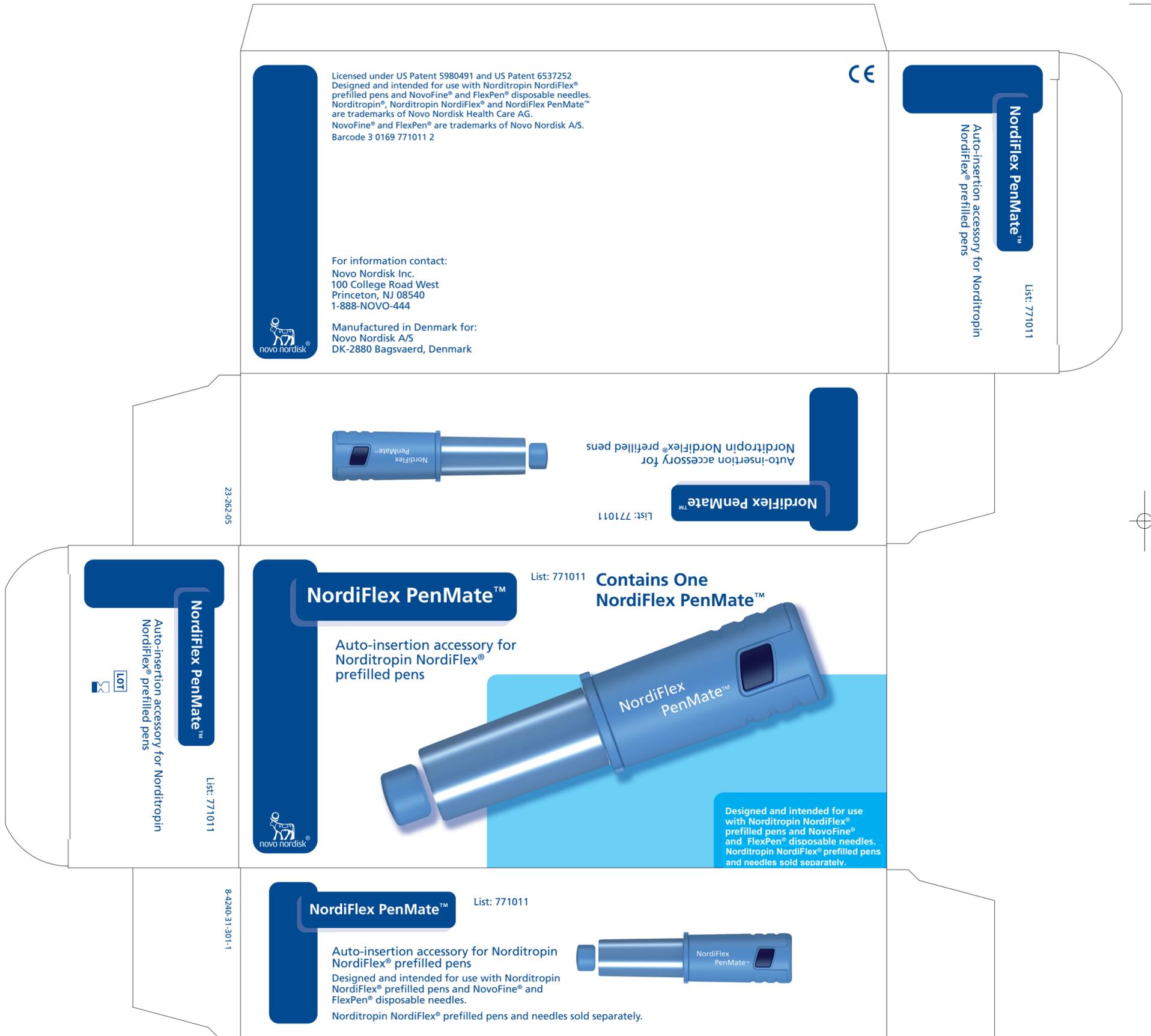


RA
Labelling & Graphics
Carton: 23-262-05-313-dev
Current: 2.0

Lacquer free area:
Lacquerform: 30016-1-dev

Colour:
PMS 280C + CMYK



RA
Labelling & Graphics

Insert size: 148,5x115-003-dev
Current 2.0

Colour:
PMS 280C + CMYK

◀ Making your NordiFlex PenMate personal



For assistance or further information, write to:

Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540
Visit www.norditropin-us.com
or call: 1-888-NOVO-444

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NordiFlex PenMate™ are trademarks of
Novo Nordisk Health Care AG.

NovoFine® and FlexPen® are trademarks of
Novo Nordisk A/S

Date of Issue
Version 1

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Novo Nordisk Inc.
Princeton, NJ 08540

8-4240-31-001-1

NordiFlex PenMate™

Auto-insertion accessory for Norditropin
NordiFlex® prefilled pen

User Manual

Please read this manual carefully before
using NordiFlex PenMate™



Introduction

Dear NordiFlex PenMate™ User:

The NordiFlex PenMate™ is an auto-insertion accessory designed to be used with Norditropin NordiFlex® prefilled pens. NordiFlex PenMate helps you to insert the needle and to give injections easily and conveniently.



This manual includes everything you need to know about using NordiFlex PenMate. Read it carefully before using NordiFlex PenMate for the first time.

NordiFlex PenMate is designed for use with:

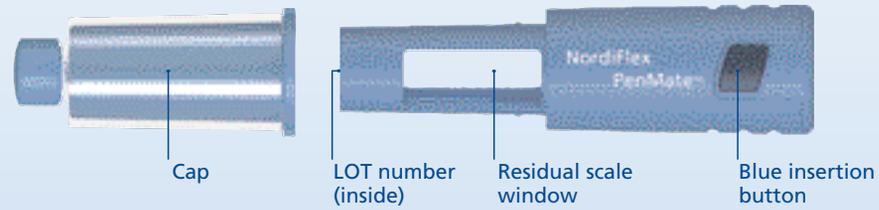
- Norditropin NordiFlex® (somatropin [rDNA origin] injection) prefilled pens
- NovoFine® and FlexPen® disposable needles

Customer service and satisfaction are our top concern. If you have any questions about NordiFlex PenMate or Norditropin NordiFlex prefilled pens please call **Novo Nordisk Inc. at 1-888-NOVO-444.** Thank you for choosing NordiFlex PenMate.

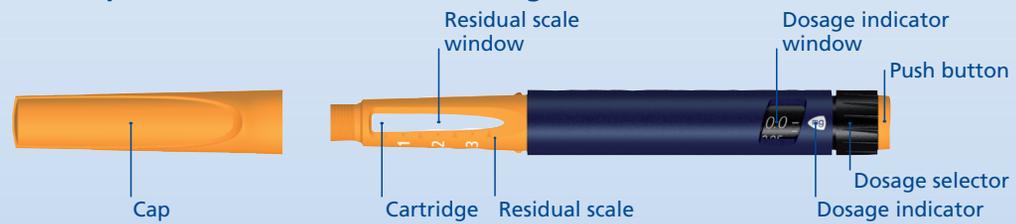
(See Important Things to Know and Important Notes on pages 19-20)

Open this flap for a drawing of NordiFlex PenMate and Norditropin NordiFlex.

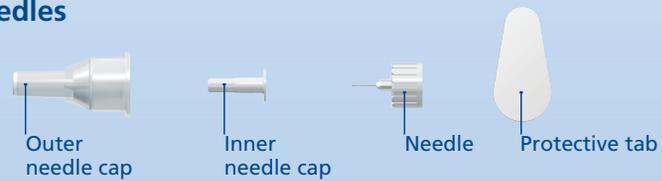
NordiFlex PenMate™



Norditropin NordiFlex Prefilled Pen 5 mg/1.5 mL



NovoFine® disposable needles



NordiFlex PenMate™ is designed for use with NovoFine® and FlexPen® disposable needles and Norditropin NordiFlex® prefilled pens.

Norditropin®, Norditropin NordiFlex® and NordiFlex PenMate™ are trademarks of Novo Nordisk Health Care AG. NovoFine® and FlexPen® are trademarks of Novo Nordisk A/S.



How to use this manual

This manual gives you step-by-step instructions for using NordiFlex PenMate in combination with Norditropin NordiFlex. A Norditropin NordiFlex 5 mg/1.5 mL prefilled pen (orange) is used to show the correct use of NordiFlex PenMate. Norditropin NordiFlex is also available as a 10 mg/1.5 mL prefilled pen (blue) and 15 mg/1.5 mL prefilled pen (green).

Begin by reviewing the drawings of the parts of NordiFlex PenMate, Norditropin NordiFlex prefilled pen and NovoFine disposable needle. The inside front cover opens out so you have a handy reference while you read the rest of the manual.

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

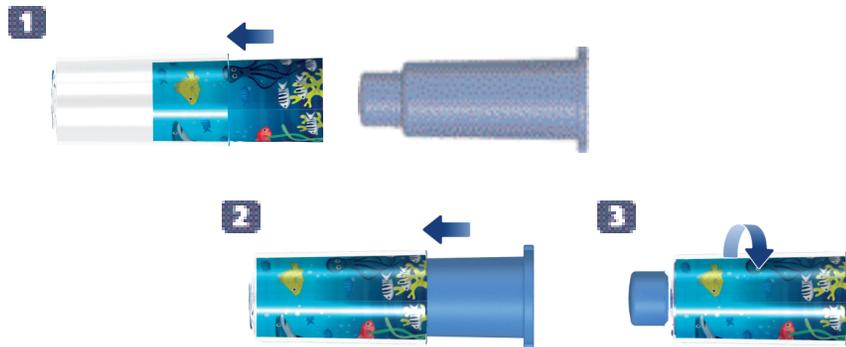
Read the text carefully and look at the drawings to make sure that you understand each step well.

