

Norditropin[®] SimpleXx[®] 5mg, 10mg, and 15mg

Somatropin (rbe)

Consumer Medicine Information

What is in this leaflet

What Norditropin[®] SimpleXx[®] is used for 1

Before using Norditropin[®] SimpleXx[®] 1

Using Norditropin[®] SimpleXx[®] 2

While you or your child are using Norditropin[®] SimpleXx[®] 2

Side effects..... 3

Storage..... 3

Product Description 3

This leaflet answers some common questions about Norditropin[®] SimpleXx[®]. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child using Norditropin SimpleXx against the benefits they expect it will have.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Norditropin[®] SimpleXx[®] is used for

Norditropin SimpleXx is human growth hormone [also called somatropin (rbe)], used to treat:

1. growth failure in children, which may be due to:
 - a condition called Growth Hormone Deficiency, where the gland at the base of the brain (pituitary gland) does not make enough growth

hormone

- a condition called either Small for Gestational Age (SGA) or Intrauterine Growth Retardation (IUGR), where growth failure started during the mother's pregnancy.

Children with SGA/IUGR do not lack growth hormone and are therefore not treated for growth hormone deficiency. Treatment with Norditropin SimpleXx promotes catch-up growth and increases final height.

- Chronic kidney disease
 - Turner Syndrome, a genetic condition in girls
2. growth hormone deficiency in adults

You or your child may have been prescribed Norditropin SimpleXx for another reason.

Ask your doctor if you have any questions about why Norditropin SimpleXx has been prescribed.

There is no evidence that Norditropin SimpleXx is addictive.

Before using Norditropin[®] SimpleXx[®]

When you or your child must not use it

You or your child should not use Norditropin SimpleXx if you/your child:

- are allergic to phenol or any other ingredient listed in the ingredient section
- have cancer or another form of active tumour
- have not finished treatment for cancer or another form of tumour
- have slow growth for reasons other than a lack of growth hormone, except where

specific uses are described above

- have had a kidney transplant in the last 12 months or have had more than one episode of acute rejection (ask your doctor if unsure what this means)
- have an acute critical illness due to complications following open heart or abdominal surgery or multiple accident trauma
- have acute respiratory failure

Do not use Norditropin SimpleXx if:

- it is after the expiry date (Expiry) printed on the label and carton
- the packaging is torn, shows signs of tampering or does not look quite right
- the solution is not clear or does not look quite right

Before you or your child start to use it

Tell your doctor if you or your child have any medical conditions, especially the following:

- diabetes
- cancer or any other kind of tumour
- impaired kidney function

If any of the above applies, Norditropin SimpleXx may not be suitable. Your doctor will give you advice.

Your doctor will measure your child's height and weight before he or she is prescribed Norditropin SimpleXx. If you or your child are growth hormone deficient, your doctor will also need to measure your ability to produce growth hormone.

Taking other medicines

Tell your doctor if you or your child are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with the growth effect of Norditropin SimpleXx. These include:

- glucocorticoids
- sex steroids
- thyroid hormone

If you are unsure whether you are taking these medicines talk to your doctor or pharmacist.

If you or your child are being treated with insulin, the dosage of insulin may have to be adjusted.

If you have not told your doctor about any of the above, tell them before you or your child use Norditropin SimpleXx.

Pregnancy and breast-feeding

There is no information on the effects of Norditropin SimpleXx during pregnancy or breast-feeding. Norditropin SimpleXx should be used during pregnancy only if clearly needed.

Using Norditropin® SimpleXx®

How much to use

Your doctor will tell you how much Norditropin SimpleXx you or your child should use. It depends on factors such as body weight and body surface area.

How and when to use it

Norditropin SimpleXx is given as an injection with NordiPen® (an injection pen) under the skin in the evening, 6 or 7 days per week. Injection sites should be varied as shown to you by your doctor or other health professional. This will lessen the risk of damage to the fat and tissues under the skin.

Norditropin SimpleXx cartridges MUST be used with the matching

colour coded NordiPen to give the correct dose. For example:

- Norditropin SimpleXx 5mg (yellow) MUST be used with NordiPen 5mg (yellow)
- Norditropin SimpleXx 10mg (blue) MUST be used with NordiPen 10mg (blue)
- Norditropin SimpleXx 15mg (green) MUST be used with NordiPen 15mg (green)

Carefully follow the instructions contained in the NordiPen package insert.

If you have any questions or concerns about how to use Norditropin SimpleXx, talk to your doctor or pharmacist.

Norditropin SimpleXx is prescribed for you or your child's personal use only. **Do not give it to anyone else.**

How long to use it

You or your child may stop using Norditropin SimpleXx at any time. Before doing so, you should discuss this first with your doctor.

If you are unsure how long to use Norditropin SimpleXx, talk to your doctor.

If you or your child miss a dose

Inject the next dose as normal the next evening. Do not inject extra to make up for the missed dose.

If you or your child use too much (overdose)

If you inject too much Norditropin SimpleXx, contact your doctor.

You or your child should not be given more Norditropin SimpleXx than the doctor has prescribed, as it may increase the risk of side effects.

Long term overdosage could result in signs and symptoms of growth hormone excess. Extreme growth hormone excess can result in overgrowth of bones and enlargement of hands and feet.

