

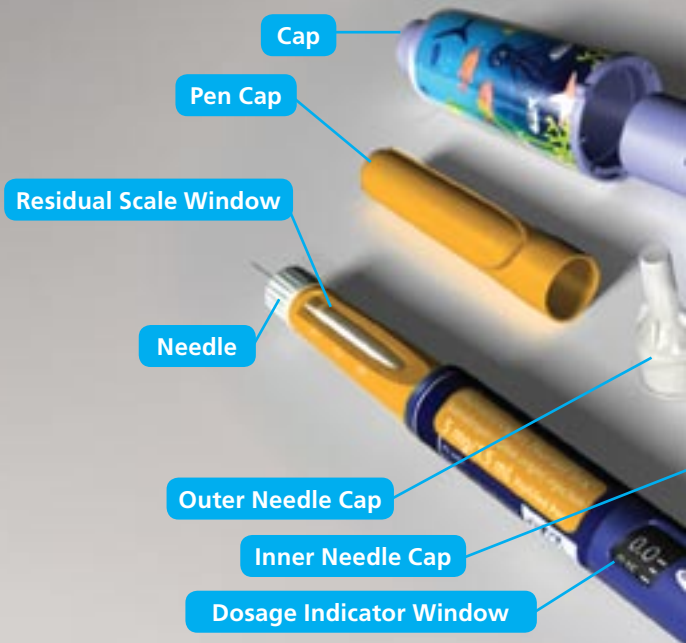
The NordiFlex PenMate®

An Auto-Insertion Accessory for
Your Norditropin NordiFlex® Pen

Designed and intended for use with Norditropin NordiFlex® 5 mg/1.5 mL, 10 mg/1.5 mL, and 15 mg/1.5 mL prefilled pens and NovoFine® disposable needles. Do not use Norditropin NordiFlex® 30 mg/3 mL pens with the NordiFlex PenMate® auto-insertion accessory.



norditropin®
somatropin (rDNA origin) injection



The Norditropin NordiFlex® Pen

Read these instructions carefully. You should use the NordiFlex PenMate® ONLY for the disposable Norditropin NordiFlex® pen, not for the nondisposable NordiPen®.

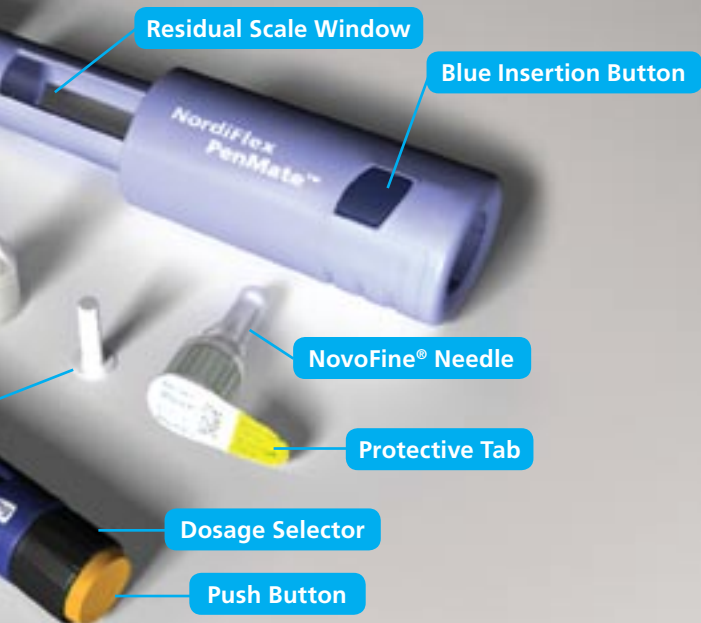
If you have any questions about the Norditropin NordiFlex® pen or the NordiFlex PenMate®, please call Novo Nordisk at 1-888-668-6444.