Making NordiFlex PenMate™ Personal

Making the NordiFlex PenMate™ Personal

Between the outer cap and the inner cap you can place a drawing or picture to give your NordiFlex PenMate a personal look.

You can cut out the illustration placed on the page to the right, create the drawing yourself or find illustrations on www.norditropin-us.com to print out.



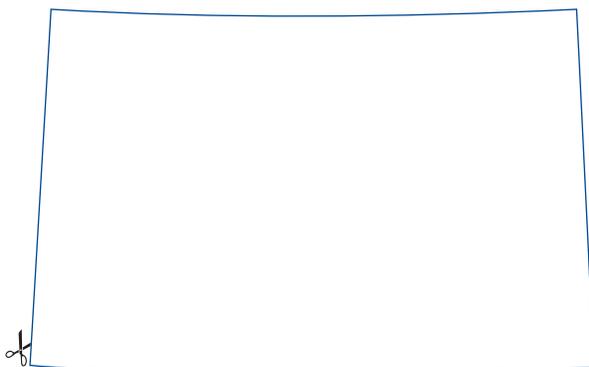




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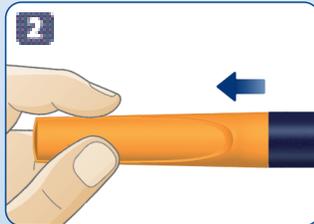
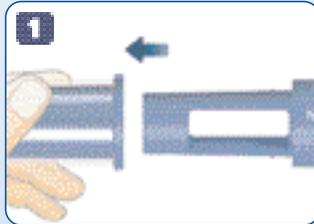
Section 1:	Assembling NordiFlex PenMate
Section 2:	Performing an Air Shot
Section 3:	Preparing NordiFlex PenMate for Injection
Section 4:	Giving the Injection
Section 5:	Removing the NovoFine Disposable Needle
Section 6:	Replacing an Empty Norditropin NordiFlex
	Storage
	Maintenance
	Important Things to Know
	Important Notes
	What to do if...
	Warranty
	Making NordiFlex PenMate personal

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4 Section 1: Assembling NordiFlex PenMate



1 Remove the NordiFlex PenMate cap.

2 A. Pull off the cap of Norditropin NordiFlex. You will not need it with NordiFlex PenMate. **DO NOT** use Norditropin NordiFlex if the liquid is cloudy or contains particles. Use it only if it is clear and colorless. Check this by turning Norditropin NordiFlex upside down once or twice and view the liquid through the residual scale window.

B. Wash hands well then wipe the front rubber stopper on the threaded plastic cap with an alcohol swab.

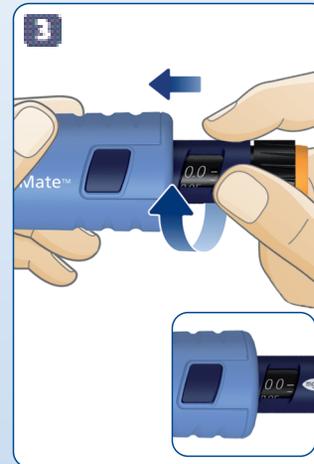
Note:

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

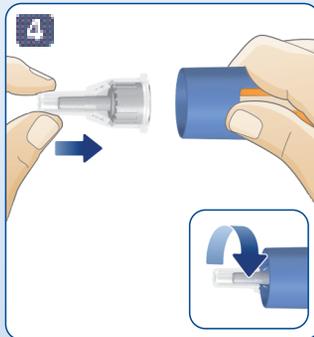
Section 1 (cont.): Assembling NordiFlex PenMate

5

- 3 Grasp the body of Norditropin NordiFlex and insert Norditropin NordiFlex into NordiFlex PenMate and turn Norditropin NordiFlex clockwise until you feel a "click", the dose indicator window should be set at "0.0" after assembly. **The dosage indicator window on Norditropin NordiFlex must align with the insertion button on NordiFlex PenMate.**



6 Section 1 (cont.): Assembling NordiFlex PenMate



Place a new NovoFine disposable needle onto Norditropin NordiFlex immediately before use.

- 4 Remove the protective tab off the needle and screw the needle tightly onto Norditropin NordiFlex prefilled pen.

Note:

- Never place a NovoFine disposable needle on Norditropin NordiFlex until you are ready to give an injection. If the NovoFine disposable needle is "left on" Norditropin NordiFlex, some liquid may leak out.
- NovoFine needles have an inner and outer cap that must be removed prior to injection.



Note:

Always use a new NovoFine disposable needle for each injection.

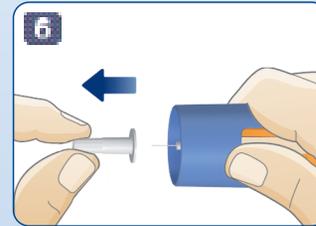
Section 1 (cont.): Assembling NordiFlex PenMate

7

5 Pull off the outer needle cap and keep it within reach.



6 Carefully remove the inner needle cap and dispose of it properly.



 **Note:**
To minimize the risks of unintended needle stick injuries never replace the inner needle cap once it has been removed.

8 Section 2: Performing an Air Shot



Small amounts of air may collect in the needle and cartridge. To ensure proper dosing and to avoid injecting air, perform an air shot before administering your first injection with a new Norditropin NordiFlex.

- 1 Turn the dosage selector to the first line after 0.0.

Each line between labeled dosages is 0.025 mg for a Norditropin NordiFlex 5 mg/1.5 mL, 0.05 mg for a Norditropin NordiFlex 10 mg/1.5 mL and 0.075 mg for a Norditropin NordiFlex 15 mg/1.5 mL.

- 2 Hold NordiFlex PenMate with the NovoFine disposable needle pointing upwards and tap NordiFlex PenMate gently with your finger a few times to make any air bubbles rise to the top of the cartridge.

Section 2 (cont.): Performing an Air Shot

9

- 3 Still holding NordiFlex PenMate with the needle up, press the push button all the way in. A drop of liquid should appear at the needle tip. If not, repeat steps 1-3 until a drop of liquid appears at the needle tip. Repeat the procedure, no more than 6 times.

Always perform an air shot before your next injection if Norditropin NordiFlex or NordiFlex PenMate has been dropped or knocked against hard surfaces.

If a drop of liquid still does not appear or if you have any questions, call 1-888-NOVO-444 for help.



10 Section 3: Preparing NordiFlex PenMate for Injection



Preparing NordiFlex PenMate:

- 1 To prepare NordiFlex PenMate, grip both NordiFlex PenMate and Norditropin NordiFlex firmly and pull in opposite directions until you hear a click.

Now the needle is hidden in NordiFlex PenMate.

Section 4: Giving the Injection

11

Setting the Dose

Check that the dosage indicator on Norditropin NordiFlex is set at 0.0.

- 1** Select the number of milligrams you need to inject.
The dose can be corrected up or down by turning the dosage selector in either direction. When turning the dosage selector backwards, be careful not to press the push button as liquid will come out. **DO NOT use the clicking sound as a guide for selecting the dose.**
The numbers on the residual scale can be used to estimate the amount left in the cartridge. **DO NOT use these numbers to measure the dose.**

You cannot select a dose larger than the number of milligrams left in the cartridge. Use a new Norditropin NordiFlex pen to inject the remaining amount of your dose. Be sure to remember the dose already received with the first dose. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.4 mg. You will need to inject an additional 0.2 mg with a new Norditropin NordiFlex pen. See page 14 for detailed instructions.



12 Section 4 (cont.): Giving the Injection



Giving the Injection

Use the injection technique recommended by your healthcare professional. This product is for subcutaneous injection only.

- 1 Hold NordiFlex PenMate against your skin. Press the blue insertion button with your finger. The needle will automatically enter your skin.

2 Press the push button as far as it will go to deliver the dose. **To ensure that the full dose 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 needle has been removed from the skin. Vary the injection site using the injection procedure recommended by your healthcare professional.

3 After the injection 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. Call 1-888-NOVO-444 for assistance.



Note:

Always **press** the push button to inject the dose. **Turning** the dosage selector will **not** inject the dose.



14 Section 4 (cont.): Giving the Injection

With Norditropin NordiFlex it is not possible to select a dose that is larger than the amount left in the cartridge. If you need more somatropin than the amount left in the cartridge, you must spread your dose over two injections. Follow the steps below:

To get the remaining part of your dose:

- a. Inject the dose left in the cartridge, making a note of the number of milligrams you inject. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.4 mg. You will need to inject an additional 0.2 mg with a new Norditropin NordiFlex pen.
- b. Remove the NovoFine disposable needle from Norditropin NordiFlex (see Section 5).
- c. Remove Norditropin NordiFlex (see Section 6).
- d. Insert a new Norditropin NordiFlex (see Section 1 and 6).
- e. Attach a new NovoFine disposable needle (see Section 1, pages 6 and 7).
- f. Perform an air shot (see Section 2).
- g. Select the number of milligrams still needed to complete your dose.
- h. Give the injection.

Need Help? Call 1-888-NOVO-444

Section 5: Removing the NovoFine Disposable Needle

15

Remove the NovoFine Disposable Needle

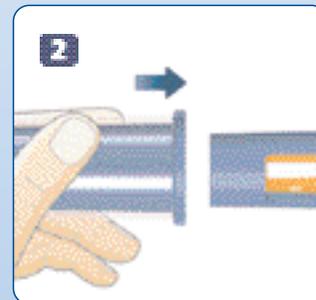
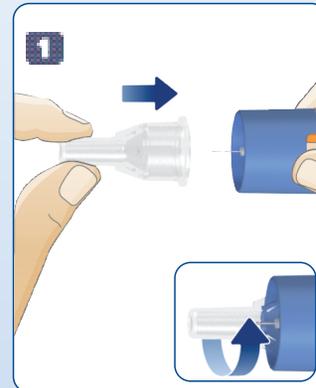
- 1** Carefully replace the **outer** needle cap onto the needle immediately after the injection. Follow the instructions you received for removal and disposal of needles to reduce the risk of needle stick injuries.