While you or your child are using Norditropin® SimpleXx®

Things you must do

You must tell your doctor if you or your child:

- get severe or recurring headaches, visual problems, nausea and vomiting. These may be symptoms of raised pressure of the fluid around the brain.
- experience tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain. These may be signs and symptoms of hypothyroidism (an under-active thyroid gland causing a decrease in metabolism).
- develop a limp or complain of knee or hip pain.

If you or your child are taking Norditropin SimpleXx due to growth problems associated with a kidney disease, it is important to continue with any treatment for the kidney condition while Norditropin SimpleXx is being used.

As growth hormone can affect your levels of blood sugar, your doctor may perform regular blood checks on you or your child.

Things you must not do

Do not give Norditropin SimpleXx to anyone else, even if they have the same condition as you or your child.

Do not use Norditropin SimpleXx to treat any other complaints unless your doctor tells you to.

Do not stop using Norditropin SimpleXx or lower the dosage, without first checking with your doctor.

Things to be careful of

Tell your doctor if you or your child are scheduled to have surgery.

If you or your child has a kidney condition, your doctor will closely monitor the kidney function (how well the kidneys are working). If there is any decrease in function, it may be necessary to stop using Norditropin.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while taking Norditropin SimpleXx. Ask your doctor or pharmacist to answer any questions you may have.

The following side effects of Norditropin are usually mild and temporary:

- swollen hands and feet due to fluid retention
- redness and itching around the area you inject. Some patients may develop local skin reactions at the injection site which appear and disappear during treatment. If you inject too often in the same small area, damage may occur to the fat and tissues under the skin.

Less common unwanted effects that have been reported with Norditropin are:

- convulsions, motor problems, joint pain, skin rash, headache, curvature of the spine and fluid retention. Allergy and hair loss have been reported on rare occasions.
- some cases of benign raised pressure of the fluid around the brain have been reported. Symptoms of this can include severe or recurring headaches, problems with eye sight, feeling sick or vomiting.

If you or your child experience any of these symptoms, the dosage of Norditropin may need to be reduced. **Discuss this with your doctor.**

In rare cases, the body may form antibodies to Norditropin SimpleXx. These antibodies could reduce further growth with Norditropin SimpleXx treatment.

In very rare cases, children treated with growth hormone have felt pain in the hip or knee, or have experienced limping. These symptoms may be caused by Legg-Calvé-Perthes disease (disease at the top of the thigh bone) or slipped capital femoral epiphysis (the end of the bone slips from the cartilage) and may not be due to the medicine.

The following have been reported in a small number of patients treated with growth hormone. However, there is no evidence that growth hormone is responsible for causing cancer, including leukaemia or relapse of brain tumours, or raised levels of glucose in the blood (a condition called 'impaired glucose tolerance' (IGT)).

If you think that you or your child are suffering from any of these symptoms or from any other side effects not mentioned here, speak to your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

Storage

Norditropin SimpleXx must be stored between 2°C-8°C, in a refrigerator, but not in or near the freezing compartment. Norditropin SimpleXx must not be frozen or exposed to heat or direct light.

Norditropin SimpleXx that you are using (in NordiPen) should be stored in the refrigerator (2°C-8°C) and used within 28 days.

Keep out of the reach of children.

Do not use Norditropin SimpleXx which has been frozen or exposed to excess heat.

Never use Norditropin SimpleXx after the expiry date printed on the label and carton.

Product Description

What it looks like

Norditropin SimpleXx is a 1.5mL clear solution for injection into the layer under the skin. It is available in a glass cartridge, ready to go into NordiPen. Three NordiPens are available - a different one for each strength of Norditropin SimpleXx.

Norditropin SimpleXx cartridges **MUST** be used with the matching colour coded NordiPen to give the correct dose. For example:

- Norditropin SimpleXx 5mg (yellow) **MUST** be used with NordiPen 5mg (yellow)
- Norditropin SimpleXx 10mg (blue) **MUST** be used with NordiPen 10mg (blue)
- Norditropin SimpleXx 15mg (green) **MUST** be used with NordiPen 15mg (green)

NordiPen is for use with NovoFine® needles.

Ingredients

Norditropin SimpleXx contains the active ingredient, biosynthetic human growth hormone, which is called somatotropin (rbe). It is identical to the growth hormone produced in the human body. The abbreviation 'rbe' indicates the method of genetic engineering used to manufacture the growth hormone.

Other ingredients in Norditropin SimpleXx are: mannitol, histidine, poloxamer, phenol, and water for injections. The quantity of each ingredient is on the label of the box.

Norditropin SimpleXx is available in three strengths: 5mg, 10mg, and 15mg. Your doctor will decide which strength is suitable for you or your child.

Manufacturer

Norditropin SimpleXx is made in Denmark and supplied in Australia by:

***Novo Nordisk Pharmaceuticals
Pty. Ltd.***

A.B.N. 40 002 879 996
Level 3, 21 Solent Circuit,
Baulkham Hills NSW 2153.

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Norditropin SimpleXx 5mg:
AUST R 69360

Norditropin SimpleXx 10mg:
AUST R 69361

Norditropin SimpleXx 15mg:
AUST R 69362

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on 1800 668 626.