

Answering Patient and Caregiver Questions

answering patient and caregiver questions about pediatric growth hormone therapy

Patients and caregivers usually have many questions about growth hormone-related disorders and their treatment. Below is a list of some of these

questions and possible responses in terminology patients may understand. You can also [download and print](#) a version of this Patient FAQ.

How are growth hormone-related disorders treated?

Diagnosis of a specific condition will determine how a doctor approaches treatment. Many growth hormone disorders can be treated effectively. Norditropin® is a recombinant human growth hormone indicated for treatment of children with growth failure due to growth hormone deficiency (GHD), short stature associated with Noonan syndrome, short stature associated with Turner syndrome, and short stature born small for gestational age (SGA) with no catch-up growth by age 2-4 years, as well as the treatment of adults with either adult onset or childhood onset GHD.

Which delivery devices should you choose?

There are many devices available for the delivery of growth hormone therapy. Your physician can help you decide which device is best for you. FlexPro® devices are convenient and easy to use, providing patients with the first prefilled, preloaded, multi-dose delivery pen that does not require refrigeration.*

FlexPro® is supported by NordiCare® programs designed to improve your treatment experience.

[Learn More](#)

The Norditropin® Device Pledge



If, after filling three paid prescriptions for Norditropin®, your patient is not satisfied with his or her pen, Novo Nordisk will pay up to \$125 of the patient's first copay for a competing medication.†

* All Norditropin® products must be refrigerated prior to first use. Do not freeze. After initial use, FlexPro® 5 mg/1.5 mL and 10 mg/1.5 mL delivery pens and 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 three weeks, or in the refrigerator (between 36°F and 46°F) for use within four weeks. These storage flexibility guidelines also apply to Norditropin® cartridge 5 mg/1.5 mL. FlexPro® 15 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°and 46°F) - both prior to and after the initial injection – for use within four weeks. These guidelines for continuous refrigerated storage also apply to Norditropin® cartridge 15

mg/1.5 mL.

† Norditropin® Device Pledge Terms and Conditions

Patients must be new to therapy with Norditropin®, but could have previously taken a competing product. Patients receiving copay assistance with NordiSure™ are eligible. Patients must provide proof of three paid months of therapy with Norditropin® in compliance with their treatment plan, proof of purchase of a competing product, and a letter stating the reason why they are dissatisfied. Offer expires 60 days after the date of the last script filled by a pharmacy. Patients cannot be receiving copay assistance or a free product from the manufacturer of a competing product. Novo Nordisk reserves the right to rescind, revoke, or amend this offer without notice at any time. This offer is not valid for individuals who are covered by Medicaid or Medicare and in certain states. Not valid for residents of Massachusetts. Offer good only in the United States.

What is Norditropin®?

Norditropin® is recombinant growth hormone that has been produced by Novo Nordisk. It contains the identical sequence of 191 amino acids constituting the naturally occurring pituitary human growth hormone.⁴

How will I know how to give the injection?

There are many educational materials available to explain how to give your growth hormone injection. Each Norditropin® Starter Kit from Novo Nordisk contains an instructional video and booklet on using Norditropin®. If you still have questions after watching the video and reading the brochure, your nurse or doctor can answer them. Your doctor and nurse are always the best source of medical information.

How should I inject my growth hormone?

Always follow your doctor's and nurse's instructions for taking any medication, including your growth hormone. The video and brochure in the Norditropin® Starter Kit give clear directions on how to use Norditropin® products. More information is also available in the NordiFlex™ and FlexPro® Instructions for Use.

Your doctor will probably tell you to inject the growth hormone every evening just before bedtime. After you take your injection, always dispose of the needles properly. Remove the needle without recapping and then carefully put it in the sharps container such as the one included in your Norditropin® Starter Kit.

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 injuries. When the cartridge is empty, throw away NordiFlex™ without the needle attached.

Please refer to the [Important Safety Information for more information](#)

No one LIKES needles. Maybe needles scare me. What can I do?

If you don't like needles, ask your doctor if the NordiFlex PenMate™ is right for you. With the NordiFlex PenMate™, the needle is hidden from sight during injection. The NordiFlex PenMate™ also has an insertion button that allows the needle to be automatically inserted quickly with a single touch. The NordiFlex PenMate™ cannot be used with the 30 mg/3 mL pen. PenMate™ is not yet available for FlexPro®.

What happens if I leave my Norditropin® delivery pen in an area that gets warmer than 77°F?

If you leave your Norditropin® 5 mg/1.5 mL delivery pen or 10 mg/1.5 mL delivery pen in an area that gets warmer than 77°F, call your health care provider or NordiCare® representative at 1-888-668-6444 before you use it again. They will let you know what to do.

Remember that all Norditropin® products must be refrigerated prior to first use. Do not freeze. After initial use, FlexPro® 5 mg/1.5 mL and 10 mg/1.5 mL delivery pens and 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 three weeks, or in the refrigerator (between 36°F and 46°F) for use within four weeks. These storage flexibility guidelines also apply to Norditropin® cartridge 5 mg/1.5 mL, FlexPro® 15 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°and 46°F) - both prior to and after the initial injection – for use within four weeks. These guidelines for continuous refrigerated storage also apply to Norditropin® cartridge 15 mg/1.5 mL.