Hold the NordiFlex PenMate firmly while you unscrew NovoFine disposable needle. 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.

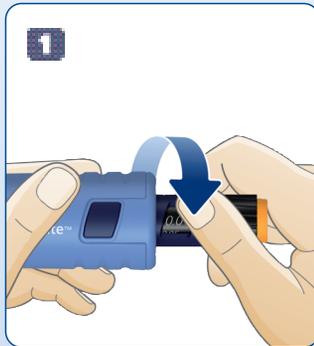
- 2** Replace NordiFlex PenMate cap after use.



Note: 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. It is important that you use a new needle for each injection. **Healthcare professionals, relatives and other caregivers should follow general precautionary measures for removal and disposal of needles to reduce the risk of unintended needle stick injuries.**



16 Section 6: Replacing an Empty Norditropin NordiFlex



You will need to remove the Norditropin NordiFlex prefilled pen when it is empty.

- 1 When Norditropin NordiFlex is empty, turn the Norditropin NordiFlex counterclockwise until you feel a “click” and gently pull it out of NordiFlex PenMate. Dispose of the Norditropin NordiFlex properly without the needle attached.

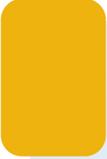
Screw a new Norditropin NordiFlex and the NordiFlex PenMate together as described on pages 4 to 5.

To prepare for a new injection continue as described on pages 6 to 9.

Guidelines for storing the NordiFlex PenMate and Norditropin NordiFlex

- Protect NordiFlex PenMate against water, dust and dirt.
- Always remove the NovoFine disposable needle and replace NordiFlex PenMate cap after use.
- When Norditropin NordiFlex is inserted in NordiFlex PenMate, store NordiFlex PenMate as described in the leaflet in Norditropin NordiFlex pack.
- When using a NordiFlex PenMate with a Norditropin NordiFlex 5 mg/1.5 mL or a Norditropin NordiFlex 10 mg/1.5 mL 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 NordiFlex PenMate with a Norditropin NordiFlex 15 mg/1.5 mL keep refrigerated (2-8°C/36-46°F) for 4 weeks.
- Do not freeze. Norditropin **MUST NOT BE INJECTED** if the liquid is cloudy or contains particles matter. Use it only if it is clear and colorless.
- Keep NordiFlex PenMate and Norditropin NordiFlex in the supplied case whenever possible. Inside the case you can also keep 3 extra NovoFine disposable needles.





18 Maintenance

Guidelines for maintaining the NordiFlex PenMate and Norditropin NordiFlex:

Be sure to:

- Clean the outside surface by wiping it with a soft cloth moistened with a mild detergent.
- Protect the NordiFlex PenMate and Norditropin NordiFlex from dust, dirt, and direct sunlight when not in its case.

Make certain that you:

- Handle the NordiFlex PenMate and Norditropin NordiFlex with care. Do not drop it and avoid knocking it against hard surfaces.
- Do not soak the NordiFlex PenMate and/or Norditropin NordiFlex in alcohol, wash, or lubricate it since this may cause damage.

- Always screw Norditropin NordiFlex and NordiFlex PenMate tightly together.
- NordiFlex PenMate and Norditropin NordiFlex are not recommended for people who are blind or who have trouble seeing unless they have a sighted individual trained to use NordiFlex PenMate and Norditropin NordiFlex.
- If your NordiFlex PenMate becomes lost or damaged, you can still use your Norditropin NordiFlex without NordiFlex PenMate.
- Keep Norditropin NordiFlex, NordiFlex PenMate and NovoFine disposable needles out of the reach of children.
- With Norditropin NordiFlex it is not possible to select a dose larger than the number of mg left in the cartridge.
- When using a NordiFlex PenMate with a Norditropin NordiFlex 5 mg/1.5 mL or a Norditropin NordiFlex 10 mg/1.5 mL 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 NordiFlex PenMate with a Norditropin NordiFlex 15 mg/1.5 mL keep refrigerated (2-8°C/36-46°F) for 4 weeks. Do not freeze.
- NordiFlex PenMate and Norditropin NordiFlex are designed for use with NovoFine and FlexPen disposable needles.
- Novo Nordisk is not responsible for any consequences arising from the use of NordiFlex PenMate and Norditropin NordiFlex with products that are not recommended by Novo Nordisk.

20 Important Notes

The following is a review of some important information about the use and care of your NordiFlex PenMate and Norditropin NordiFlex.

Before using a new Norditropin NordiFlex, be certain to:

- Always perform an air shot with the NovoFine disposable needle pointing upward.

Be sure to:

- Remove the NovoFine disposable needle immediately after each injection.
- Select your dose only by using the number in the dosage indicator window.
- Perform an air shot before injection if you dropped Norditropin NordiFlex or knocked it against a hard surface.

Make certain you:

- Do not place a NovoFine disposable needle on Norditropin NordiFlex until you are ready to do an air shot and/or give an injection. Remove the needle immediately after each injection. If the NovoFine disposable needle is not removed, some liquid may leak out of Norditropin NordiFlex.
- Do not use the clicking sound to set your dose.
- Avoid dropping Norditropin NordiFlex or knocking it against hard surfaces.
- DO NOT leave Norditropin NordiFlex in a car or other location where it can get too hot or too cold.
- Always have a spare Norditropin NordiFlex in order to avoid running out of this product.
- Do not use the same Norditropin NordiFlex 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 NordiFlex is for single-person use only.

Here are the answers to some questions you might ask when using the NordiFlex PenMate.

Question	Answer
No liquid appears at the needle tip when I perform an air shot.	<ul style="list-style-type: none"> • 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 clock-wise direction to tighten the NovoFine disposable needle. <p>The needle may be blocked.</p> <ul style="list-style-type: none"> • Screw on a new NovoFine disposable needle and perform one or more air shots until a drop of liquid appears at the needle tip (see pages 8 to 9). <p>Norditropin NordiFlex may be damaged.</p> <ul style="list-style-type: none"> • Remove the NovoFine disposable needle carefully (see page 15). Unscrew Norditropin NordiFlex and replace it with a new Norditropin NordiFlex (see page 16). Attach a new NovoFine disposable needle, and perform an air shot (see page 8).
I want to change the selected dose before injection.	<ul style="list-style-type: none"> • Turn the dosage selector forwards or backwards until the number of milligrams you need lines up with the dosage indicator.
You think the needle has not entered the skin.	<ul style="list-style-type: none"> • Make sure the needle caps are removed. • Check that the needle is not bent. • Check NordiFlex PenMate for damage (that it is not broken or cracked) and that it works normally.

22 What to do if...

Question

I turn the dosage selector but my Norditropin NordiFlex does not release any liquid.

The push button stops during the injection, before 0.0 lines up with the dosage indicator.

Answer

This is normal.

Always press the push button to inject the dose. Turning the dosage selector will not inject the dose.

The needle may be blocked.

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

- Check the dosage indicator window. The number that lines up with the dosage indicator is the number of milligrams that you need to inject to complete your dose. Make a note of this number.
- Turn the dosage selector until 0.0 lines up with the dosage indicator.
- Screw on a new needle and perform an air shot as described on pages 6 to 9.
- Select the number of milligrams you need to complete your dose. This is the number that you made a note of. Prepare NordiFlex PenMate as described on page 10. Inject as described on pages 11 to 14.

Question**Answer**

When selecting a dose the dosage selector stops before I have selected the required number of milligrams.

Either, you are trying to select a dose larger than there is left in NordiFlex prefilled pen or you are trying to select a dose larger than the maximum dose for one injection.

- If you need a dose larger than the number of milligrams left in the cartridge, follow the instructions on milligrams page 14.
- If you need a dose larger than the maximum dose for one injection you must spread the dose over two injections.

Question	Answer
My Norditropin NordiFlex and/or my NordiFlex PenMate has been dropped or knocked.	<ul style="list-style-type: none"><li data-bbox="848 659 1393 742">• Unscrew Norditropin NordiFlex and pull it gently out of NordiFlex PenMate. Check that Norditropin NordiFlex is intact.<li data-bbox="848 769 1393 822">• Make sure that the cartridge is intact, e.g. no cracks.<li data-bbox="848 848 1393 901">• Screw NordiFlex PenMate and Norditropin NordiFlex together as described on page 5.<li data-bbox="848 927 1393 980">• Screw on a new NovoFine disposable needle (see pages 6 to 7).<li data-bbox="848 1007 1393 1033">• Perform an air shot (see pages 8 to 9).

If you have any questions, please call 1-888-NOVO-444.

Should your NordiFlex PenMate be defective in materials or workmanship within five (5) 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 Patents 5980491 and 6537252.

Designed and intended for use with Norditropin NordiFlex prefilled pens, NordiFlex PenMate and NovoFine disposable needles.

If you need the LOT number of your NordiFlex PenMate it is located as illustrated in the diagram inside the cover.

PATIENT INFORMATION

Norditropin NordiFlex®

Somatropin (rDNA origin) injection

5 mg/1.5 mL Prefilled Pen

Your doctor will discuss with you the benefits and risks of Norditropin NordiFlex® (pronounced Nor-dee-tro-pin Nor-dee-flex). Read all of the information in this patient guide because it contains important information for you. If you have further questions, please ask your doctor or your pharmacist. Norditropin NordiFlex® has been prescribed for you and you must not pass it on to others.

What is the most important information I should know about Norditropin NordiFlex®?

Store non-injected/unused Norditropin NordiFlex® in a refrigerator. Do not freeze it or expose it to heat.

