Norditropin® FlexPro®

Somatropin (rbe)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Norditropin® FlexPro®. 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® FlexPro® 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® FlexPro® is used for

Norditropin® FlexPro® is a pre-filled dial-a-dose pen containing Norditropin®, a solution of human growth hormone. Norditropin® [also called somatropin (rbe)], is 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® FlexPro® 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® FlexPro® for another reason.

Ask your doctor if you have any questions about why Norditropin® FlexPro® has been prescribed for you or your child.

There is no evidence that Norditropin® is addictive.

Before using Norditropin® FlexPro®

When you or your child must not use it

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

- are allergic to phenol or any other ingredient listed in the ingredient section of this leaflet.
- Some of the symptoms of an allergic reaction may include:
    - rash
    - wheezing
    - swelling of the eyelids, face or lips
    - complete collapse
- 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® FlexPro® 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 cloudy or discoloured.

Before you or your child starts to use it

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

- diabetes

- cancer or any other kind of tumour

- impaired kidney function

- severe or recurring headaches, visual problems, nausea and vomiting. These may be symptoms of raised pressure of the fluid around the brain.

- 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 underactive thyroid gland causing a decrease in metabolism).

- development of curvature in the spine (scoliosis) in your child
- if your child has Turner syndrome and:
    - you notice increased growth of your child's hands and feet that is not in proportion to their height, or
    - they develop an ear infection.
- Norditropin® 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 aches after taking Norditropin®.

If any of the above applies, Norditropin® FlexPro® 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® FlexPro®. If you or your child is growth hormone deficient, your doctor will also need to measure your/their ability to produce growth hormone.

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

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

Taking other medicines

Tell your doctor if you or your child is 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®. These include:

- glucocorticoids
- sex steroids
- thyroid hormone

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

If you or your child is 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® FlexPro®.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

There is no information on the effects of Norditropin® during pregnancy or breast-feeding.

Norditropin® FlexPro® should be used during pregnancy only if clearly needed.

Using Norditropin® FlexPro®

How much to use

Your doctor will tell you how much Norditropin® 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® is given as an injection with Norditropin® FlexPro® 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 healthcare professional. This will lessen the risk of damage to the fat and tissues under the skin (lipodystrophy).

NovoFine® needles (8 mm 30 G or smaller) are designed to be used with Norditropin® FlexPro®.

Follow the detailed instructions on how to use Norditropin® FlexPro® in the Instructions For Use supplied with the product.

These instructions are also available via the following hyperlinks:

- http://medsinfo.com.au/media/noinor05
- http://medsinfo.com.au/media/noinor10
- http://medsinfo.com.au/media/noinor15

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

Norditropin® FlexPro® 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® FlexPro® at any time. Before doing so, you should discuss this first with your doctor.

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

If you or your child misses 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 uses too much (overdose)

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

You or your child should not inject more Norditropin® 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 is using Norditropin® FlexPro®

Things you must not do

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

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

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

Do not shake Norditropin® FlexPro® vigorously at any time. It should be handled with care.

Things to be careful of

Tell your doctor if you or your child is 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 using Norditropin® FlexPro®. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- breast enlargement
- 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 (lipodystrophy).

The above list includes the more common side effects of Norditropin® FlexPro®. They are usually mild and temporary.

Tell your doctor as soon as possible if you notice any of the following:

- joint and muscle pain

- skin rash
- headache
- curvature of the spine
- fluid retention

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reaction. Symptoms of this may include rash; wheezing; swelling of the eyelids, face or lips; complete collapse.
- benign raised pressure of the fluid around the brain. Symptoms of this can include severe or recurring headaches, problems with eye sight, feeling sick or vomiting.

The above list includes serious side effects. You may need urgent medical attention. These side effects are very rare.

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

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

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

Store unused Norditropin® FlexPro® pens in a refrigerator (2°C-8°C) in the outer carton to protect them from light. Do not use if frozen. Do not freeze or expose to heat. Do not store close to any cooling elements.

Always keep the pen cap fully closed on Norditropin® FlexPro® when you are not using it.

While using Norditropin® FlexPro® you can either:

- Keep it for up to 4 weeks in a refrigerator (2°C to 8°C),

or

- Keep it for up to 3 weeks at room temperature (below 25°C).

Keep out of the reach of children.

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

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

The expiry date refers to the last day of that month.

Disposal

If your doctor tells you or your child to stop using Norditropin® FlexPro®, or the medicine has passed its expiry date, return any unused medicine to your pharmacist for disposal.

Product Description

What it looks like

The Norditropin® in Norditropin® FlexPro® is a clear, colourless solution for subcutaneous injection contained in a multi-dose, disposable 1.5 mL pre-filled pen.

Norditropin® FlexPro® 5 mg/1.5 mL has a yellow push button, pen cap and cartridge holder. It delivers a maximum dose of 2.0 mg per dose, in increments of 0.025 mg somatropin.

Norditropin® FlexPro® 10 mg/1.5 mL has a blue push button, pen cap and cartridge holder. It delivers a maximum of 4.0 mg per dose, in increments of 0.050 mg somatropin.

Norditropin® FlexPro® 15 mg/1.5 mL has a green push button, pen cap and cartridge holder. It delivers a maximum dose of 8.0 mg per dose in increments of 0.1 mg somatropin.

Norditropin® FlexPro® is for use with NovoFine® needles (8 mm 30 G or smaller).

Ingredients

The Norditropin® in Norditropin® FlexPro® contains the active ingredient biosynthetic human growth hormone, which is called somatropin (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® FlexPro® are: mannitol, histidine, poloxamer, phenol and water for injections. The quantity of each ingredient is on the label of the carton.

Manufacturer

Norditropin® FlexPro® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10, 118 Mount Street, North Sydney NSW 2060, Australia

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Norditropin® FlexPro® 5mg: AUST R 173396

Novo Nordisk A/S

2880 Bagsvaerd, Denmark

Further information

For further information call the NovoCare® Customer Care Centre on 1800 668 626.

www.novonordisk.com.au

Current 'Product Information' documents are available from the following websites:

www.novonordisk.com.au (AU)

https://www.ebs.tga.gov.au/ (AU)