

FlexPro[®]

Quick Reference

This is not the complete FlexPro[®] Instructions for Use. This guide should be used in conjunction with your FlexPro[®] Instructions for Use, which is available by contacting NordiCare[®].

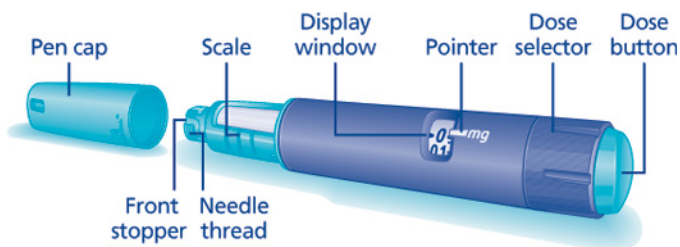


norditropin[®]
somatropin (rDNA origin) injection

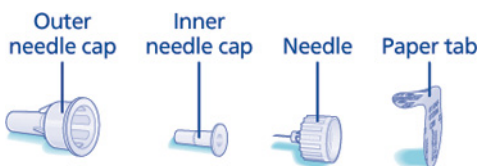
FlexPro®

Quick Reference

Device Features



Needle (example)




Norditropin® is only available by prescription. For more information about Norditropin®, please visit norditropin-us.com.

Novo Nordisk provides patient assistance for those who qualify. Please call **1-866-310-7549** 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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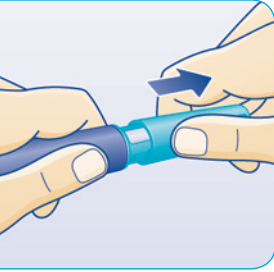
Novo Nordisk Inc., 100 College Road West, Princeton, New Jersey 08540 U.S.A.

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Step 1

Preparing the Pen

Never prepare your FlexPro[®] pen with a disposable needle until you are ready to give an injection.



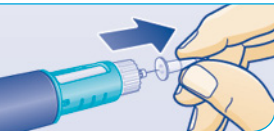
- Pull off pen cap. Check that liquid in pen is clear and colorless. **If the liquid looks unclear or cloudy, do not use the pen.**
- With clean, dry hands, wipe the **front stopper** on the **needle thread** with an alcohol swab.



- Tear the **paper tab** off of a new disposable needle. Screw the needle straight onto the pen tightly. **Always use a new needle for each injection. This will help prevent contamination.**



- Pull off the **outer needle cap** and the **inner needle cap** and throw them away.



Step 2

Performing an Air Shot

Before you inject your first dose using a new FlexPro[®] pen, you must check the medication flow by performing an air shot.

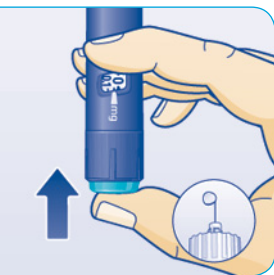


10 mg/1.5 mL pen is shown.

- Turn the **dose selector** to the smallest amount of medicine for your pen.
 - For the 5 mg/1.5 mL (orange) pen, this is 0.025 mg
 - For the 10 mg/1.5 mL (blue) pen, this is 0.05 mg
 - For the 15 mg/1.5 mL (green) pen, this is 0.1 mg



- Hold the pen with the **needle** pointing up. Tap the pen gently to let any air bubbles rise to the top.



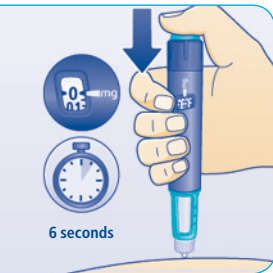
- Press the **dose button** until the "0" in the **display window** lines up with the **pointer** and a drop of liquid appears at the needle tip.
- If no drop appears, repeat the air shot up to 6 times. If no drop appears, you may change the needle and perform an air shot **one more time**. If a drop of liquid still does not appear, call 1-888-NOVO-444 (1-888-668-6444) for help.

Step 3

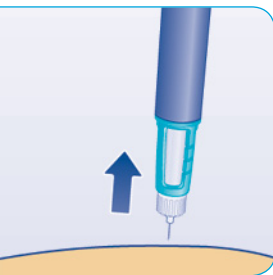
Select and Inject Your Dose



- Select the dose you need by turning the **dose selector** forward or backward until the right number in the **display window** lines up with the **pointer**.
- If there is not enough Norditropin® left in the pen to deliver your full dose, you may deliver the amount left in the pen. Then, inject the remainder of your dose using a new FlexPro® pen, prepared as described in steps 1 and 2.



- It is generally accepted practice to swab the injection site before injecting.
- Insert the **needle** into your skin as your health care provider has shown you.
- Press and hold the **dose button** to inject until the "0" in the **display window** lines up with the **pointer**. You may hear or feel a firm click.
- After the "0" in the **display window** lines up with the **pointer**, leave the needle in your skin **for at least 6 seconds** to make sure you get your full dose.



- Remove the needle from your skin. You may see a drop of liquid at the needle tip. This is normal and does not affect the dose you received.
- After injection, you must remove the needle right away. Unscrew the needle and throw away the needle and any empty FlexPro® pen as directed by your health care professional.
- You can store all FlexPro® pens that have been used at least once in the refrigerator for 4 weeks. If you choose, the 5 mg/1.5 mL (orange) pen and the 10 mg/1.5 mL (blue) pen may also be stored at room temperature (up to 77 degrees F) after first use for 3 weeks. The 15 mg/1.5 mL (green) pen must be stored in the refrigerator at all times.

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.

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For assistance or further information, write to:

Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540, USA
1-888-NOVO-444 (1-888-668-6444)
norditropin-us.com

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

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