Please refer to the [Important Safety Information](#) for more information

How long will my child have to continue taking Norditropin®?

The amount of time a child should take Norditropin® can vary. Check with your doctor to see how long your child is likely to need Norditropin®.

Will the Norditropin® dose change?

Your doctor will advise you if he/she believes your child's Norditropin® dose should be adjusted at any point during treatment.

Where can I give the Norditropin® injections?

Follow the instructions your health care provider gave you for injecting Norditropin®, including where to give the injections. Remember to rotate injection sites to avoid skin irritation.¹

Please refer to the [Important Safety Information](#) for more information

When and how do I order more medicine?

Check with the pharmacy that delivers your Norditropin® to find out when you should order more Norditropin® and how to place the order.

What's the best time of day to give the medication?

You should inject Norditropin® under the skin in the evening just before bedtime.

Should Norditropin® be taken if I have a cold or I don't feel well?

Many people mistakenly believe that growth hormone injections should not be given when someone is sick, has a cold, or is taking antibiotics. Talk to your doctor or pharmacist about taking other medications with Norditropin®. Unless your doctor tells you otherwise, you should make every effort to try not to miss any days.

If you are hospitalized due to an illness, be sure to tell the hospital that you take Norditropin® injections.

Will the injection hurt?

NovoFine® disposable needles, which are recommended for use with Norditropin® products, were designed with comfort in mind. Their walls are very thin and they are electropolished and silicone coated to be extremely smooth. A majority of patients using the NovoFine® 32-gauge Tip needle experience little or no pain. NovoFine® needles may require a prescription in some states.

How hard do I need to push when giving an injection?

Norditropin® delivery pens are designed with an easy-to-push button that allows the needle to be automatically inserted quickly with a single touch.

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); swollen hands and feet due to fluid retention; decrease in thyroid hormone levels; hip and knee pain or a limp in children (slipped capital femoral epiphysis); worsening of pre-existing curvature of the spine (scoliosis); middle ear infection, hearing problems or ear problems in patients with Turner syndrome.

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, and redness and itching in the area you inject. If you have headaches, eye problems, nausea or vomiting (these may be symptoms of raised pressure in the brain), contact your healthcare provider right away.

Please refer to the [Important Safety Information](#) for more information

What interactions will Norditropin® have with other medications?

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; a thyroid hormone; insulin and/or oral diabetes medication; drugs metabolized by the liver, such as corticosteroids, sex steroids, anticonvulsants, or cyclosporine; or an oral estrogen replacement.¹

An undiagnosed/untreated hypothyroidism and excessive use of glucocorticoid use may prevent an optimal response to Norditropin®.¹ If you are treated with insulin/oral diabetes medicine, your insulin/oral diabetes medicine dose may need to be adjusted.¹

Please refer to the [Important Safety Information](#) for more information

How many individual doses of Norditropin® are in each pen?

The number of individual doses of Norditropin® varies depending on your dose and the milligram size of your pen.

How much does the medication cost?

The cost of Norditropin® varies depending on your health insurance. Check with your provider to see if you are covered for Norditropin®, and if so, what your copay will be. If you have issues regarding insurance coverage or reimbursement, please contact the NordiCare® patient support program at 1-888-668-6444 Monday through Friday between the hours of 8 AM and 8 PM EST.

How do I store Norditropin®?

Please follow the instructions below:

Storage Flexibility for Norditropin®:

Remember that all Norditropin® products must be refrigerated prior to first use. Do not freeze. After initial use, FlexPro® 5 mg/1.5 mL and 10 mg/1.5 mL delivery pens and 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 three weeks, or in the refrigerator (between 36°F and 46°F) for use within four weeks. These storage flexibility guidelines also apply to Norditropin® cartridge 5 mg/1.5 mL, FlexPro® 15 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° and 46°F) - both prior to and after the initial injection – for use within four weeks. These guidelines for continuous refrigerated storage also apply to Norditropin® cartridge 15 mg/1.5 mL.

Please refer to the [Important Safety Information](#) for more information

How do I dispose of the needles?

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.

Who do I contact if there is something wrong with my pen?

For assistance with your Norditropin® delivery device, please call us at our toll-free number at 1-888-668-6444.

Are there any special preparations that I need to take when traveling with Norditropin®?

Novo Nordisk recommends that you always travel with a spare delivery pen in order to avoid running out of Norditropin®.¹ When traveling always follow the appropriate storage conditions.

If you are traveling by air please note that growth hormone is affected by extreme temperatures and therefore should not be stored in checked luggage. Please carry your Norditropin® on you. To insure a smooth travel and pass through security please obtain a travel letter from your health care provider.

References

1. Norditropin NordiFlex® 30 mg/3.0 mL [instructions for use]. Princeton, NJ: Novo Nordisk Inc; 2010.

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.

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For assistance or further information, write to:

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