Package leaflet: Information for the user

Norditropin® FlexPro® 5 mg/1.5 ml solution for injection in pre-filled pen

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 FlexPro is and what it is used for
2. What you need to know before you use Norditropin FlexPro
3. How to use Norditropin FlexPro
4. Possible side effects
5. How to store Norditropin FlexPro
6. Contents of the pack and other information
Instructions on how to use Norditropin FlexPro

1. What Norditropin FlexPro is and what it is used for

Norditropin FlexPro 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 FlexPro 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 FlexPro is used as a growth hormone replacement in adults
In adults Norditropin FlexPro 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 FlexPro

Do not use Norditropin FlexPro
- 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 FlexPro
- 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 FlexPro
- 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 FlexPro, 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 FlexPro 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 FlexPro.

Other medicines and Norditropin FlexPro
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 FlexPro or of the other medicines:
- **Glucocorticoids** – your adult height may be affected if you use Norditropin FlexPro 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 FlexPro
- **Breast-feeding** – do not use Norditropin FlexPro while you are breast-feeding because somatropin might pass into your milk.

Driving and using machines
Norditropin FlexPro 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 FlexPro

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 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 m^2 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 m^2 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 m^2 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 m^2 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 getting the dose you need. The usual maximum dose is 1.0 mg per day.

When to use Norditropin FlexPro
Inject your daily dose into the skin every evening just before bedtime.

How to use Norditropin FlexPro
Norditropin FlexPro growth hormone solution comes in a multidose disposable 1.5 ml pre-filled pen. Full instructions on how to use Norditropin FlexPro 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 (see step A)
- Norditropin FlexPro 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 before the first injection from a new Norditropin FlexPro pen. Do not use the pen if a drop of growth hormone solution does not appear at the needle tip (see steps E to G)
- Do not share your Norditropin FlexPro pen 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 FlexPro without discussing it with your doctor first.

If you use more Norditropin FlexPro than you should
Tell your doctor if you inject too much somatropin. Long-term overdosing can cause abnormal growth and coarsening of facial features.

If you forget to use Norditropin FlexPro
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 FlexPro
Do not stop using Norditropin FlexPro 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 FlexPro 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 FlexPro), 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 FlexPro have experienced hip and knee pains 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 FlexPro.

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 HPRA 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 FlexPro

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 carton and pre-filled pen after EXP. The expiry date refers to the last day of that month.

Store unused Norditropin FlexPro 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 FlexPro 5 mg/1.5 ml 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 FlexPro pens if they have been frozen or exposed to excessive temperatures.
Do not use Norditropin FlexPro pens where the growth hormone solution is cloudy or discoloured.
Always store Norditropin FlexPro without a needle attached.
Always keep the pen cap fully closed on the Norditropin FlexPro pen when you are not using it.
Always use a new needle for each injection.

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 FlexPro 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 FlexPro looks like and contents of the pack
Norditropin FlexPro is a clear and colourless solution for injection in a multidose disposable 1.5 ml pre-filled pen.
1 ml of solution contains 3.3 mg somatropin.
1 mg of somatropin corresponds to 3 IU of somatropin.

Norditropin FlexPro 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) in pack sizes of 1 pre-filled pen.

Manufacturer: Novo Nordisk A/S Novo Allé DK-2880 Bagsværd Denmark

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number: PPA0465/523/001

This medicine is authorised in the Member States of the European Economic Area under the following names: Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Finland, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden: Norditropin FlexPro 5 mg/1.5 ml

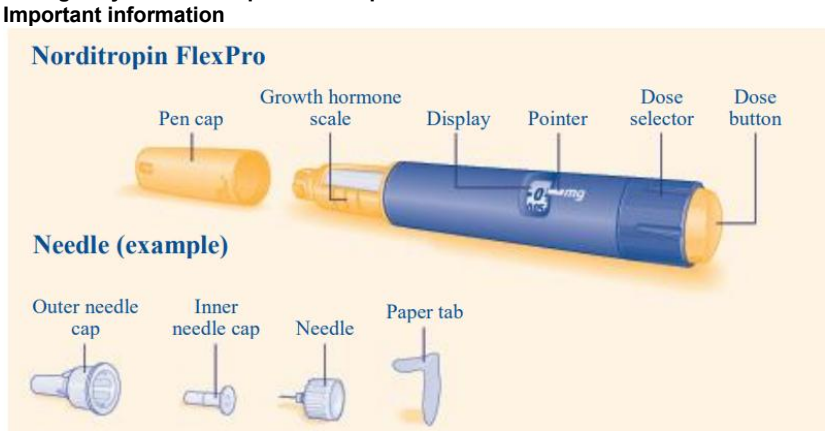
France: Norditropine FlexPro 5 mg/1.5 ml

