1. Name of the medicinal product

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

2. Qualitative and quantitative composition

Norditropin® FlexPro: 5 mg/1.5 ml
One ml of solution contains 3.3 mg somatropin

somatropin (recombinant DNA origin produced in E-coli)

1 mg of somatropin corresponds to 3 IU (International Unit) of somatropin

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Solution for injection in pre-filled pen

Clear, colourless solution

4. Clinical particulars

4.1 Therapeutic indications

Children:
Growth failure due to growth hormone deficiency (GHD)

Growth failure in girls due to gonadal dysgenesis (Turner syndrome)

Growth retardation in prepubertal children due to chronic renal disease and short children born small for gestational age (SGA), who failed to show catch-up growth by 4 years of age.

Adults:
Childhood onset growth hormone deficiency:
Patients with childhood onset GHD should be re-evaluated for growth hormone secretory capacity after growth completion. Testing is not required for those with more than three pituitary hormone deficits, with severe GHD due to a defined genetic cause, due to structural hypothalamic pituitary abnormalities, due to central nervous system tumours or due to high-dose cranial irradiation, or with GHD secondary to a pituitary/hypothalamic disease or insult, if measurements of serum insulin-like growth factor 1 (IGF-1) is <-2 SDS after at least four weeks off growth hormone treatment.
In all other patients an IGF-1 measurement and one growth hormone stimulation test is required.

Adult onset growth hormone deficiency:
Pronounced GHD in known hypothalamic-pituitary disease, cranial irradiation and traumatic brain injury. GHD should be associated with one other deficient axis, other than prolactin.

GHD should be demonstrated by one provocative test after institution of adequate replacement therapy for any other deficient axis.

In adults, the insulin tolerance test is the provocative test of choice. When the insulin tolerance test is contraindicated, alternative provocative tests must be used. The combined arginine-growth hormone releasing hormone is recommended. An arginine or glucagon test may also be considered; however, these tests have less established diagnostic value than the insulin tolerance test.

4.2 Posology and method of administration

Norditropin® should only be prescribed by doctors with special knowledge of the therapeutic indication of use.

Posology

The dosage is individual and must always be adjusted in accordance with the individual's clinical and biochemical response to therapy.

Generally recommended dosages:

Paediatric population:
Growth hormone deficiency:
0.025 – 0.035 mg/kg/day or 0.7 – 1.0 mg/m²/day
When GHD persists after growth completion, growth hormone treatment should be continued to achieve full somatic adult development including lean body mass and bone mineral accrual (for guidance on dosing, see Replacement therapy in adults).

Turner syndrome
0.045 – 0.067 mg/kg/day or 1.3 – 2.0 mg/m²/day

Chronic renal disease
0.050 mg/kg/day or 1.4 mg/m²/day (see section 4.4)

Small for Gestational Age
0.033 to 0.067 mg/kg/day or 1.0 to 2.0 mg/m²/day

Adult population:
Replacement therapy in adults
The dosage must be adjusted to the need of the individual patient.
In patients with childhood onset GHD, the recommended dose to restart is 0.2 – 0.5 mg/day with subsequent dose adjustment on the basis of IGF-1 concentration determination.
In patients with adult onset GHD, it is recommended to start treatment with a low dose: 0.1 – 0.3 mg/day. It is recommended to increase the dosage gradually at monthly intervals based on the clinical response and the patient's experience of adverse events. Serum IGF-1 can be used as guidance for the dose titration. Women may require higher doses than men, with men showing an increasing IGF-1 sensitivity over time. This means that there is a risk that

women, especially those on oral oestrogen replacement, are undertreated while men are overtreated.
Dose requirements decline with age. Maintenance dosages vary considerably from person to person, but seldom exceed 1.0 mg/day.