Do not use Norditropin NordiFlex® if the solution in the cartridge does not appear clear and colorless. Check this by turning the pen upside down once or twice.

Norditropin NordiFlex® is for use by one person only.

Do not use Norditropin NordiFlex® if you need to make more than 6 air shots before the first injection.

Your doctor will measure your height, weight and your ability to produce growth hormone before you are prescribed Norditropin NordiFlex®.

What is Norditropin NordiFlex®?

Norditropin® is a clear and colorless solution used to treat children with growth failure caused by very low or no production of growth hormone, as well as adults who lack growth hormone.

Norditropin® is injected using the Norditropin NordiFlex®, a multi-dose disposable 1.5 mL prefilled pen. Norditropin NordiFlex® contains several doses of growth hormone solution. A dose is injected into the thigh in the evening 6-7 times a week.

Norditropin NordiFlex® is available in three strengths: 5 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL (i.e. 3.3 mg/mL, 6.7 mg/mL and 10.0 mg/mL respectively).

Throw away the Norditropin NordiFlex® when the cartridge is empty.

Medicines are sometimes prescribed for purposes other than those listed in a patient guide. Patients should ask their doctor about any concerns and refer to the professional labeling for additional information.

What does Norditropin NordiFlex® contain?

The cartridge in Norditropin NordiFlex® contains human growth hormone called somatropin (so-ma-tro-pin) made through biotechnology. It is identical to the growth hormone produced in the human body.

The cartridge contains other ingredients: Histidine, Poloxamer 188, Phenol, Mannitol and Water for Injection.

Who should not take Norditropin NordiFlex®?

Do not use Norditropin NordiFlex® if you have any of the following conditions:

- child with closed epiphyses (closed bone growth plates)
- child with Prader-Willi syndrome
- allergic to phenol or any other ingredients in the medicine
- had a kidney transplant
- pregnant
- breast-feeding
- cancer or other forms of tumor
- acute critical illness

What should you consider if you are pregnant or breast-feeding?

If you become pregnant while you are receiving Norditropin NordiFlex®, you are recommended to stop the treatment and discuss this with your doctor.

You are recommended not to take Norditropin NordiFlex® while you are breast-feeding because somatropin might pass into your milk.

Be sure to tell your doctor if you:

- have diabetes mellitus
- had cancer or other forms of tumor

If any of the above applies to you, Norditropin NordiFlex® may not be suitable. Your doctor will give you advice.

How should I take Norditropin NordiFlex®?

Carefully follow the "Instructions for Use" on the other side of this patient guide.

You should inject Norditropin NordiFlex® in the thigh in the evening just before bedtime.

8-2084-31-001-2

You should change the injection area on the thigh so you do not harm your skin.

NovoFine® disposable needles are designed to be used with Norditropin NordiFlex®.

How much Norditropin® should you take?

Your doctor will tell you how much Norditropin® you should take. In children it depends on the body weight.

General guidelines for dosages are shown below.

Children: 0.024 to 0.034 mg/kg body weight, 6-7 times a week.

Adults: Not more than 0.004 mg/kg/day at start of therapy. Dosage may be increased as tolerated to not more than 0.016 mg/kg/day after approximately 6 weeks. If you forget to take a dose, take the next dose as usual - do not double your dose.

What should you do if you inject too much growth hormone using Norditropin NordiFlex®?

If you inject too much growth hormone, contact your doctor.

How long should you continue to take Norditropin®?

Discuss with your doctor if you want to stop taking Norditropin®.

What should I avoid while taking Norditropin NordiFlex®?

Be sure to tell your doctor about all of the medications you are taking especially if you are taking:

a glucocorticoid medication such as hydrocortisone or cortisone acetate
thyroid hormone
insulin

Adult height can be influenced if you are on Norditropin NordiFlex® for growth failure and using glucocorticoids or thyroid hormone at the same time.

If you are treated with insulin, your insulin dose may need to be adjusted.

What are the possible or reasonably likely side effects of Norditropin NordiFlex®?

The following side effects are usually mild and temporary:

- headaches
- muscle pain
- joint stiffness
- weakness
- high blood sugar (hyperglycemia)
- sugar in your urine (glucosuria)

- swollen hands and feet due to fluid retention
- redness and itching in the area you inject

If you experience any of these symptoms, you may need to reduce your dose. Discuss this with your doctor. In rare cases you may develop antibodies to growth hormone or suffer raised pressure within the brain. If you get headaches, eyesight problems, feel sick or vomit, contact your doctor as these complaints could be signs of raised pressure within your brain.

Be sure to tell your doctor if you have any other side effects not mentioned here.

Special warnings

In very rare cases children treated with somatropin have experienced pain in the hip or knee or a limp. These symptoms may be caused by slipped capital femoral epiphysis (the end of the bone slips from the cartilage).

Scoliosis (curvature of the spine) can occur in children who experience rapid growth. Because growth hormone increases growth rate, patients should be monitored for progression of scoliosis.

Patients should have periodic thyroid function tests.

The following tumors have been reported in patients treated with somatropin: Leukemia in children, relapse of brain tumors in children and adults. However, there is no evidence that somatropin is responsible for causing these diseases.

Talk to your doctor if you think you have any of these conditions.

How to store Norditropin NordiFlex®?

Store non-injected/unused Norditropin NordiFlex® in a refrigerator (2°C - 8°C/36°F - 46°F). Do not freeze or expose it to heat. Avoid direct light.

After the initial injection, Norditropin NordiFlex® may be **EITHER** stored in the refrigerator (2°C - 8°C/36°F - 46°F) and used within 4 weeks **OR** may be stored for up to 3 weeks at not more than 25°C (77°F). Discard unused portion.

Do not use Norditropin NordiFlex® which has been frozen or exposed to excessive temperatures.

Always use a new needle for each injection. Do not keep the needle screwed onto the Norditropin NordiFlex® when you are not using it.

Always keep the pen cap closed on the Norditropin NordiFlex® when you are not using it.

Never use Norditropin NordiFlex® after the expiry date printed on the pen and on the carton.

Date of issue: April 2005

INSTRUCTIONS FOR USE

Norditropin NordiFlex®

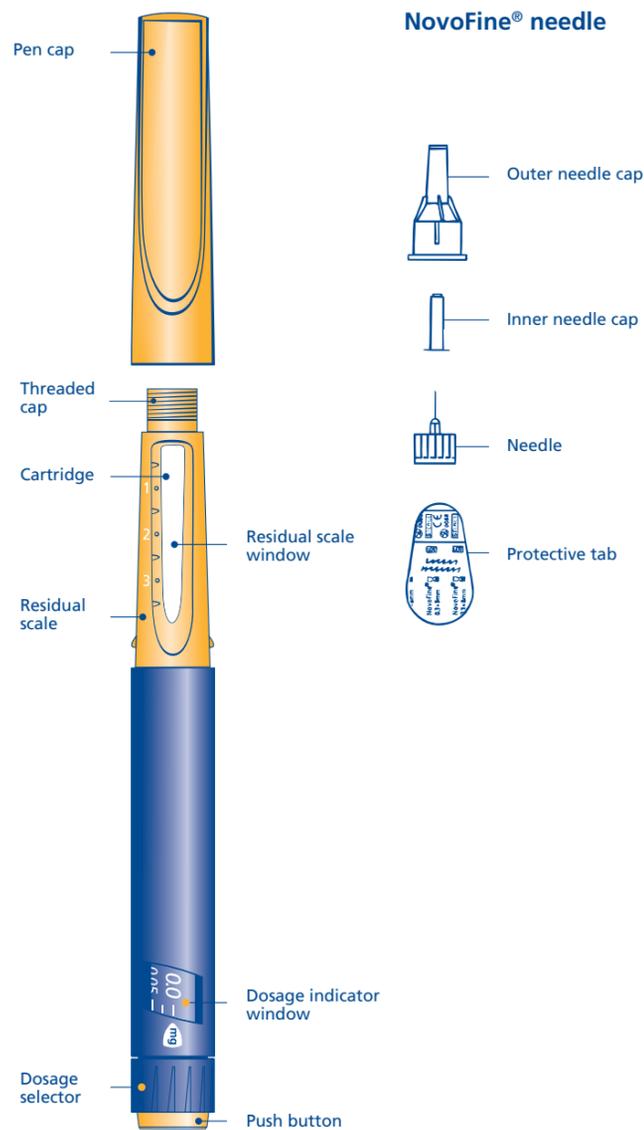
Somatotropin (rDNA origin) injection

5 mg/1.5 mL Prefilled Pen

Using the disposable Norditropin NordiFlex® 5 mg/1.5 mL Prefilled Pen

Norditropin NordiFlex® 5 mg/1.5 mL is a disposable dial-a-dose growth hormone delivery system able to deliver doses from 0.025 to 1.5 mg. The dose can be adjusted in increments of 0.025 mg. Your doctor will determine the correct dose for you. Norditropin NordiFlex® prefilled pen is designed to be used with NovoFine® disposable needles (sold separately). Norditropin NordiFlex® prefilled pen is not recommended for people who are blind or have trouble seeing unless they have the help of a sighted individual trained to use the Norditropin NordiFlex®.

Please read these instructions carefully before using this device



1 Preparing Norditropin NordiFlex® 5 mg/1.5 mL for injection

A. Wash hands well. Pull off the pen cap and wipe the front rubber stopper on the threaded plastic cap with an alcohol swab. **DO NOT use Norditropin NordiFlex® if the growth hormone solution is cloudy or contains particles. Use it only if it is clear and colorless.** Check this by turning the Norditropin NordiFlex® upside down once or twice and view the solution through the residual scale window.

