

Package leaflet: Information for the user

Norditropin SimpleXx 10 mg/1.5 ml solution for injection in cartridge somatropin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What Norditropin SimpleXx is and what it is used for**
2. **What you need to know before you use Norditropin SimpleXx**
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1. What Norditropin SimpleXx is and what it is used for

Norditropin SimpleXx contains a biosynthetic human growth hormone called somatropin which is identical to the growth hormone produced naturally in the body. Children need growth hormone to help them grow, but adults also need it for their general health.

Norditropin SimpleXx comes as a solution in a cartridge ready for you to inject after you have put it in the matching NordiPen injection pen.

Norditropin SimpleXx is used to treat growth failure in children:

- If they have no or very low production of growth hormone (growth hormone deficiency)
- If they have Turner syndrome (a genetic problem which may affect growth)
- If they have reduced kidney function
- If they are short and were born small for gestational age (SGA)
- If they have Noonan syndrome (a genetic problem which may affect growth).

Norditropin SimpleXx is used as a growth hormone replacement in adults:

In adults Norditropin SimpleXx is used to replace growth hormone if their growth hormone production has been decreased since childhood or has been lost in adulthood because of a tumour, treatment of a tumour, or a disease that affects the gland which produces growth hormone. If you have been treated for growth hormone deficiency during childhood, you will be retested after completion of growth. If growth hormone deficiency is confirmed, you should continue treatment.

2. What you need to know before you use Norditropin SimpleXx

Do not use Norditropin SimpleXx

- If you are **allergic** to somatropin, to phenol, or to any of the other ingredients of this medicine (listed in section 6)
- If you have had a **kidney transplant**
- If you have an **active tumour (cancer)**. Tumours must be inactive and you must have finished your antitumour treatment before you start your treatment with Norditropin SimpleXx
- If you have an **acute critical illness** e.g. open heart surgery, abdominal surgery, multiple accidental trauma or acute respiratory failure

- If you have stopped growing (closed epiphyses) and you do not have growth hormone deficiency.

Warnings and precautions

Talk to your doctor or pharmacist before using Norditropin SimpleXx

- If you have **diabetes**
- If you have ever had a **cancer** or another kind of **tumour**
- If you have recurrent **headaches, eyesight problems, nausea** or if **vomiting** occurs
- If you have abnormal **thyroid** function
- An increase in sideways curvature of the spine (scoliosis) may progress in any child during rapid growth. During treatment with Norditropin SimpleXx, your doctor will check you (or your child) for signs of scoliosis
- If you walk with a limp or if you start to limp during your growth hormone treatment, you should inform your doctor
- If you are **over 60 years of age**, or have received somatropin treatment as an adult for more than 5 years, as experience is limited
- If you suffer from **kidney disease**, as your kidney function should be monitored by your physician
- If you have a **replacement therapy with glucocorticoids**, you should consult your doctor regularly, as you may need adjustment of your glucocorticoid dose
- Norditropin SimpleXx may cause an inflammation of the pancreas, which causes severe pain in the abdomen and back. Contact your doctor if you or your child develops stomach ache after taking Norditropin SimpleXx.

Other medicines and Norditropin SimpleXx

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, inform your doctor if you are taking or have recently taken any of the following medicines. Your doctor may need to adjust the dose of Norditropin SimpleXx or of the other medicines:

- **Glucocorticoids** – your adult height may be affected if you use Norditropin SimpleXx and glucocorticoids at the same time
- **Cyclosporine** (immunosuppressive) – as your dose may need to be adjusted
- **Insulin** – as your dose may need to be adjusted
- **Thyroid** hormone – as your dose may need to be adjusted
- **Gonadotropin** (gonad stimulating hormone) – as your dose may need to be adjusted
- **Anticonvulsants** – as your dose may need to be adjusted
- **Oestrogen** taken orally or other sex hormones.

Pregnancy and breast-feeding

Somatropin containing products are not recommended in women of childbearing potential not using contraception.