This leaflet was last revised in June 2026

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

Instructions on how to use Norditropin FlexPro
Please read these instructions carefully before using your Norditropin FlexPro pen.
Start by checking the name, strength and coloured label of your Norditropin FlexPro pen to make sure that it contains the growth hormone strength you need.

Read on to learn about:
Preparing your Norditropin FlexPro pen
Checking the growth hormone flow with each new pen
Selecting your dose
Injecting your dose
Caring for your Norditropin FlexPro pen
Important information

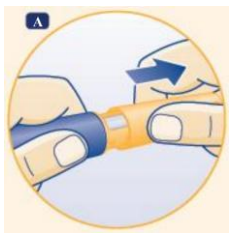


Your Norditropin FlexPro pen is a pre-filled growth hormone pen. Norditropin FlexPro contains 5 mg human growth hormone solution and delivers doses from 0.025 mg to 2.0 mg, in increments of 0.025 mg. Norditropin FlexPro is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm.

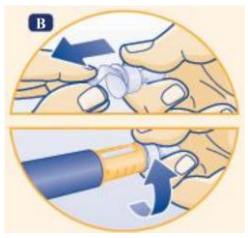
Preparing your Norditropin FlexPro pen
Check the name, strength and coloured label of your Norditropin FlexPro pen to make sure that it contains the growth hormone strength you need.

A Pull off the pen cap.

Check that the growth hormone solution in the pen is clear and colourless by tipping it upside down once or twice. If the solution looks unclear or cloudy, do not use the pen.



B Take a new disposable needle. Tear the paper tab off and screw the needle straight onto the pen. Make sure the needle is on tight.

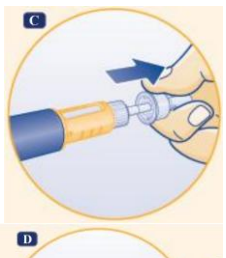


⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of growth hormone, blocked needles and inaccurate dosing.

⚠ Never bend or damage the needle.

C Pull off the outer needle cap and save it.

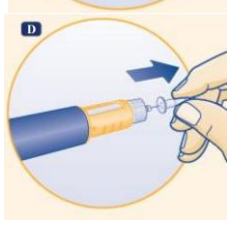
After injection, you will need it to correctly remove the needle from the pen.



D Pull off the inner needle cap and throw it away.

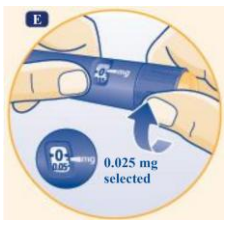
If you try to put it back on, you may accidentally stick yourself with the needle.

A drop of growth hormone may appear at the needle tip. This is normal.



Checking the growth hormone flow with each new pen
Make sure that you receive your full dose by checking the growth hormone flow before you select and inject your first dose with each new pen.

E Turn the dose selector to select the **minimum** dose, 0.025 mg.



F Hold the pen with the needle pointing up.

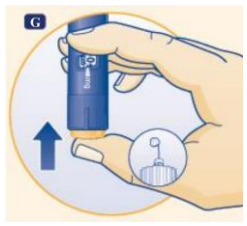
Tap the top of the pen a few times to let any air bubbles rise to the top.



G Press the dose button until the figure 0 in the display lines up with the pointer and a drop of growth hormone appears at the needle tip.

If no drop appears, repeat steps E to G up to 6 times. If no drop appears after these new attempts, change the needle and repeat steps E to G once more.

Do not use the pen if a drop of growth hormone still does not appear.

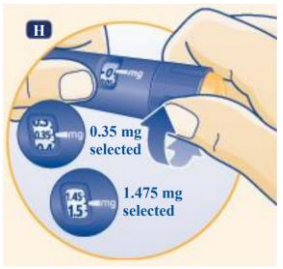


⚠ Always make sure that a drop appears at the needle tip before you inject your first dose with each new pen.