Method of administration

Generally, daily subcutaneous administration in the evening is recommended. The injection site should be varied to prevent lipoatrophy.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Somatropin must not be used when there is any evidence of activity of a tumour. Intracranial tumours must be inactive and antitumour therapy must be completed prior to starting growth hormone (GH) therapy. Treatment should be discontinued if there is evidence of tumour growth.

Somatropin should not be used for longitudinal growth promotion in children with closed epiphyses.

Patients with acute critical illness suffering complications following open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure, or similar conditions should not be treated with somatropin (see section 4.4).

In children with chronic renal disease, treatment with Norditropin® FlexPro should be discontinued at renal transplantation.

Pregnancy and lactation.

4.4 Special warnings and precautions for use

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Children treated with somatropin should be regularly assessed by a specialist in child growth. Somatropin treatment should always be instigated by a physician with special knowledge of growth hormone insufficiency and its treatment. This is true also for the management of Turner syndrome, chronic renal disease and SGA. Data of final adult height following the use of Norditropin® for children with chronic renal disease are not available.

The maximum recommended daily dose should not be exceeded (see section 4.2).

The stimulation of longitudinal growth in children can only be expected until epiphyseal closure.

Children

Treatment of growth hormone deficiency in patients with Prader-Willi syndrome

There have been reports of sudden death after initiating somatropin therapy in patients with Prader-Willi syndrome, who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnoea, or unidentified respiratory infection.

Small for Gestational Age

In short children born SGA other medical reasons or treatments that could explain growth disturbance should be ruled out before starting treatment.

Experience in initiating treatment in SGA patients near onset of puberty is limited. It is therefore not recommended to initiate treatment near onset of puberty.
Experience with patients with Silver-Russell syndrome is limited.

Turner syndrome

Monitoring of growth of hands and feet in Turner syndrome patients treated with somatropin is recommended, and a dose reduction to the lower part of the dose range should be considered if increased growth is observed.

Girls with Turner syndrome generally have an increased risk of otitis media, which is why otological evaluation is recommended on at least an annual basis.

Chronic renal disease

The dosage in children with chronic renal disease is individual and must be adjusted according to the individual response to therapy (see section 4.2). The growth disturbance should be clearly established before somatropin treatment by following growth on optimal treatment for renal disease over one year. Conservative management of uraemia with customary medicinal product and if needed dialysis should be maintained during somatropin therapy.

Patients with chronic renal disease normally experience a decline in renal function as part of the natural course of their illness. However, as a precautionary measure during somatropin treatment, renal function should be monitored for an excessive decline or increase in the glomerular filtration rate (which could imply hyperfiltration).

Scoliosis

Scoliosis is known to be more frequent in some of the patient groups treated with somatropin for example Turner syndrome. In addition, rapid growth in any child can cause progression of scoliosis. Somatropin has not been shown to increase the incidence or severity of scoliosis. Signs of scoliosis should be monitored during treatment.

Blood glucose and insulin

In Turner syndrome and SGA children it is recommended to measure fasting insulin and blood glucose before start of treatment and annually thereafter. In patients with increased risk of diabetes mellitus (e.g. familial history of diabetes, obesity, severe insulin resistance, acanthosis nigricans), oral glucose tolerance testing (OGTT) should be performed. If overt diabetes occurs, somatropin should not be administered.

Somatropin has been found to influence carbohydrate metabolism, therefore, patients should be observed for evidence of glucose intolerance.

IGF-1
In Turner syndrome and SGA children it is recommended to measure the IGF-1 level before start of treatment and twice a year thereafter. If on repeated measurements IGF-1 levels exceed +2 SD compared to references for age and pubertal status, the dose should be reduced to achieve an IGF-1 level within the normal range.
Some of the height gain obtained with treating short children born SGA with somatropin may be lost if treatment is stopped before final height is reached.

Adults
Growth hormone deficiency in adults
Growth hormone deficiency in adults is a lifelong disease and needs to be treated accordingly, however, experience in patients older than 60 years and in patients with more than five years of treatment in adult growth hormone deficiency is still limited.