Step 1: Assembling the NordiFlex PenMate®

- Wash hands well and dry completely
- Remove the **Pen Cap** from the Norditropin NordiFlex® pen. **DO NOT** use it if the liquid is cloudy or contains particles. Use the Norditropin NordiFlex® pen **ONLY** if the solution is clear and colorless. To check this, turn the Norditropin NordiFlex® pen upside down once or twice and look at the liquid through the **Residual Scale Window**



The NordiFlex PenMate®



- Wipe the front rubber stopper on the **Needle Thread** with an alcohol swab before each injection with the NordiFlex PenMate®, even if you are still using the same Norditropin NordiFlex® pen
- Grasp the body of the NordiFlex PenMate® and insert the Norditropin NordiFlex® pen into the NordiFlex PenMate®. Next, turn the Norditropin NordiFlex® pen clockwise until you feel a “click.” The **Dose Indicator Window** should be set at 0.0 after assembly. The **Dosage Indicator Window** on the Norditropin NordiFlex® pen should be in line with the **Blue Insertion Button** on the NordiFlex PenMate®
- When it's time for injection, place a new NovoFine®* disposable needle onto the Norditropin NordiFlex® pen by removing the **Protective Tab** from the needle and screwing the needle tightly onto the Norditropin NordiFlex® pen. Always use a new NovoFine® needle for each injection



*Needles may require a prescription in some states.

- Pull off the **Outer Needle Cap** and keep it within reach; this cap will be used to remove the needle after injection. Carefully remove the **Inner Needle Cap** and dispose of it properly

Step 2: Performing an Air Shot

- You must perform an air shot before starting a new Norditropin NordiFlex® to ensure proper dosing and to avoid injecting air
- Perform an air shot by turning the **Dosage Selector** to the first hash mark after 0.0
 - 5 mg/1.5 mL—turn to 0.025
 - 10 mg/1.5 mL—turn to 0.05
 - 15 mg/1.5 mL—turn to 0.075
- Then, while holding the NordiFlex PenMate® with the needle pointing up, tap the pen gently with your finger a few times
- With the needle still pointing up, press the **Push Button** all the way in. A drop of liquid should appear at the needle tip. If not, repeat the procedure until a drop of liquid appears. If a drop of liquid does not appear after 4 attempts, call 1-888-668-6444 for help



Step 3: Preparing for Injection

- Firmly grip both the NordiFlex PenMate® and the Norditropin NordiFlex® pen and pull in opposite directions until you hear a “click”



Step 4: Setting the Dose and Giving the Injection

- Check that the **Dosage Selector** is set to 0.0. Dial the dose you need to inject by turning the **Dosage Selector** in either direction. When dialing back, be careful not to press the **Push Button** because liquid may come out
- If the Norditropin NordiFlex® pen is nearly empty, inject what you can dial. Then, with a new Norditropin NordiFlex® pen, dial and inject the rest of your full dose. Be sure to remember the quantity of product delivered in the first dose
- Use the injection procedure recommended by your health care professional. Injection site should always be rotated to avoid tissue damage
- Hold the NordiFlex PenMate® against your skin. Press the **Blue Insertion Button** with your finger. When this button is pushed, the NordiFlex PenMate® will automatically insert the needle into the skin
- Press the **Push Button** all the way, keeping it fully depressed with the needle under the skin for at least 6 seconds to ensure the full dose has been delivered
- While keeping the **Push Button** fully depressed, remove the needle from the skin



Step 5: Removing the Needle

- Remove the NovoFine® disposable needle by carefully replacing the **Outer Needle Cap** onto the needle immediately after your injection
- Hold the NordiFlex PenMate® firmly while you unscrew the NovoFine® disposable needle
- Place the used NovoFine® needle in a sharps container or other hard plastic or metal container
- Replace the NordiFlex PenMate® cap after use



How to Replace an Empty Norditropin NordiFlex® Pen

- When the Norditropin NordiFlex® pen is empty, turn the pen counterclockwise until you feel a “click,” and then gently pull the pen out of the NordiFlex PenMate®
- Dispose of the Norditropin NordiFlex® pen properly, without the needle attached
- With a new Norditropin NordiFlex® pen, assemble the NordiFlex PenMate® as described in Step 1



Personalizing Your NordiFlex PenMate®

- Between the **Outer Cap** and the **Inner Cap**, place a drawing or photograph to give your NordiFlex PenMate® a personal look
- You can cut out the illustrations provided with the pen, create a drawing yourself, or download additional illustrations from norditropin-us.com for printing and application



NordiCare® Comprehensive Support Services

Novo Nordisk is committed to setting the course for a smooth process that's as easy as our pen. We offer the comprehensive support services of NordiCare® to anyone who uses Norditropin NordiFlex® or NordiPen® delivery systems.

We want to help you get started on therapy as soon as possible and stay on therapy through the course of your treatment period. A dedicated Case Manager will help make the process smooth. Contact us at 1-888-668-6444 to learn more about our service offerings.

