom diagram, then call our toll free number (1-888-NOVO-444) so that we may review your operating technique with you.



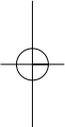
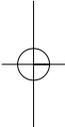


Warranty

Should your NordiPenMate be defective in materials or workmanship within two (2) years of use, Novo Nordisk Inc. will replace it at no charge if you mail the defective unit, postage prepaid to:

Novo Nordisk Inc.
Product Safety
100 College Road West
Princeton, NJ 08540

Licensed under US Patent 5,980,491. Designed and intended for use with NordiPen delivery systems, Norditropin cartridges and NovoFine disposable needles.



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For assistance or further information, write to:
Novo Nordisk Inc.
Drug Information
100 College Road West
Princeton, NJ 08540
Visit www.norditropin-us.com
or call: 1-888-NOVO-444

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