

Your Norditropin NordiFlex® Pen

Simple Steps for Use



norditropin®
somatropin (rDNA origin) injection

The Norditropin NordiFlex® Pen



Please read these instructions carefully before using this device. If you have any questions about the Norditropin NordiFlex® pen, please call Novo Nordisk at 1-888-NOVO-444.

Step 1: Preparing the Pen

- 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**
- Wipe the front rubber stopper on the **Needle Thread** with an alcohol swab before each injection
- Remove the **Protective Tab** from a NovoFine®* single-use needle and screw it onto the prefilled Norditropin NordiFlex® pen. Always use a new NovoFine® needle for each injection
- Remove both the **Outer Needle Cap** and **Inner Needle Cap**



*Needles may require a prescription in some states.

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
 - 30 mg/3 mL—turn to 0.100
- Then, while holding the pen with the needle pointing up, tap the pen gently with your finger a few times
- With the needle still pointing upward, 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 does not appear after 4 attempts, call 1-888-NOVO-444 for help



Step 3: Setting the Dose

- Check that the **Dosage Selector** is set at 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 pen, dial and inject the rest of your full dose. Be sure to remember the quantity of product delivered in the first dose



Step 4: Giving the Injection

- Use the injection procedure recommended by your health care professional. Injection site should always be rotated to avoid tissue damage
- Push the needle under the skin, using the injection technique recommended by your doctor or health care professional
- 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
- The dose scale will reset to 0.0



Step 5: Removing the Needle From the Pen

- Remove the NovoFine® needle from the pen, without recapping it to avoid needle stick injury
- Place the NovoFine® needle in a sharps container or other hard plastic or metal container
- Put the **Pen Cap** back on the pen for storage
- If the pen is empty, remove the needle from the pen, and dispose of the needle and pen separately and appropriately



Step 6: Maintenance

- Protect your Norditropin NordiFlex® pen from dust, dirt, and direct sunlight
- Clean the outside of your Norditropin NordiFlex® pen by wiping it with a soft cloth moistened with water
- Do not wash or lubricate the Norditropin NordiFlex® pen or soak it in alcohol

Later Injections

To inject your next dose of Norditropin® with the Norditropin NordiFlex® pen, simply follow steps 1 through 5, making sure to:

- Use a new NovoFine® needle for each injection
- Dispose of NovoFine® needles appropriately in a sharps container or other hard plastic or metal container
- Never freeze the liquid
- Handle your Norditropin NordiFlex® pen with care
- Store your Norditropin NordiFlex® pen appropriately
- Call Novo Nordisk with any questions and/or concerns

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-NOVO-444 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-NOVO-444.

How to Store the Norditropin NordiFlex® Pen

Storage flexibility* for Norditropin NordiFlex®

Norditropin NordiFlex® (somatropin (rDNA origin) injection)	Before use Always Refrigerate 36°F-46°F	After first use	
		Refrigerate Store for 4 weeks at 36°F-46°F	OR Do Not Refrigerate Store for 3 weeks at up to 77°F
5 mg/ 1.5 mL	✓	✓	✓
10 mg/ 1.5 mL	✓	✓	✓
15 mg/ 1.5 mL	✓	✓	Does not apply
30 mg/ 3 mL	✓	✓	Does not apply

*All Norditropin® products must be refrigerated prior to use. Do not freeze. After initial use, Norditropin NordiFlex® 5 mg/1.5 mL and 10 mg/1.5 mL delivery pens can either be stored outside of the refrigerator (at up to 77°F) for use within 3 weeks, or in the refrigerator (between 36°F and 46°F) for use within 4 weeks. These storage flexibility guidelines also apply to Norditropin® cartridge 5 mg/1.5 mL, Norditropin NordiFlex® 15 mg/1.5 mL and Norditropin NordiFlex® 30 mg/3 mL delivery pens must always be refrigerated (between 36°F and 46°F)—both prior to and after the initial injection—for use within 4 weeks. These guidelines for continuous refrigerated storage also apply to Norditropin® cartridge 15 mg/1.5 mL.

Important Things to Know

- Norditropin NordiFlex® 30 mg/3 mL cannot be used with the NordiFlex PenMate® auto-insertion accessory
- Store unused Norditropin NordiFlex® pens in a refrigerator (2°C - 8°C/36°F - 46°F). After the initial injection, Norditropin NordiFlex® 5 mg/1.5 mL and 10 mg/1.5 mL delivery pens can either be stored outside of the refrigerator (at up to 77°F) for use within 3 weeks, or in the refrigerator (between 36°F and 46°F) for use within 4 weeks. Norditropin NordiFlex® 15 mg/1.5 mL and Norditropin NordiFlex® 30 mg/3 mL delivery pens must always be refrigerated (between 36°F and 46°F)—both prior to and after the initial injection—for use within 4 weeks
- 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
- If you need to perform more than 4 air shots before the first use of Norditropin NordiFlex® to get a droplet of liquid at the needle tip, **DO NOT** use Norditropin NordiFlex®. Call 1-888-NOVO-444 for help
- Take care not to drop Norditropin NordiFlex® or knock it against a hard surface
- 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® 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 needle on Norditropin NordiFlex® until you are ready to use it. Remove the needle right after use without recapping
- Dispose of 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**

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.

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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

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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.

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For assistance or further information, write to:

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