B. Place the NovoFine® needle onto the Norditropin NordiFlex® immediately before use. Remove the protective tab from the disposable needle and screw the needle tightly onto Norditropin NordiFlex®. Pull off the outer and inner needle caps. Never place a disposable needle on your Norditropin NordiFlex® until you are ready to give an injection. Remove the needle immediately after use. If the needle is not removed, some growth hormone may be expelled from the Norditropin NordiFlex®.

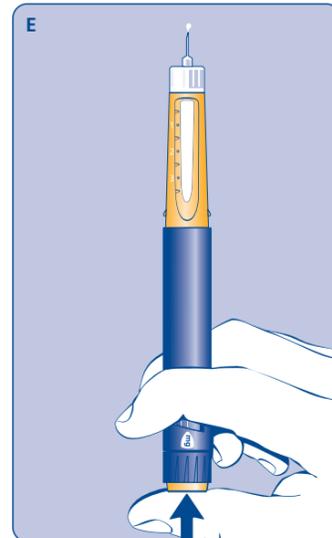
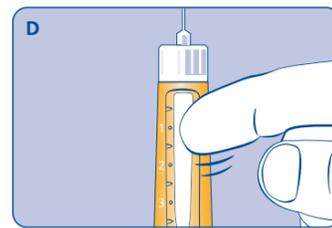
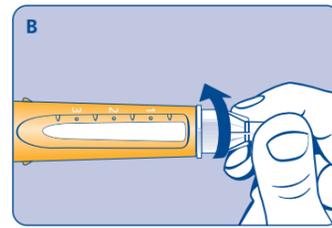
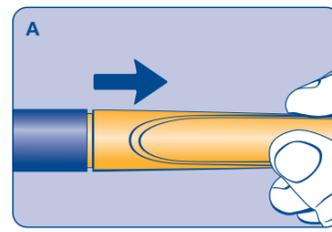
C. Do an air shot before each injection as follows:

Small amounts of air may collect in the needle and cartridge during normal use. To avoid injecting air and ensure proper dosing, set the dosage selector to 0.05 mg. Each line between labeled dosages is 0.025 mg. **Dial 0.05 mg**

D. Hold Norditropin NordiFlex® with the needle pointing up, tap the cartridge gently with your finger a few times to raise any air bubbles to the top of the cartridge.

E. Still holding Norditropin NordiFlex® with the needle up, press the push button all the way in. A drop of growth hormone should appear at the needle tip. If not, repeat the procedure, no more than 6 times.

If a drop of growth hormone still does not appear, call 1-888-NOVO-444 for help.



2 Setting the dose

F. Check that the dose selector is set at **0.0**. Dial the number of mg that you need to inject. The dose can be changed up or down by turning the dose selector in either direction. When dialing back, be careful not to press the push button as growth hormone liquid will come out. **DO NOT use the clicking sound as a guide for selecting dose.**

The numbers on the residual scale can be used to estimate the mg left in the cartridge.

DO NOT use these numbers to measure the growth hormone dose.

You cannot set a dose higher than the number of mg left in the cartridge. Use a new Norditropin NordiFlex® pen to inject the remaining amount of your dose. Be sure to remember the dose already received with the first dose. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.4 mg. You will need to inject an additional 0.2 mg with a new Norditropin NordiFlex® pen.

3 Giving the injection

Use the injection procedure recommended by your doctor or health care professional.

G. This product is for subcutaneous use only. Insert the needle into your thigh and deliver the dose by pressing the push button all the way in. Press the push button only when injecting.

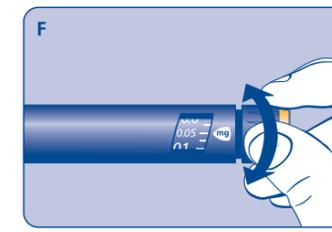
After the injection, the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle is removed from the skin. This will ensure that the full dose has been delivered. Vary the injection site on the thigh using the injection procedure recommended by your doctor.

4 Removing the needle

H. After the injection, remove the needle **without recapping** and dispose of it in a puncture-resistant container. Used needles should be placed in sharps container (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.

It is important that you use a new needle for each injection. Health care professionals, relatives and other caregivers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle stick.

When the cartridge is empty, throw away the Norditropin NordiFlex® without the needle attached.



5 Maintenance

Norditropin NordiFlex® should be handled with care. Protect Norditropin NordiFlex® from dust, dirt, and direct sunlight. You can clean the outside of your Norditropin NordiFlex® by wiping it with a soft cloth moistened with water. Do not soak Norditropin NordiFlex® in alcohol, wash, or lubricate it.

6 Important Notes

- Store non-injected/unused Norditropin NordiFlex® pens in a refrigerator (2°C - 8°C/36°F - 46°F). After the initial injection, Norditropin NordiFlex® may be **EITHER** stored in the refrigerator (2°C - 8°C/36°F - 46°F) and used within 4 weeks **OR** may be stored for up to 3 weeks at not more than 25°C (77°F).
- Remember to perform an air shot before each injection. See diagrams **C, D** and **E**.
- If you need to perform more than 6 air shots before the first use of the Norditropin NordiFlex® to get a droplet of growth hormone at the needle tip, **DO NOT** use the Norditropin NordiFlex®. Call 1-888-NOVO-444 for help.
- Take care not to drop the Norditropin NordiFlex®.
- **DO NOT** leave the Norditropin NordiFlex® in a car or other location where it can get too hot or too cold.
- Always have a spare Norditropin NordiFlex® disposable pen in order to avoid running out of this product.
- Norditropin NordiFlex® is designed to be used with NovoFine® disposable needles.
- **NEVER** place a NovoFine® needle on the Norditropin NordiFlex® until you are ready to use it. Remove the needle right after use without recapping.
- **Throw away used needles properly, so people will not be harmed.**
- Throw away the used Norditropin NordiFlex®, without the needle attached.
- To avoid spread of disease, do not let anyone else use your Norditropin NordiFlex®, even if you attach a new needle.
- Keep the Norditropin NordiFlex® out of the reach of children.
- **Novo Nordisk is not responsible for harm due to using the Norditropin NordiFlex® with products that are not recommended by Novo Nordisk.**

7 Warranty

If your Norditropin NordiFlex® is defective in materials or workmanship, 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, USA

PATIENT INFORMATION

Norditropin NordiFlex®

Somatropin (rDNA origin) injection

10 mg/1.5 mL Prefilled Pen

Your doctor will discuss with you the benefits and risks of Norditropin NordiFlex® (pronounced Nor-dee-tro-pin Nor-dee-flex). Read all of the information in this patient guide because it contains important information for you. If you have further questions, please ask your doctor or your pharmacist. Norditropin NordiFlex® has been prescribed for you and you must not pass it on to others.

What is the most important information I should know about Norditropin NordiFlex®?

Store non-injected/unused Norditropin NordiFlex® in a refrigerator. Do not freeze it or expose it to heat.

Do not use Norditropin NordiFlex® if the solution in the cartridge does not appear clear and colorless. Check this by turning the pen upside down once or twice.

Norditropin NordiFlex® is for use by one person only.

Do not use Norditropin NordiFlex® if you need to make more than 6 air shots before the first injection.

Your doctor will measure your height, weight and your ability to produce growth hormone before you are prescribed Norditropin NordiFlex®.

What is Norditropin NordiFlex®?

Norditropin® is a clear and colorless solution used to treat children with growth failure caused by very low or no production of growth hormone, as well as adults who lack growth hormone.

Norditropin® is injected using the Norditropin NordiFlex®, a multi-dose disposable 1.5 mL prefilled pen. Norditropin NordiFlex® contains several doses of growth hormone solution. A dose is injected into the thigh in the evening 6 - 7 times a week. Norditropin NordiFlex® is available in three strengths: 5 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL (i.e. 3.3 mg/mL, 6.7 mg/mL and 10.0 mg/mL respectively).

Throw away the Norditropin NordiFlex® when the cartridge is empty.

Medicines are sometimes prescribed for purposes other than those listed in a patient guide. Patients should ask their doctor about any concerns and refer to the professional labeling for additional information.

What does Norditropin NordiFlex® contain?

The cartridge in Norditropin NordiFlex® contains human growth hormone called somatropin (so-ma-tro-pin) made through biotechnology. It is identical to the growth hormone produced in the human body.

The cartridge contains other ingredients: Histidine, Poloxamer 188, Phenol, Mannitol and Water for Injection.

Who should not take Norditropin NordiFlex®?

Do not use Norditropin NordiFlex® if you have any of the following conditions:

- child with closed epiphyses (closed bone growth plates)
- child with Prader-Willi syndrome
- allergic to phenol or any other ingredients in the medicine
- had a kidney transplant
- pregnant
- breast-feeding
- cancer or other forms of tumor
- acute critical illness

What should you consider if you are pregnant or breast-feeding?

If you become pregnant while you are receiving Norditropin NordiFlex®, you are recommended to stop the treatment and discuss this with your doctor.

You are recommended not to take Norditropin NordiFlex® while you are breast-feeding because somatropin might pass into your milk.

Be sure to tell your doctor if you:

- have diabetes mellitus
- had cancer or other forms of tumor

If any of the above applies to you, Norditropin NordiFlex® may not be suitable. Your doctor will give you advice.

How should I take Norditropin NordiFlex®?

Carefully follow the "Instructions for Use" on the other side of this patient guide.

You should inject Norditropin NordiFlex® in the thigh in the evening just before bedtime.

8-2085-31-001-2

You should change the injection area on the thigh so you do not harm your skin.

NovoFine® disposable needles are designed to be used with Norditropin NordiFlex®.

How much Norditropin® should you take?

Your doctor will tell you how much Norditropin® you should take. In children it depends on the body weight.

General guidelines for dosages are shown below.

Children: 0.024 to 0.034 mg/kg body weight, 6-7 times a week.