Customer Satisfaction

Customer service and satisfaction are our top concerns. If you have any questions about Norditropin NordiFlex® prefilled pens or the NordiFlex PenMate®, please call Novo Nordisk Inc. at 1-888-668-6444.

Important Things to Know

- Do not use Norditropin NordiFlex® 30 mg/3 mL pens with the NordiFlex PenMate® auto-insertion accessory
- 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 the help of 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
- Remember to perform an air shot before starting a new Norditropin NordiFlex® or before the injection if you dropped or knocked the pen against a hard surface
- 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® disposable needles
- **Novo Nordisk is not responsible for harm due to using NordiFlex PenMate® and Norditropin NordiFlex® with products that are not recommended by Novo Nordisk**
- **DO NOT** leave Norditropin NordiFlex® in a car or other location where it can get too hot or too cold
- Norditropin NordiFlex® is designed to be used with NovoFine® disposable needles
- **To avoid spread of disease, do not let anyone else use your Norditropin NordiFlex®, even if you attach a new needle**

Norditropin® is available only by prescription.

Novo Nordisk provides its medicines, including Norditropin®, for free or at a discount to certain people who do not have prescription drug or health insurance coverage and who, without assistance, cannot afford the medicines Novo Nordisk makes. Please call 866-310-7549 to learn more about Novo Nordisk assistance programs.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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 inside the cover.

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Printed in the U.S.A. 136103R1 July 2009



norditropin[®]

somatropin (rDNA origin) injection

PATIENT INFORMATION

Norditropin[®] (Nor-dee-tro-pin) (somatropin [rDNA origin] injection)

Read the Patient Information that comes with Norditropin[®] before you start to take it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is Norditropin[®]?

Norditropin[®] is a prescription medicine given by injection under the skin (subcutaneous) that contains human growth hormone, identical to the growth hormone produced in the human body, used to treat:

- children who are not growing because of low or no growth hormone
- children who are short (in stature) and who have Noonan syndrome or Turner syndrome
- children who are short (in stature) because they were born small (small for gestational age-SGA) and have not caught-up in growth by age 2 to 4 years
- adults who do not make enough growth hormone

Who should not use Norditropin[®]?

Do not use Norditropin[®] if:

- you have a critical illness caused by certain types of heart or stomach surgery, trauma or breathing (respiratory) problems
- you are a child with Prader-Willi syndrome who is severely obese or has breathing problems including sleep apnea
- you have cancer or other tumors
- your healthcare provider tells you that you have certain types of eye problems caused by diabetes
- you are a child with closed bone growth plates (epiphyses)
- you are allergic to any of the ingredients in Norditropin[®]. See the end of this leaflet for a complete list of ingredients in Norditropin[®].

What should I tell my healthcare provider before I start Norditropin[®]?

Before you take Norditropin[®], tell your healthcare provider if you:

- have diabetes
- had cancer or any tumor
- have any other medical condition
- are pregnant or plan to become pregnant. It is not known if Norditropin[®] will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed. It is not known if Norditropin[®] passes into your breast milk. You and your healthcare provider should decide if you will take Norditropin[®] while you breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Norditropin[®] may affect how other medicines work, and other medicines may affect how Norditropin[®] works.

Especially tell your healthcare provider if you take:

- glucocorticoid medication
- thyroid hormone
- insulin or other medicine for diabetes
- medicines that are metabolized by the liver
- estrogen replacement medicines

Ask your healthcare provider if you are not sure if any of your medicines are the kind listed above. Keep a list of your medicines with you and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use Norditropin[®]?

- Read the detailed Instructions for Use that come with Norditropin[®]. Your healthcare provider will show you how to inject Norditropin[®].
- Take Norditropin[®] exactly as prescribed.
- **Norditropin[®] FlexPro[®] pens, NordiFlex[®] pens and cartridges are for use by one person only.**
- Novo Nordisk disposable needles are designed to be used with Norditropin[®] for each injection.
- Always keep the pen cap closed on Norditropin[®] when you are not using it.
- **Norditropin[®] comes in 3 dose strengths for FlexPro[®] prefilled color coded pens, 4 dose strengths for NordiFlex[®] prefilled color coded pens, and 2 dose strengths for color coded cartridges.**
- If you inject too much Norditropin[®], call your healthcare provider.
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time. Do not take 2 doses at the same time unless your healthcare provider tells you to. If you are not sure about your dosing, call your healthcare provider.
- Throw away Norditropin[®] when the cartridge is empty.
- Refer to the Instructions for Use about what to do if you have less than a full dose left in your pen.