Adults and Children
Pancreatitis
Although rare, pancreatitis should be considered in somatropin-treated patients who develop abdominal pain, especially in children.

General
Neoplasms
There is no evidence for increased risk of new primary cancers in children or in adults treated with somatropin.

In patients in complete remission from tumours or malignant disease, somatropin therapy has not been associated with an increased relapse rate.

An overall slight increase in second neoplasms has been observed in childhood cancer survivors treated with growth hormone, with the most frequent being intracranial tumours. The dominant risk factor for second neoplasms seems to be prior exposure to radiation.

Patients who have achieved complete remission of malignant disease should be followed closely for relapse after commencement of somatropin therapy.

Leukaemia
Leukaemia has been reported in a small number of growth hormone deficient patients, some of whom have been treated with somatropin. However, there is no evidence that leukaemia incidence is increased in somatropin recipients without predisposition factors.

Benign intracranial hypertension
In the event of severe or recurrent headache, visual problems, nausea, and/or vomiting, a funduscopy for papilloedema is recommended. If papilloedema is confirmed, a diagnosis of benign intracranial hypertension should be considered and if appropriate the somatropin treatment should be discontinued.

At present there is insufficient evidence to guide clinical decision making in patients with resolved intracranial hypertension. If somatropin treatment is restarted, careful monitoring for symptoms of intracranial hypertension is necessary.

Patients with growth hormone deficiency secondary to an intracranial lesion should be examined frequently for progression or recurrence of the underlying disease process.

Thyroid function
Somatropin increases the extrathyroidal conversion of T4 to T3 and may, as such, unmask incipient hypothyroidism. Monitoring of thyroid function should therefore be conducted in all patients. In patients with hypopituitarism, standard replacement therapy must be closely monitored when somatropin therapy is administered.

In patients with a pituitary disease in progression, hypothyroidism may develop.
Patients with Turner syndrome have an increased risk of developing primary hypothyroidism associated with anti-thyroid antibodies. As hypothyroidism interferes with the response to somatropin therapy patients should have their thyroid function tested regularly and should receive replacement therapy with thyroid hormone when indicated.

Insulin sensitivity
Because somatropin may reduce insulin sensitivity, patients should be monitored for evidence of glucose intolerance (see section 4.5). For patients with diabetes mellitus, the insulin dose may require adjustment after somatropin containing product therapy is instituted. Patients with diabetes or glucose intolerance should be monitored closely during somatropin therapy.

Antibodies
As with all somatropin containing products, a small percentage of patients may develop antibodies to somatropin. The binding capacity of these antibodies is low, and there is no effect on growth rate. Testing for antibodies to somatropin should be carried out in any patient who fails to respond to therapy.

Acute adrenal insufficiency
Introduction of somatropin treatment may result in inhibition of 11βHSD-1 and reduced serum cortisol concentrations. In patients treated with somatropin, previously undiagnosed central (secondary) hypoadrenalism may be unmasked and glucocorticoid replacement may be required. In addition, patients treated with glucocorticoid replacement therapy for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses, following initiation of somatropin treatment (see section 4.5).

Use with oral oestrogen therapy
If a woman taking somatropin begins oral oestrogen therapy, the dose of somatropin may need to be increased to maintain the serum IGF-1 levels within the normal age-appropriate range. Conversely, if a woman on somatropin discontinues oral oestrogen therapy, the dose of somatropin may need to be reduced to avoid excess of growth hormone and/or side effects (see section 4.5).

Slipped capital femoral epiphysis

In patients with endocrine disorders, including growth hormone deficiency, slipped epiphyses of the hip may occur more frequently than in the general population. A patient treated with somatropin who develops a limp or complains of hip or knee pain should be evaluated by a physician.