Adults: Not more than 0.004 mg/kg/day at start of therapy. Dosage may be increased as tolerated to not more than 0.016 mg/kg/day after approximately 6 weeks. If you forget to take a dose, take the next dose as usual - do not double your dose.

What should you do if you inject too much growth hormone using Norditropin NordiFlex®?

If you inject too much growth hormone, contact your doctor.

How long should you continue to take Norditropin®?

Discuss with your doctor if you want to stop taking Norditropin®.

What should I avoid while taking Norditropin NordiFlex®?

Be sure to tell your doctor about all of the medications you are taking especially if you are taking: a glucocorticoid medication such as hydrocortisone or cortisone acetate thyroid hormone insulin

Adult height can be influenced if you are on Norditropin NordiFlex® for growth failure and using glucocorticoids or thyroid hormone at the same time.

If you are treated with insulin, your insulin dose may need to be adjusted.

What are the possible or reasonably likely side effects of Norditropin NordiFlex®?

The following side effects are usually mild and temporary:

- headaches
- muscle pain
- joint stiffness
- weakness
- high blood sugar (hyperglycemia)
- sugar in your urine (glucosuria)

- swollen hands and feet due to fluid retention
- redness and itching in the area you inject

If you experience any of these symptoms, you may need to reduce your dose. Discuss this with your doctor.

In rare cases you may develop antibodies to growth hormone or suffer raised pressure within the brain. If you get headaches, eyesight problems, feel sick or vomit, contact your doctor as these complaints could be signs of raised pressure within your brain.

Be sure to tell your doctor if you have any other side effects not mentioned here.

Special warnings

In very rare cases children treated with somatropin have experienced pain in the hip or knee or a limp. These symptoms may be caused by slipped capital femoral epiphysis (the end of the bone slips from the cartilage).

Scoliosis (curvature of the spine) can occur in children who experience rapid growth. Because growth hormone increases growth rate, patients should be monitored for progression of scoliosis. Patients should have periodic thyroid function tests. The following tumors have been reported in patients treated with somatropin: Leukemia in children, relapse of brain tumors in children and adults. However, there is no evidence that somatropin is responsible for causing these diseases.

Talk to your doctor if you think you have any of these conditions.

How to store Norditropin NordiFlex®?

Store non-injected/unused Norditropin NordiFlex® in a refrigerator (2°C - 8°C/36°F - 46°F). Do not freeze or expose it to heat. Avoid direct light.

After the initial injection, Norditropin NordiFlex® may be **EITHER** stored in the refrigerator (2°C - 8°C/36°F - 46°F) and used within 4 weeks **OR** may be stored for up to 3 weeks at not more than 25°C (77°F). Discard unused portion.

Do not use Norditropin NordiFlex® which has been frozen or exposed to excessive temperatures.

Always use a new needle for each injection. Do not keep the needle screwed onto the Norditropin NordiFlex® when you are not using it.

Always keep the pen cap closed on the Norditropin NordiFlex® when you are not using it.

Never use Norditropin NordiFlex® after the expiry date printed on the pen and on the carton.

Date of issue: April 2005

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US Patent Nos. 6,235,004; 6,004,297 and other patents pending.

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

Manufactured by:
Novo Nordisk A/S
2880 Bagsvaerd, Denmark

INSTRUCTIONS FOR USE

Norditropin NordiFlex®

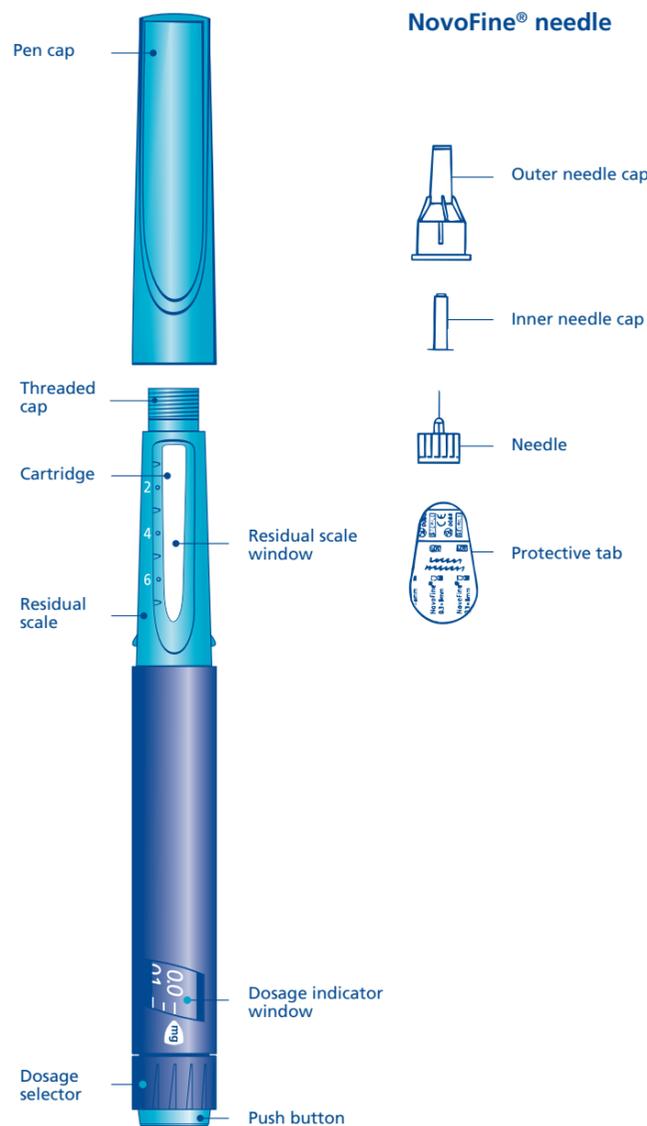
Somatotropin (rDNA origin) injection

10 mg/1.5 mL Prefilled Pen

Using the disposable Norditropin NordiFlex® 10 mg/1.5 mL Prefilled Pen

Norditropin NordiFlex® 10 mg/1.5 mL is a disposable dial-a-dose growth hormone delivery system able to deliver doses from 0.05 to 3.0 mg. The dose can be adjusted in increments of 0.05 mg. Your doctor will determine the correct dose for you. Norditropin NordiFlex® prefilled pen is designed to be used with NovoFine® disposable needles (sold separately). Norditropin NordiFlex® pre-filled pen is not recommended for people who are blind or have trouble seeing unless they have the help of a sighted individual trained to use the Norditropin NordiFlex®.

Please read these instructions carefully before using this device



1 Preparing Norditropin NordiFlex® 10 mg/1.5 mL for injection

A. Wash hands well. Pull off the pen cap and wipe the front rubber stopper on the threaded plastic cap with an alcohol swab. **DO NOT use Norditropin NordiFlex® if the growth hormone solution is cloudy or contains particles. Use it only if it is clear and colorless.** Check this by turning the Norditropin NordiFlex® upside down once or twice and view the solution through the residual scale window.

B. Place the NovoFine® needle onto the Norditropin NordiFlex® immediately before use. Remove the protective tab from the disposable needle and screw the needle tightly onto Norditropin NordiFlex®. Pull off the outer and inner needle caps. Never place a disposable needle on your Norditropin NordiFlex® until you are ready to give an injection. Remove the needle immediately after use. If the needle is not removed, some growth hormone may be expelled from the Norditropin NordiFlex®.

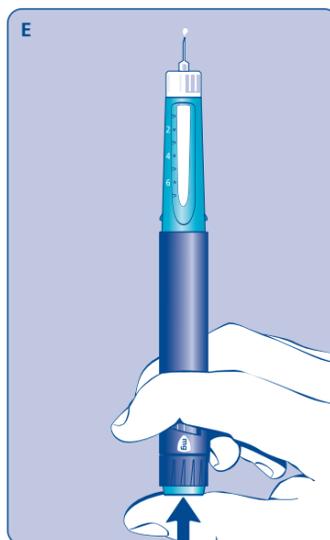
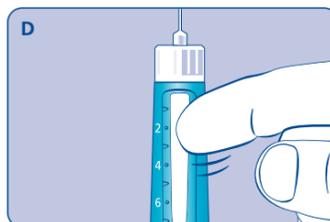
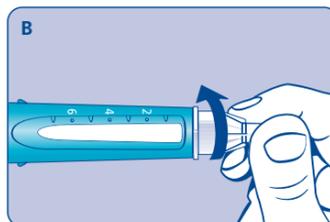
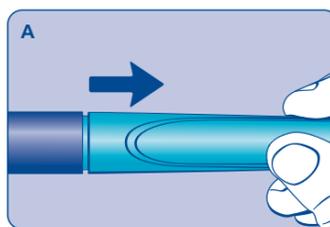
C. Do an air shot before each injection as follows: Small amounts of air may collect in the needle and cartridge during normal use. To avoid injecting air and ensure proper dosing, set the dosage selector to 0.1 mg. Each line between labeled dosages is 0.05 mg.

Dial 0.1 mg

D. Hold Norditropin NordiFlex® with the needle pointing up, tap the cartridge gently with your finger a few times to raise any air bubbles to the top of the cartridge.

E. Still holding Norditropin NordiFlex® with the needle up, press the push button all the way in. A drop of growth hormone should appear at the needle tip. If not, repeat the procedure, no more than 6 times.

If a drop of growth hormone still does not appear, call 1-888-NOVO-444 for help.



2 Setting the dose

F. Check that the dose selector is set at **0.0**. Dial the number of mg that you need to inject. The dose can be changed up or down by turning the dose selector in either direction. When dialing back, be careful not to press the push button as growth hormone liquid will come out. **DO NOT use the clicking sound as a guide for selecting dose.**

The numbers on the residual scale can be used to estimate the mg left in the cartridge. **DO NOT use these numbers to measure the growth hormone dose.**

You cannot set a dose higher than the number of mg left in the cartridge. Use a new Norditropin NordiFlex® pen to inject the remaining amount of your dose. Be sure to remember the dose already received with the first dose. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.4 mg. You will need to inject an additional 0.2 mg with a new Norditropin NordiFlex® pen.