- **Pregnancy** – Stop the treatment and tell your doctor if you become pregnant while you are using Norditropin SimpleXx
- **Breast-feeding** – Do not use Norditropin SimpleXx while you are breast-feeding as somatropin might pass into your milk.

Driving and using machines

Norditropin SimpleXx does not affect the use of any machines or the ability to drive safely.

Norditropin contains sodium

Norditropin contains less than 1 mmol sodium (23 mg) per 1.5 ml, that is to say essentially ‘sodium-free’.

3. How to use Norditropin SimpleXx

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose

The dose for children depends on their body weight and body surface area. Later in life, the dose depends on height, weight, gender and growth hormone sensitivity and will be adjusted until you are on the right dose.

- **Children with low production or lack of growth hormone:**
The usual dose is 0.025 to 0.035 mg per kg body weight per day or 0.7 to 1.0 mg per m² body surface area per day
- **Children with Turner syndrome:**
The usual dose is 0.045 to 0.067 mg per kg body weight per day or 1.3 to 2.0 mg per m² body surface area per day
- **Children with kidney disease:**
The usual dose is 0.050 mg per kg body weight per day or 1.4 mg per m² body surface area per day
- **Children born small for gestational age (SGA):**
The usual dose is 0.035 mg per kg body weight per day or 1.0 mg per m² body surface area per day until final height is reached. (In clinical trials of short children born SGA doses of 0.033 and 0.067 mg per kg body weight per day have typically been used)
- **Children with Noonan syndrome:**
The usual dose is 0.066 mg per kg body weight per day, however your doctor may decide that 0.033 mg per kg body weight per day is sufficient
- **Adults with low production or lack of growth hormone:**
If your growth hormone deficiency continues after completion of growth, treatment should be continued. The usual starting dose is 0.2 to 0.5 mg per day. The dose will be adjusted until you are on the right dose. If your growth hormone deficiency starts during adult life, the usual starting dose is 0.1 to 0.3 mg per day. Your doctor will increase this dose each month until you are on the right dose. The usual maximum dose is 1.0 mg per day.

When to use Norditropin SimpleXx

Inject your daily dose into the skin every evening just before bedtime.

How to use Norditropin SimpleXx

- Norditropin SimpleXx solution comes in cartridges with a colour-coded cap and is ready to be used in the matching colour-coded NordiPen. If the corresponding NordiPen is not used it will result in incorrect dosing. The NordiPen instruction manual tells you how to use the cartridges in the injection pen
- Check each new Norditropin SimpleXx cartridge before you use it. Do not use any cartridge that is damaged or cracked
- Do not use the Norditropin SimpleXx cartridges if the solution inside is cloudy or discoloured
- Vary the area you inject so you do not harm your skin
- Do not share your Norditropin SimpleXx cartridge with anyone else.

How long you will need treatment for

- Children with growth failure because of Turner syndrome, kidney disease, SGA or Noonan syndrome: Your doctor will recommend you continue treatment until you stop growing
- Children or adolescents who lack growth hormone: Your doctor will recommend you continue treatment into adulthood

Do not stop using Norditropin SimpleXx without discussing it with your doctor first.

If you use more Norditropin SimpleXx than you should

Tell your doctor if you inject too much somatotropin. Long-term overdosing can cause abnormal growth and coarsening of facial features.

If you forget to use Norditropin SimpleXx

Take the next dose as usual, at the normal time. **Do not take a double dose** to make up for a forgotten dose.

If you stop using Norditropin SimpleXx

Do not stop using Norditropin SimpleXx without discussing it with your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Effects seen in children and adults (unknown frequency):

- **Rash; wheezing; swollen eyelids, face or lips; complete collapse.** Any of these may be signs of an allergic reaction
- **Headache, eyesight problems, feeling sick** (*nausea*) and **being sick** (*vomiting*). These may be signs of raised pressure in the brain
- **Serum thyroxin** levels may decrease
- **Hyperglycaemia** (elevated levels of blood glucose).

If you get any of these effects, **see a doctor as soon as possible**. Stop using Norditropin SimpleXx until your doctor says you can continue treatment.

Formation of antibodies directed against somatotropin has rarely been observed during Norditropin therapy.