Selecting your dose
Use the dose selector on your Norditropin FlexPro pen to select up to 2.0 mg per dose.

H Select or adjust the dose you need by turning the dose selector forwards or backwards until the right number of mg lines up with the pointer.

When the pen contains less than 2.0 mg, the dose selector stops at the number of mg left.



ⓘ The dose selector clicks differently when turned forwards, backwards or past the number of mg left.

ⓘ **How much growth hormone is left?**
You can use the growth hormone scale to see approximately how much growth hormone is left in the pen.

You can use the dose selector to see exactly how much growth hormone is left – if the pen contains less than 2.0 mg:

Turn the dose selector until it stops. The figure that lines up with the pointer shows how many mg are left.

If you need more growth hormone than you have left in your pen, you can use a new pen or split your dose between your current pen and a new pen.

⚠ Never use the pen clicks to count the number of mg you select. Only the display and pointer will indicate the exact number of mg.

⚠ Never use the growth hormone scale to measure how much growth hormone to inject. Only the display and pointer will indicate the exact number of mg.

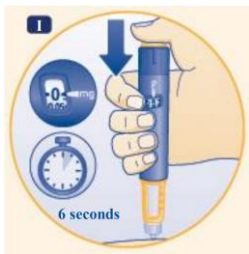
Injecting your dose
Make sure that you receive your full dose by using the right injection technique.

I Insert the needle into your skin as your doctor or nurse has shown you. Press the dose button to inject until the figure 0 in the display lines up with the pointer.

As you do this, you may hear or feel a click.

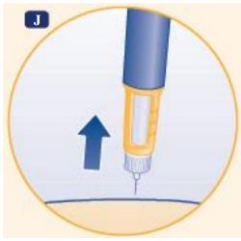
Leave the needle under the skin for at least **6 seconds** to make sure that you get your full dose.

You can let go of the dose button while you wait.



J Remove the needle from the skin.

After that, you may see a drop of growth hormone at the needle tip. This is normal and has no effect on the dose you just received.

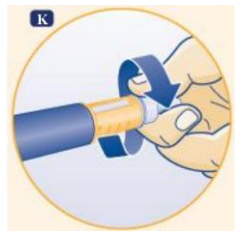


⚠ Never use the pen clicks to count the number of mg you inject. Only the display and pointer will indicate the exact number of mg.

⚠ Never touch the display when you inject, as this can block the injection.

K Put the outer needle cap back on carefully without touching the needle. Unscrew the needle and throw it away carefully as instructed by your doctor or nurse.

Put the pen cap back on after every use.
When the pen is empty, throw it away without a needle on as advised by your doctor or nurse and local authorities.



⚠ Never put the inner needle cap back on once you have removed it from the needle. You may accidentally stick yourself with the needle.

⚠ Always store the pen without a needle attached. This reduces the risk of contamination, infection, leakage of growth hormone, blocked needles and inaccurate dosing.

Caring for your Norditropin FlexPro pen
Treat your Norditropin FlexPro pen with care:
- Do not drop your pen or knock it against hard surfaces. If you do drop it or suspect that something is wrong with it, always screw on a new disposable needle and check the growth hormone flow before you inject.
- Do not try to refill your pen – it is pre-filled.
- Do not try to repair your pen or pull it apart.
- Do not expose your pen to dust, dirt, liquid or direct light.
- Do not try to wash, soak or lubricate your pen. If necessary, clean it with a mild detergent on a moistened cloth.
- Do not freeze your pen or store it close to any cooling element, e.g. in a refrigerator.
- See section 5 ‘How to store Norditropin FlexPro’ for information about how to store your pen.

⚠ **Important information**
- Always keep your pen and needles out of reach of others, especially children.
- **Never share** your pen or your needles with other people. It might lead to cross-infection.
- Caregivers must **be very careful when handling used needles** – to reduce the risk of needle injury and cross-infection.

⚠ **Important information**
Pay special attention to these notes as they are important for safe use of the pen.

ⓘ **Additional information**
Norditropin FlexPro
5 mg/1.5 ml
Somatropin

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