3 Giving the injection

Use the injection procedure recommended by your doctor or health care professional.

G. This product is for subcutaneous use only. Insert the needle into your thigh and deliver the dose by pressing the push button all the way in. Press the push button only when injecting.

After the injection, the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle is removed from the skin. This will ensure that the full dose has been delivered. Vary the injection site on the thigh using the injection procedure recommended by your doctor.

4 Removing the needle

H. After the injection, remove the needle **without recapping** and dispose of it in a puncture-resistant container. Used needles should be placed in sharps container (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.

It is important that you use a new needle for each injection. Health care professionals, relatives and other caregivers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle stick.

When the cartridge is empty, throw away the Norditropin NordiFlex® without the needle attached.



5 Maintenance

Norditropin NordiFlex® should be handled with care. Protect Norditropin NordiFlex® from dust, dirt, and direct sunlight.

You can clean the outside of your Norditropin NordiFlex® by wiping it with a soft cloth moistened with water. Do not soak Norditropin NordiFlex® in alcohol, wash, or lubricate it.

6 Important Notes

- Store non-injected/unused Norditropin NordiFlex® pens in a refrigerator (2°C - 8°C/36°F - 46°F). After the initial injection, Norditropin NordiFlex® may be **EITHER** stored in the refrigerator (2°C - 8°C/36°F - 46°F) and used within 4 weeks **OR** may be stored for up to 3 weeks at not more than 25°C (77°F).
- Remember to perform an air shot before each injection. See diagrams **C**, **D** and **E**.
- If you need to perform more than 6 air shots before the first use of the Norditropin NordiFlex® to get a droplet of growth hormone at the needle tip, **DO NOT** use the Norditropin NordiFlex®. Call 1-888-NOVO-444 for help.
- Take care not to drop the Norditropin NordiFlex®.
- **DO NOT** leave the Norditropin NordiFlex® in a car or other location where it can get too hot or too cold.
- Always have a spare Norditropin NordiFlex® disposable pen in order to avoid running out of this product.
- Norditropin NordiFlex® is designed to be used with NovoFine® disposable needles.
- **NEVER** place a NovoFine® needle on this Norditropin NordiFlex® until you are ready to use it. Remove the needle right after use without recapping.
- **Throw away used needles properly, so people will not be harmed.**
- Throw away the used Norditropin NordiFlex®, without the needle attached.
- To avoid spread of disease, do not let anyone else use your Norditropin NordiFlex®, even if you attach a new needle.
- Keep the Norditropin NordiFlex® out of the reach of children.
- **Novo Nordisk is not responsible for harm due to using the Norditropin NordiFlex® with products that are not recommended by Novo Nordisk.**

7 Warranty

If your Norditropin NordiFlex® is defective in materials or workmanship, 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, USA

PATIENT INFORMATION

Norditropin NordiFlex®

Somatropin (rDNA origin) injection

15 mg/1.5 mL Prefilled Pen

Your doctor will discuss with you the benefits and risks of Norditropin NordiFlex® (pronounced Nor-dee-tro-pin Nor-dee-flex). Read all of the information in this patient guide because it contains important information for you. If you have further questions, please ask your doctor or your pharmacist. Norditropin NordiFlex® has been prescribed for you and you must not pass it on to others.

What is the most important information I should know about Norditropin NordiFlex®?

Store Norditropin NordiFlex® in a refrigerator. Do not freeze it or expose it to heat.

Do not use Norditropin NordiFlex® if the solution in the cartridge does not appear clear and colorless. Check this by turning the pen upside down once or twice.

Norditropin NordiFlex® is for use by one person only.

Do not use Norditropin NordiFlex® if you need to make more than 6 air shots before the first injection.

Your doctor will measure your height, weight and your ability to produce growth hormone before you are prescribed Norditropin NordiFlex®.

What is Norditropin NordiFlex®?

Norditropin® is a clear and colorless solution used to treat children with growth failure caused by very low or no production of growth hormone, as well as adults who lack growth hormone.

Norditropin® is injected using the Norditropin NordiFlex®, a multi-dose disposable 1.5 mL prefilled pen. Norditropin NordiFlex® contains several doses of growth hormone solution. A dose is injected into the thigh in the evening 6-7 times a week.

Norditropin NordiFlex® is available in three strengths: 5 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL (i.e. 3.3 mg/mL, 6.7 mg/mL and 10.0 mg/mL respectively).

Throw away the Norditropin NordiFlex® when the cartridge is empty.

Medicines are sometimes prescribed for purposes other than those listed in a patient guide. Patients should ask their doctor about any concerns and refer to the professional labeling for additional information.

What does Norditropin NordiFlex® contain?

The cartridge in Norditropin NordiFlex® contains human growth hormone called somatropin (so-ma-tro-pin) made through biotechnology. It is identical to the growth hormone produced in the human body.

The cartridge contains other ingredients: Histidine, Poloxamer 188, Phenol, Mannitol and Water for Injection.

Who should not take Norditropin NordiFlex®?

Do not use Norditropin NordiFlex® if you have any of the following conditions:

- child with closed epiphyses (closed bone growth plates)
- child with Prader-Willi syndrome
- allergic to phenol or any other ingredients in the medicine
- had a kidney transplant
- pregnant
- breast-feeding
- cancer or other forms of tumor
- acute critical illness

What should you consider if you are pregnant or breast-feeding?

If you become pregnant while you are receiving Norditropin NordiFlex®, you are recommended to stop the treatment and discuss this with your doctor.

You are recommended not to take Norditropin NordiFlex® while you are breast-feeding because somatropin might pass into your milk.

Be sure to tell your doctor if you:

- have diabetes mellitus
- had cancer or other forms of tumor

If any of the above applies to you, Norditropin NordiFlex® may not be suitable. Your doctor will give you advice.

How should I take Norditropin NordiFlex®?

Carefully follow the "Instructions for Use" on the other side of this patient guide.

You should inject Norditropin NordiFlex® in the thigh in the evening just before bedtime.

8-2086-31-001-2

You should change the injection area on the thigh so you do not harm your skin.

NovoFine® disposable needles are designed to be used with Norditropin NordiFlex®.

How much Norditropin® should you take?

Your doctor will tell you how much Norditropin® you should take. In children it depends on the body weight.

General guidelines for dosages are shown below.

Children: 0.024 to 0.034 mg/kg body weight, 6-7 times a week.

Adults: Not more than 0.004 mg/kg/day at start of therapy. Dosage may be increased as tolerated to not more than 0.016 mg/kg/day after approximately 6 weeks.

If you forget to take a dose, take the next dose as usual - do not double your dose.

What should you do if you inject too much growth hormone using Norditropin NordiFlex®?

If you inject too much growth hormone, contact your doctor.

How long should you continue to take Norditropin®?

Discuss with your doctor if you want to stop taking Norditropin®.

What should I avoid while taking Norditropin NordiFlex®?

Be sure to tell your doctor about all of the medications you are taking especially if you are taking:

a glucocorticoid medication such as hydrocortisone or cortisone acetate
thyroid hormone
insulin

Adult height can be influenced if you are on Norditropin NordiFlex® for growth failure and using glucocorticoids or thyroid hormone at the same time.

If you are treated with insulin, your insulin dose may need to be adjusted.

What are the possible or reasonably likely side effects of Norditropin NordiFlex®?

The following side effects are usually mild and temporary:

- headaches
- muscle pain
- joint stiffness
- weakness
- high blood sugar (hyperglycemia)

- sugar in your urine (glucosuria)
- swollen hands and feet due to fluid retention
- redness and itching in the area you inject

If you experience any of these symptoms, you may need to reduce your dose. Discuss this with your doctor.

In rare cases you may develop antibodies to growth hormone or suffer raised pressure within the brain. If you get headaches, eyesight problems, feel sick or vomit, contact your doctor as these complaints could be signs of raised pressure within your brain.

Be sure to tell your doctor if you have any other side effects not mentioned here.

Special warnings

In very rare cases children treated with somatropin have experienced pain in the hip or knee or a limp. These symptoms may be caused by slipped capital femoral epiphysis (the end of the bone slips from the cartilage).

Scoliosis (curvature of the spine) can occur in children who experience rapid growth. Because growth hormone increases growth rate, patients should be monitored for progression of scoliosis.

Patients should have periodic thyroid function tests.

The following tumors have been reported in patients treated with somatropin: Leukemia in children, relapse of brain tumors in children and adults.

However, there is no evidence that somatropin is responsible for causing these diseases.

Talk to your doctor if you think you have any of these conditions.

How to store Norditropin NordiFlex®?

Store non-injected/unused Norditropin NordiFlex® in a refrigerator (2°C - 8°C/36°F - 46°F). Do not freeze or expose it to heat. Avoid direct light.

After the initial injection, Norditropin NordiFlex® must be kept in a refrigerator and used within 4 weeks. Discard unused portion after 4 weeks.

Do not use Norditropin NordiFlex® which has been frozen or exposed to excessive temperatures.

Always use a new needle for each injection. Do not keep the needle screwed onto the Norditropin NordiFlex® when you are not using it.

Always keep the pen cap closed on the Norditropin NordiFlex® when you are not using it.

Never use Norditropin NordiFlex® after the expiry date printed on the pen and on the carton.

Date of issue: September 2005

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

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US Patent Nos. 6,235,004; 6,004,297 and other patents pending.

