

Norditropin NordiFlex[®]

Consumer Medication Information Leaflet (RiMUP)

Somatropin (10 mg/1.5 ml)

What is in this leaflet

1. What Norditropin NordiFlex[®] is used for
2. How Norditropin NordiFlex[®] works
3. Before you use Norditropin NordiFlex[®]
4. How to use Norditropin NordiFlex[®]
5. While you are using it
6. Side effects
7. Storage and Disposal of Norditropin NordiFlex[®]
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of revision

1. What Norditropin NordiFlex[®] is used for

Norditropin NordiFlex[®] 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.

2. How Norditropin NordiFlex[®] works

Norditropin NordiFlex[®] 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).

Norditropin NordiFlex[®] is used as a growth hormone replacement in adults:

Norditropin NordiFlex[®] is used to replace growth hormone if the production has been decreased since childhood or is 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.

3. Before you use Norditropin NordiFlex[®]

- When you must not use Norditropin NordiFlex[®]

Do not use Norditropin NordiFlex[®]

▶ If you are **allergic** to somatropin, phenol or any other ingredients in this medicine.

▶ If you have had a **kidney transplant**.

▶ If you have an **active tumour (cancer)**. Tumours must be inactive and you must have finished your anti-tumour treatment before you start your treatment with Norditropin[®] NordiFlex[®].

▶ 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.

- Before you start to use Norditropin NordiFlex[®]

Talk to your doctor or pharmacist before using Norditropin NordiFlex[®]

▶ 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 NordiFlex[®], 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 NordiFlex[®] 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 NordiFlex[®].

If any of the above applies to you, Norditropin NordiFlex[®] may not be suitable. Your physician/specialist will give you advice.

Your physician/specialist will measure your height, weight and your ability to produce growth hormone before you are prescribed Norditropin NordiFlex[®].

- Taking other medicines

Remember to tell your doctor/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 NordiFlex[®] or of the other medicines:

▶ **Glucocorticoids** – your adult height may be affected if you use Norditropin NordiFlex[®] 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.

4. How to use Norditropin NordiFlex®

Norditropin NordiFlex® growth hormone solution comes in a multidose disposable 1.5 ml pre-filled pen.

Full instructions on how to use the Norditropin NordiFlex® pen are given overleaf. The instructional key points are as follows:

- Check the solution before use by turning the pen upside down once or twice. Do not use the pen if the solution is cloudy or discoloured
- Norditropin NordiFlex® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm
- Always use a new needle for each injection
- Vary the area you inject so you do not harm your skin
- To make sure you get the proper dose and do not inject air, check the growth hormone flow (called 'priming' the pen) before the first injection from a new Norditropin NordiFlex® pen. Do not use the pen if a drop of growth hormone solution does not appear at the needle tip
- Do not share your Norditropin NordiFlex® pen with anyone else.

- How much to use

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

General recommendations for dosages are shown below. The dose for children depends on their body weight and body surface area. Later in life, the dose depends on your 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)

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 getting the dose you need. The usual maximum dose is 1.0 mg per day.

- When to use it

You should inject your daily dose into the skin every evening just before bedtime. You should change areas you inject so you do not harm your skin.

Norditropin NordiFlex® is designed to be used with NovoFine® disposable needles.

Carefully follow the instructions given in this leaflet on how to use Norditropin NordiFlex®.

- How long to use it

► Children with growth failure because of Turner syndrome, kidney disease or SGA: 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 NordiFlex® without discussing it with your doctor first.

- If you forget to use it

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 use too much (overdose)

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

- If you stop using Norditropin NordiFlex®:

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

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

5. While you are using it

- Things you must do

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

- Things you must not do

Do not use Norditropin NordiFlex® if the solution for injection does not appear clear and colourless. Check this by turning the pen upside down once or twice. To make sure you get the proper dose and do not inject air, check the flow (prime the

pen) before the first injection from a new Norditropin NordiFlex[®] pen. Do not use the pen if a drop of growth hormone solution does not appear at the needle tip.

Norditropin NordiFlex[®] should not be shaken vigorously at any time. It should be handled with care.

- Things to be careful of

Pregnancy and breastfeeding

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 NordiFlex[®].

► **Breastfeeding** – Do not use Norditropin NordiFlex[®] while you are breastfeeding because somatropin might pass into your milk.

Driving and using machines

Norditropin NordiFlex[®] 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'.

6. 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 NordiFlex[®] until your doctor says you can continue treatment.

Formation of antibodies directed against somatropin 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 somatropin (the active ingredient in Norditropin NordiFlex[®]), although there is no evidence that somatropin 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 NordiFlex[®] 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 NordiFlex[®].

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 may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of Norditropin NordiFlex[®]

- Storage

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

Store unused Norditropin NordiFlex® pens 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 NordiFlex® you can **either:**

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

Do not continue to use Norditropin NordiFlex® pens if they have been frozen or exposed to excessive temperatures.

Do not use Norditropin NordiFlex® pens if the growth hormone solution is cloudy or discoloured.

Always store Norditropin NordiFlex® without a needle attached.

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

Always use a new needle for each injection.

- **Disposal**

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.

8. Product Description

- **What it looks like**

Norditropin NordiFlex® is a clear and colourless solution for injection in a multidose disposable 1.5 ml pre-filled pen.

1 ml of solution contains 6.7 mg somatropin.

Norditropin NordiFlex® is available in three strengths: 5 mg/1.5 ml, 10 mg/1.5 ml and 15 mg/1.5 ml (i.e. 3.3

mg/ml, 6.7 mg/ml and 10 mg/ml, respectively).

- **Ingredients**

- Active ingredient

The active substance is somatropin.

1 mg of somatropin corresponds to 3 IU of somatropin.

- Inactive ingredients

The other excipients are mannitol, histidine, poloxamer 188, phenol, water for injection, hydrochloric acid, and sodium hydroxide.

- **MAL number**

MAL20034589AZ

9. Manufacturer

Manufactured by

Novo Nordisk A/S
Hagedornsvej 1
DK-2820 Gentofte, Denmark

Novo Nordisk A/S
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Released by

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10. Product Registration Holder

Novo Nordisk Pharma (Malaysia)
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