Norditropin® FlexPro®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Norditropin® FlexPro®?

Norditropin® FlexPro® is a dial-a-dose pen containing the active ingredient somatropin, human growth hormone. Norditropin® FlexPro® is used to treat growth failure in children and growth hormone deficiency in adults.

For more information, see Section 1. Why am I using Norditropin® FlexPro®? in the full CMI.

2. What should I know before I use Norditropin® FlexPro®?

Do not use if you have ever had an allergic reaction to phenol or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or plan to become pregnant, or are breastfeeding.

For more information, see Section 2. What should I know before I use Norditropin® FlexPro®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Norditropin® FlexPro® and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Norditropin® FlexPro®?

- Your doctor will tell you how much Norditropin® to use. Inject under the skin in the evening, 6 or 7 days per week.
- Refer to the directions for use leaflet on how to use Norditropin® FlexPro®.

More instructions can be found in Section 4. How do I use Norditropin® FlexPro®? in the full CMI.

5. What should I know while using Norditropin® FlexPro®?

Things you should do	• Remind any doctor, dentist, pharmacist or other health professionals you or your child visit that you or your child are using Norditropin® FlexPro®.
Things you should not do	• Do not stop using this medicine or lower the dosage without first checking with your doctor. • Do not give to anyone else or use to treat other complaints.
Driving or using machines	• Be careful before driving or operating machinery until you know how Norditropin® affects you.
Drinking alcohol	• N/A
Looking after your medicine	• Store unused Norditropin® FlexPro® pens in a refrigerator (2°C to 8°C) in the outer carton to protect from light. Do not use if frozen. Do not freeze or expose to heat. • While using Norditropin® FlexPro®, store for up to 4 weeks in a refrigerator (2°C to 8°C) or for up to 3 weeks at room temperature (below 25°C).

For more information, see Section 5. What should I know while using Norditropin® FlexPro®? in the full CMI.

6. Are there any side effects?

Common side effects: Headache, abnormal sensation/tingling/burning, bone pain or stiffness, muscle pain or stiffness, fluid retention, carpel tunnel syndrome, redness and itching around the injection site. Serious, uncommon side effects: allergic reactions, benign raised pressure of the fluid around the brain.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Norditropin® FlexPro®

Active ingredient(s): *somatropin (rbe)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Norditropin® FlexPro®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Norditropin® FlexPro®.**

Where to find information in this leaflet:

1. Why am I using Norditropin® FlexPro®?

Norditropin® FlexPro® is a pre-filled dial-a-dose pen that contains the active ingredient somatropin, a solution of human growth hormone.

Norditropin® FlexPro® is used to treat:

- 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
- 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.

2. What should I know before I use Norditropin® FlexPro®?

Warnings

Do not use Norditropin® if you/your child:

- are allergic to phenol or any of the ingredients listed at the end 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 moderate to advanced diabetic eye disease
- 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.

Check with your doctor if you or your child has:

- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you or your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these affect Norditropin® FlexPro®.

4. How do I use 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.
- Follow the instructions provided and use Norditropin® FlexPro® until your doctor tells you to stop.

When to use Norditropin® FlexPro®

- 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).
- Carefully follow the instructions given in this leaflet on how to use Norditropin® FlexPro®.
- NovoFine® needles (8 mm 30 G or smaller) are designed to be used with Norditropin® FlexPro®.
- 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.

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.

How to use Norditropin® FlexPro®

Follow the detailed instructions on how to inject Norditropin® FlexPro® in the instructions for use supplied with the product.

These instructions are also available via the following hyperlinks:

Norditropin® FlexPro® 5 mg/1.5 mL pen
https://medsinfo.com.au/media/noinor05
Norditropin® FlexPro® 10 mg/1.5 mL pen
https://medsinfo.com.au/media/noinor10
Norditropin® FlexPro® 15 mg/1.5 mL pen
https://medsinfo.com.au/media/noinor15

If you forget to use Norditropin® FlexPro®

If you miss your dose at the usual time:

Inject the next dose as normal the next evening.

Do not inject extra to make up for the missed dose.

If you use too much Norditropin® FlexPro®

If you think that you have used 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.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should you know while using Norditropin® FlexPro®?

Things you should do

Remind any doctor, dentist, pharmacist or other health professional you or your child visit that Norditropin® FlexPro® is being used.

Things you should 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.

Other conditions

- 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®.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Norditropin® affects you.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

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.

When to discard your medicine

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).

Getting rid of any unwanted medicine

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 safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

Less serious side effects

Less serious side effects	What to do (note)
• 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).	**Speak to your doctor if you have any of these less serious side effects and they worry you.** They are usually mild and temporary.

Less serious side effects	What to do (tell)
• joint and muscle pain • skin rash • headache • curvature of the spine • fluid retention	**Tell your doctor if you or your child have any of these side effects.** The dosage of Norditropin® may need to be reduced.

Serious side effects

Serious side effects	What to do
• 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.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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

In rare cases, children using Norditropin® have experienced hip and knee pain or have started limping. These symptoms may be a consequence of the end of the bone having slipped from the cartilage (slipped capital femoral epiphysis) or caused by a disease affecting the top of the thigh bone (osteonecrosis of femoral head e.g., Legg-Calvé disease) and may not be due to treatment with Norditropin®.

Talk to your doctor about persistent pain.

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.

Tell your doctor or pharmacist if you notice anything else that may be making you or your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you or your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Norditropin® FlexPro® contains

Active ingredient (main ingredient)	biosynthetic human growth hormone, which is called somatropin (rbe)*
	It is identical to the growth hormone produced in the human body.
Other ingredients (inactive ingredients)	mannitol, histidine, poloxamer, phenol and water for injections.

*'rbe' indicates the method of genetic engineering used to manufacture the growth hormone.

Do not take this medicine if you or your child are allergic to any of these ingredients.

What Norditropin® FlexPro® 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. It delivers a maximum dose of 2.0 mg per dose, in increments of 0.025 mg somatropin. (AUST R 173396)

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. (AUST R 173398)

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. (AUST R 173399)

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

Who distributes Norditropin® FlexPro®

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10

118 Mount Street

North Sydney NSW 2060

Australia

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NovoFine® is a registered trademark of Novo Nordisk A/S.

Novo Nordisk A/S

2880 Bagsvaerd, Denmark

Further information

For further information call Medical Information on 1800 668 626.

Current product information documents are available from the following websites:

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

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