For assistance or further information, write to:

Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540, USA
1-888-NOVO-444
www.norditropin-us.com

Manufactured by:
Novo Nordisk A/S
2880 Bagsvaerd, Denmark

INSTRUCTIONS FOR USE

Norditropin NordiFlex®

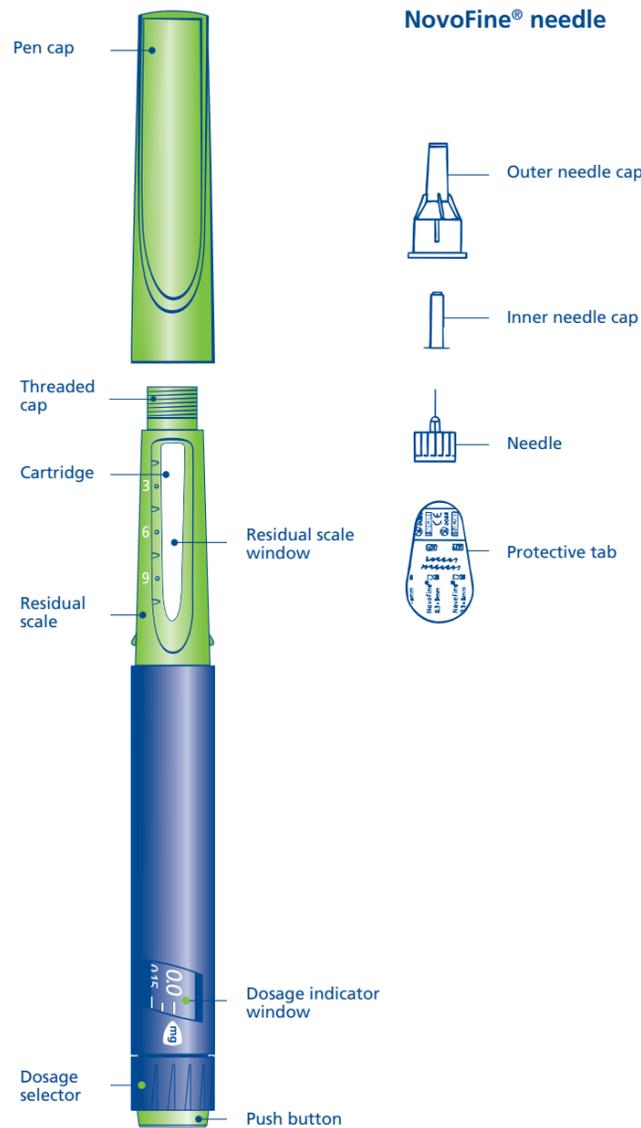
Somatotropin (rDNA origin) injection

15 mg/1.5 mL Prefilled Pen

Using the disposable Norditropin NordiFlex® 15 mg/1.5 mL Prefilled Pen

Norditropin NordiFlex® 15 mg/1.5 mL is a disposable dial-a-dose growth hormone delivery system able to deliver doses from 0.075 to 4.5 mg. The dose can be adjusted in increments of 0.075 mg. Your doctor will determine the correct dose for you. Norditropin NordiFlex® prefilled pen is designed to be used with NovoFine® disposable needles (sold separately). Norditropin NordiFlex® prefilled pen is not recommended for people who are blind or have trouble seeing unless they have the help of a sighted individual trained to use the Norditropin NordiFlex®.

Please read these instructions carefully before using this device



1 Preparing Norditropin NordiFlex® 15 mg/1.5 mL for injection

A. Wash hands well. Pull off the pen cap and wipe the front rubber stopper on the threaded plastic cap with an alcohol swab. **DO NOT use Norditropin NordiFlex® if the growth hormone solution is cloudy or contains particles. Use it only if it is clear and colorless.** Check this by turning the Norditropin NordiFlex® upside down once or twice and view the solution through the residual scale window.

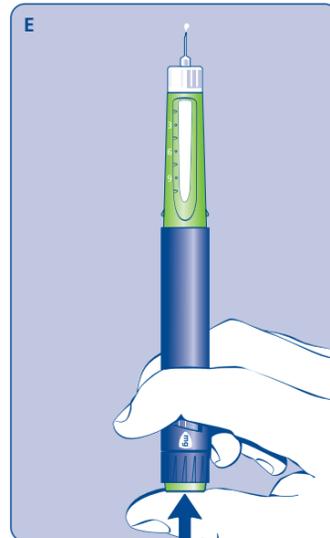
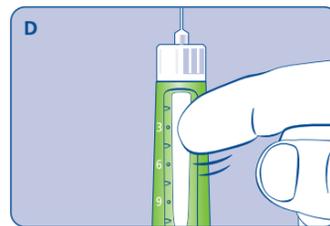
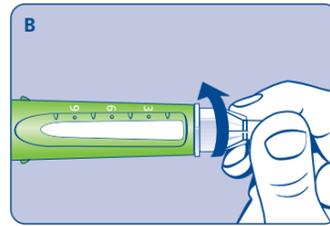
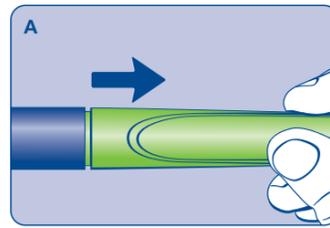
B. Place the NovoFine® needle onto the Norditropin NordiFlex® immediately before use. Remove the protective tab from the disposable needle and screw the needle tightly onto Norditropin NordiFlex®. Pull off the outer and inner needle caps. Never place a disposable needle on your Norditropin NordiFlex® until you are ready to give an injection. Remove the needle immediately after use. If the needle is not removed, some growth hormone may be expelled from the Norditropin NordiFlex®.

C. Do an air shot before each injection as follows: Small amounts of air may collect in the needle and cartridge during normal use. To avoid injecting air and ensure proper dosing, set the dosage selector to 0.15 mg. Each line between labeled dosages is 0.075 mg. **Dial 0.15 mg**

D. Hold Norditropin NordiFlex® with the needle pointing up, tap the cartridge gently with your finger a few times to raise any air bubbles to the top of the cartridge.

E. Still holding Norditropin NordiFlex® with the needle up, press the push button all the way in. A drop of growth hormone should appear at the needle tip. If not, repeat the procedure, no more than 6 times.

If a drop of growth hormone still does not appear, call 1-888-NOVO-444 for help.



2 Setting the dose

F. Check that the dose selector is set at **0.0**. Dial the number of mg that you need to inject. The dose can be changed up or down by turning the dose selector in either direction. When dialing back, be careful not to press the push button as growth hormone liquid will come out. **DO NOT use the clicking sound as a guide for selecting dose.**

The numbers on the residual scale can be used to estimate the mg left in the cartridge. **DO NOT use these numbers to measure the growth hormone dose.**

You cannot set a dose higher than the number of mg left in the cartridge. Use a new Norditropin NordiFlex® pen to inject the remaining amount of your dose. Be sure to remember the dose already received with the first dose. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.3 mg. You will need to inject an additional 0.3 mg with a new Norditropin NordiFlex® pen.

3 Giving the injection

Use the injection procedure recommended by your doctor or health care professional.

G. This product is for subcutaneous use only. Insert the needle into your thigh and deliver the dose by pressing the push button all the way in. Press the push button only when injecting.

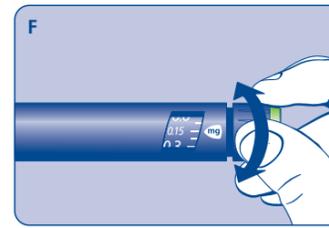
After the injection, the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle is removed from the skin. This will ensure that the full dose has been delivered. Vary the injection site on the thigh using the injection procedure recommended by your doctor.

4 Removing the needle

H. After the injection, remove the needle **without recapping** and dispose of it in a puncture-resistant container. Used needles should be placed in sharps container (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.

It is important that you use a new needle for each injection. Health care professionals, relatives and other caregivers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle stick.

When the cartridge is empty, throw away the Norditropin NordiFlex® without the needle attached.



5 Maintenance

Norditropin NordiFlex® should be handled with care. Protect Norditropin NordiFlex® from dust, dirt, and direct sunlight.

You can clean the outside of your Norditropin NordiFlex® by wiping it with a soft cloth moistened with water. Do not soak Norditropin NordiFlex® in alcohol, wash, or lubricate it.

6 Important Notes

- Store non-injected/unused Norditropin NordiFlex® pens in a refrigerator (2°C - 8°C/36°F - 46°F). After the initial injection, keep the pen refrigerated and use within 4 weeks.
- Remember to perform an air shot before each injection. See diagrams **C**, **D** and **E**.
- If you need to perform more than 6 air shots before the first use of the Norditropin NordiFlex® to get a droplet of growth hormone at the needle tip, **DO NOT** use the Norditropin NordiFlex®. Call 1-888-NOVO-444 for help.
- Take care not to drop the Norditropin NordiFlex®.
- **DO NOT** leave the Norditropin NordiFlex® in a car or other location where it can get too hot or too cold.
- Always have a spare Norditropin NordiFlex® disposable pen in order to avoid running out of this product.
- Norditropin NordiFlex® is designed to be used with NovoFine® disposable needles.
- **NEVER** place a NovoFine® needle on this Norditropin NordiFlex® until you are ready to use it. Remove the needle right after use without recapping.
- **Throw away used needles properly, so people will not be harmed.**
- Throw away the used Norditropin NordiFlex®, without the needle attached.
- To avoid spread of disease, do not let anyone else use your Norditropin NordiFlex®, even if you attach a new needle.
- Keep the Norditropin NordiFlex® out of the reach of children.
- **Novo Nordisk is not responsible for harm due to using the Norditropin NordiFlex® with products that are not recommended by Novo Nordisk.**

7 Warranty

If your Norditropin NordiFlex® is defective in materials or workmanship, 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, USA