

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 1-888-668-6444.

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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For assistance or further information, write to:
Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540, USA
1-888-668-6444
norditropin-us.com



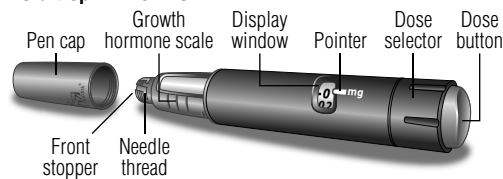
INSTRUCTIONS FOR USE

Norditropin® FlexPro® (somatropin [rDNA origin] injection)

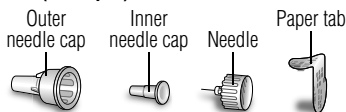
15 mg/1.5 mL (green) Prefilled Pen

Read these instructions before using your Norditropin® FlexPro® pen.

Norditropin® FlexPro®



Needle (example)

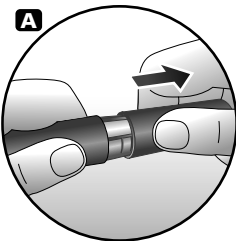


Norditropin® FlexPro® contains 15 mg human growth hormone solution and delivers doses from 0.1 mg to 8 mg, in increments of 0.1 mg. Norditropin® FlexPro® is made to be used with Novo Nordisk® disposable needles. Needles are not included with Norditropin® FlexPro®.

Prepare your Norditropin® FlexPro® pen

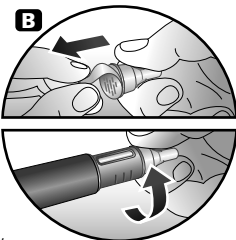
A.

- Pull off the pen cap.
- Check that the liquid in the pen is clear and colorless by tipping it upside down 1 or 2 times. If the liquid looks unclear or cloudy, do not use the pen.
- Wash hands well and dry them.
- Wipe the front stopper on the needle thread with an alcohol swab



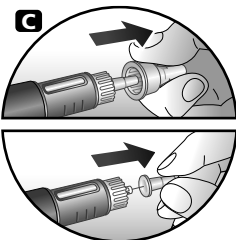
B.

- Take a new disposable needle.
- Tear the paper tab off and screw the needle straight onto the pen.
- Make sure the needle is on tight.
- Never place a disposable needle on your Norditropin® FlexPro® pen until you are ready to give an injection.



C.

- Pull off the outer needle cap and inner needle cap and throw them both away.
- If you try to put the needle caps back on, you may accidentally hurt yourself with the needle.
- A drop of liquid may appear at the needle tip. This is normal.



Important:

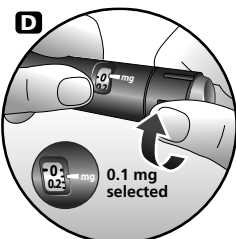
- **Always use a new needle for each injection. This will help prevent contamination.**
- **Never bend or damage the needle.**

Check the growth hormone flow (airshot)

Make sure that you receive your full dose by checking the growth hormone flow (performing an airshot) before you select and inject your first dose from a new pen.

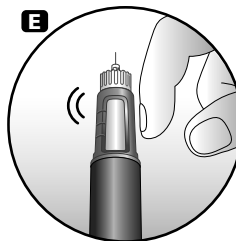
D.

Turn the dose selector to select 0.1 mg. This is the smallest amount of medicine for a dose.



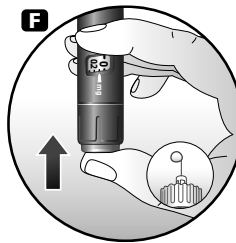
E.

- Hold the pen with the needle pointing up.
- Tap the top of the pen gently a few times to let any air bubbles rise to the top.



F.

- 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 steps D, E, and F up to 6 times.
- If no drop appears after these attempts, change the needle and repeat steps D, E, and F one more time.
- **If a drop of liquid still does not appear, call (1-888-668-6444) for help.**



Important:

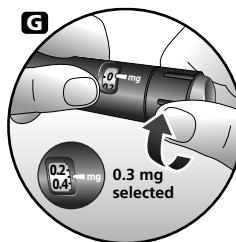
- **Be careful not to drop Norditropin® FlexPro® pen or knock it against a hard surface. If this happens you will need to repeat the airshot.**
- **Always make sure that a drop appears at the needle tip after completing your airshot.**

Select your dose

Use the dose selector on your Norditropin® FlexPro® pen to make sure you have the exact dose selected. You can select up to 8 mg per dose.