Increased levels of liver enzymes have been reported.

Cases of leukaemia and relapse of brain tumours have also been reported in patients treated with somatotropin (the active ingredient in Norditropin SimpleXx), although there is no evidence that somatotropin was responsible for this.

If you think you are suffering from any of these diseases, talk to your doctor.

Additional side effects in children:

Uncommon (may affect up to 1 in 100 children):

- **Headache**
- **Redness**, itching and pain in the area of injection
- **Breast enlargement** (gynaecomastia).

Rare (may affect up to 1 in 1,000 children):

- **Rash**
- **Muscle** and joint pain
- **Swollen hands** and feet due to fluid retention.

In rare cases, children using Norditropin SimpleXx have experienced hip and knee pain or have started limping. These symptoms may be caused by a disease affecting the top of the thigh bone (*Legg-Calvé disease*) or because the end of the bone has slipped from the cartilage (*slipped capital femoral epiphysis*) and may not be due to Norditropin SimpleXx.

In children with **Turner syndrome**, a few cases of **increased growth of hands and feet** compared to height have been observed in clinical trials.

A clinical trial in children with Turner syndrome has shown that high doses of Norditropin can possibly increase the risk of getting ear infections.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist, as the dose may need to be reduced.

Additional side effects in adults:

Very common (may affect more than 1 in 10 adults):

- **Swollen hands** and feet due to fluid retention.

Common (may affect up to 1 in 10 adults):

- **Headache**
- Feeling of **skin crawling** (*formication*) and numbness or pain mainly in fingers
- **Joint pain** and stiffness; muscle pain.

Uncommon (may affect up to 1 in 100 adults):

- **Type 2 diabetes**
- **Carpal tunnel syndrome**; tingling and pain in fingers and hands
- **Itching** (can be intense) and pain in the area of injection
- **Muscle stiffness**
- **Breast enlargement** (gynaecomastia).

Reporting of side effects

If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRÁ Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Norditropin SimpleXx

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package after EXP/. The expiry date refers to the last day of that month.

Store unused Norditropin SimpleXx cartridges in a refrigerator (2°C – 8°C) in the outer carton, in order to protect them from light. Do not freeze or expose to heat. Do not store close to any cooling elements.

While using Norditropin SimpleXx 10 mg/1.5 ml cartridge in an injection pen you can **either**:

- Keep it in the pen for up to 4 weeks in a refrigerator (2°C – 8°C), **or**
- Keep it in the pen for up to 3 weeks at room temperature (below 25°C).

Do not continue to use Norditropin SimpleXx cartridges if they have been frozen or exposed to excessive temperatures.

Check each new Norditropin SimpleXx cartridge before you use it. Do not use any cartridge that is damaged or cracked.

Do not use Norditropin SimpleXx cartridges if the solution inside is cloudy or discoloured.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Norditropin SimpleXx contains

- The active substance is somatropin
- The other excipients are mannitol, histidine, poloxamer 188, phenol, water for injection, hydrochloric acid and sodium hydroxide.

What Norditropin SimpleXx looks like and contents of the pack

Norditropin SimpleXx is a clear and colourless solution in a 1.5 ml glass cartridge ready for injection in the NordiPen injection pen.

1 ml of solution contains 6.7 mg somatropin.
1 mg of somatropin corresponds to 3 IU of somatropin.

Norditropin SimpleXx is available in three strengths:
5 mg/1.5 ml, 10 mg/1.5 ml and 15 mg/1.5 ml (equivalent to 3.3 mg/ml, 6.7 mg/ml and 10 mg/ml, respectively).

Marketing Authorisation Holder and Manufacturer

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd, Denmark

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Belgium, Cyprus, Czech Republic, Denmark, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Spain, Slovak Republic, United Kingdom (Northern Ireland): Norditropin SimpleXx 10 mg/1.5 ml

France: Norditropine SimpleXx 10 mg/1.5 ml

This leaflet was last revised in MM/YYYY.

Other sources of information

Detailed information on this medicine is available on the website of: HPRA

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