What are the possible side effects of Norditropin[®]?

Norditropin[®] can cause serious side effects, including:

- high risk of death in people who have critical illnesses because of heart or stomach surgery, trauma or serious breathing (respiratory) problems
- high risk of death in children with Prader-Willi syndrome who are severely obese or have breathing problems, including sleep apnea
- return of tumor or cancerous growths
- high blood sugar (hyperglycemia)
- increase in pressure in the skull (intracranial hypertension). If you have headaches, eye problems, nausea or vomiting, contact your healthcare provider right away.
- swollen hands and feet due to fluid retention
- decrease in thyroid hormone levels. Your healthcare provider will do blood tests to check your thyroid hormone levels.
- hip and knee pain or a limp in children (slipped capital femoral epiphysis)
- worsening of curvature of the spine (scoliosis)
- middle ear infection, hearing problems or ear problems in patients with Turner syndrome
- redness, itching and tissue weakness in the area you inject
- increase in phosphorus, alkaline phosphatase and parathyroid hormone levels in your blood. Your healthcare provider will do blood tests to check this.

The most common side effects of Norditropin[®] include:

- headaches
- muscle pain
- joint stiffness
- 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

Talk to your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Norditropin[®]. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 (1-800-332-1088). You may also report side effects to Novo Nordisk at 1-888-NOVO-444 (1-888-668-6444).

How do I store Norditropin[®]?

Unused Norditropin[®] FlexPro[®] and NordiFlex[®] pens, and cartridges:

- Keep in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Do not freeze or expose Norditropin[®] to heat.

- Keep Norditropin[®] away from direct light.
- Do not use Norditropin[®] that has been frozen or in temperatures warmer than 77°F (25°C).
- Do not use Norditropin[®] after the expiration date printed on the carton and the pen or cartridge.

After the first injection

- Norditropin[®] FlexPro[®], NordiFlex[®] and cartridge 5 mg/1.5 mL (orange):
 - **either** store in the refrigerator between 36°F to 46°F (2°C to 8°C) and use within 4 weeks
 - **or** keep for up to 3 weeks at no warmer than 77°F (25°C).
 - **Throw away any unused medicine.**
- Norditropin[®] FlexPro[®] and NordiFlex[®] 10mg/1.5mL (blue):
 - **either** store in the refrigerator between 36°F to 46°F (2°C to 8°C) and use within 4 weeks.
 - **or** keep for up to 3 weeks at no warmer than 77°F (25°C).
 - **Throw away any unused medicine.**
- Norditropin[®] FlexPro[®], NordiFlex[®] and cartridge 15 mg/1.5 mL (green):
 - store in the refrigerator between 36°F to 46°F (2°C to 8°C) and use within 4 weeks
 - **Throw away any unused medicine after 4 weeks.**
- Norditropin[®] NordiFlex[®] pens 30 mg/3 mL (purple):
 - store in the refrigerator between 36°F to 46°F (2°C to 8°C) and use within 4 weeks
 - **Throw away any unused medicine after 4 weeks.**

General Information about Norditropin[®].

Medicines are sometimes prescribed for purposes other than those listed in Patient Information. Do not use Norditropin[®] for a condition for which it was not prescribed. Do not give Norditropin[®] to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information summarizes the most important information about Norditropin[®]. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Norditropin[®] that is written for healthcare professionals.

What are the ingredients in Norditropin[®]?

Active ingredient: somatropin (rDNA origin)

Inactive ingredients: Histidine, Poloxamer 188, Phenol, Mannitol, HCl/NaOH (as needed) and Water for Injection

Date of Issue: March 2, 2010

Version: 7

US Patent Nos. 6,235,004; 6,004,297; 6,582,404; 6,716,198; 6,899,699; 5,849,704; 5,691,169; 5,618,697 and other patents pending.

Norditropin[®], FlexPro[®], and Norditropin NordiFlex[®] are registered trademarks of Novo Nordisk Health Care AG.

Novo Nordisk[®] is a registered trademark of Novo Nordisk A/S.

For assistance or further information, write to:

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Princeton, NJ 08540, USA
1-888-NOVO-444 (1-888-668-6444)
norditropin-us.com

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