G.

- Select or adjust the dose you need by turning the dose selector forwards or backwards until the right number of mg lines up with the pointer.
- When dialing back, be careful not to press the dose button as liquid will come out.
- To guide you, the dose selector clicks differently when turned forwards, backwards or past the number of mg that is left in the pen.
- When the pen has less than 8 mg, the dose selector stops at the number of mg that is left in the pen.



How much growth hormone is left in the pen?

You can use the growth hormone scale to see how much growth hormone is left in the pen.

You can use the dose selector to see exactly how much growth hormone is left in the pen. If the pen contains less than 8 mg, turn the dose selector until it stops. The figure that lines up with the pointer shows how many mg are left in the pen.

- You cannot set a dose higher than the number of mg left in the pen.
- If there is not enough Norditropin® left in the pen to deliver your full dose, use a new Norditropin® FlexPro® pen to inject the remaining amount of your dose or contact your healthcare provider.
- Be sure to subtract the dose already received. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.3 mg, you should inject another 0.3 mg with a new Norditropin® FlexPro® pen.

Important:

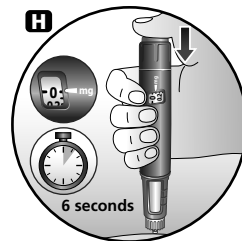
- **Never use the pen clicks to count the number of mg you select. Only the display window and pointer will show the exact number.**
- **Never use the growth hormone scale to measure how much liquid to inject. Only the display window and pointer will show the exact number.**

Inject your dose

Make sure that you receive your full dose by using the injection technique recommended by your healthcare provider. This medicine is injected under your skin (subcutaneous) only.

H.

- Insert the needle into your skin as your healthcare provider has shown you.
- Press and hold the dose button to inject until the "0" in the display window lines up with the pointer. As you do this, you may hear or feel a firm click.



If "0" does not appear in the display window, you did not receive the full dose. Call (1-888-668-6444) for assistance.

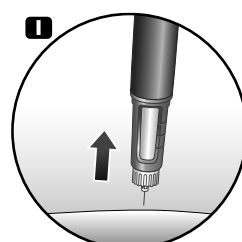
- After the "0" in the display window lines up with the pointer, leave the needle under the skin for at least **6 seconds** to make sure that you get your full dose. You can let go of the dose button while you wait.
- Change the injection site using the injection procedure recommended by your healthcare provider.

Important:

- **Always press the dose button to inject the dose. Turning the dose selector will not inject the dose.**
- **Never touch the display window when you inject, as this can block the injection.**

I.

- Remove the needle from your skin. After that, you may see a drop of liquid at the needle tip. This is normal and does not affect the dose you received.
- After the injection, remove the needle right away and put the pen cap back on. If the needle is not removed, some liquid may come out of the Norditropin® FlexPro®.
- Unscrew the needle and throw away the needle and any empty Norditropin® FlexPro® pen as directed by your healthcare provider. A special "sharps" container (such as a red biohazard container), a hard plastic container (such as an empty detergent bottle), or a metal container (such as an empty coffee can) should be used. The container should be sealed and disposed of properly.
- Caregivers should be most careful when handling used needles to avoid hurting themselves.



Care for your Norditropin® FlexPro® pen

You must take care of your Norditropin® FlexPro® pen:

- Do not drop your pen or knock it against hard surfaces. If you do drop it or think that something is wrong with it, always screw on a new disposable needle and check the growth hormone flow (airshot) before you inject.
- Do not try to refill your disposable pen – it is prefilled.
- Do not try to repair your pen or pull it apart.
- Do not expose your pen to dust, dirt or any kind of liquid.
- Do not try to wash, soak or lubricate your pen. You may clean the Norditropin® FlexPro® pen with a mild detergent on a moistened cloth. See section "How do I store Norditropin®?" above for information about how to store your pen.
- Always keep your pen and needles out of reach of others, especially children.
- Never share your needles and pen with anyone.

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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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Manufactured by:
Novo Nordisk A/S
DK-2880 Bagsvaerd, Denmark
140983 3/10