Clinical trial experience
Two placebo-controlled clinical trials of patients in intensive care units have demonstrated an increased mortality among patients suffering from acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure, who were treated with somatropin in high doses (5.3-8 mg/day). The safety of continuing somatropin treatment in patients receiving replacement doses for approved indications who concurrently develop these illnesses has not been established. Therefore, the potential benefit of treatment continuation with somatropin in patients having acute critical illnesses should be weighed against the potential risk.

One open-label, randomised clinical trial (dose range 0.045-0.090 mg/kg/day) with patients with Turner syndrome indicated a tendency for a dose-dependent risk of otitis externa and otitis media. The increase in ear infections did not result in more ear operations/tube insertions compared to the lower dose group in the trial.

Excipients
Norditropin® contains less than 1 mmol sodium (23 mg) per 1.5 ml, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant treatment with glucocorticoids inhibits the growth-promoting effect of Norditropin®. Patients with ACTH deficiency should have their glucocorticoid replacement therapy carefully adjusted to avoid any inhibitory effect on growth.
Growth hormone decreases the conversion of cortisone to cortisol and may unmask previously undiscovered central hypoadrenalism or render low glucocorticoid replacement doses ineffective (see section 4.4).

In women on oral oestrogen replacement, a higher dose of growth hormone may be required to achieve the treatment goal (see section 4.4).

Data from an interaction study performed in growth hormone deficient adults suggest that somatropin administration may increase the clearance of compounds known to be metabolised by cytochrome P450 isoenzymes. The clearance of compounds metabolised by cytochrome P450 3A4 (e.g. sex steroids, corticosteroids, anticonvulsants and cyclosporine) may be especially increased resulting in lower plasma levels of these compounds. The clinical significance of this is unknown.

The effect of somatropin on final height can also be influenced by additional therapy with other hormones, e.g. gonadotropin, anabolic steroids, oestrogen and thyroid hormone.

In insulin treated patients adjustment of insulin dose may be needed after initiation of somatropin treatment (see section 4.4).

Paediatric population

Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies are insufficient with regard to effects on pregnancy, embryo-foetal development, parturition or postnatal development. No clinical data on exposed pregnancies are available.
Therefore, somatropin containing products are not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

There have been no clinical studies conducted with somatropin containing products in breast-feeding women. It is not known whether somatropin is excreted in human milk. Therefore caution should be exercised when somatropin containing products are administered to breast-feeding women.

Fertility

Fertility studies with Norditropin® have not been performed.

4.7 Effects on ability to drive and use machines

Norditropin® FlexPro has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Growth hormone deficient patients are characterised by extracellular volume deficit. When treatment with somatropin is initiated, this deficit is corrected. Fluid retention with peripheral oedema may occur especially in adults. Carpal tunnel syndrome is uncommon, but may be seen in adults. The symptoms are usually transient, dose dependent and may require transient dose reduction.
Mild arthralgia, muscle pain and paresthesia may also occur but are usually self-limiting.

Adverse reactions in children are uncommon or rare.

Clinical trial experience:

System organ classes	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)	Rare (≥ 1/10,000 to < 1/1,000)

Metabolism and nutrition disorders			In adults: diabetes mellitus type 2	
Nervous system disorders		In adults: headache and paraesthesia	In adults: carpal tunnel syndrome. In children: headache	
Skin and subcutaneous tissue disorders			In adults: pruritus	In children: rash
Musculoskeletal, connective tissue disorders		In adults: arthralgia, joint stiffness and myalgia	In adults: muscle stiffness	In children: arthralgia and myalgia
Reproductive system and breast disorders			In adults and children: gynaecomastia	
General disorders and administration site conditions	In adults: peripheral oedema (see text above)		In adults and children: injection site pain. In children: injection site reaction	In children: peripheral oedema

In children with Turner syndrome increased growth of hands and feet has been reported during somatropin therapy.

A tendency for increased incidence of otitis media in Turner syndrome patients treated with high doses of Norditropin® has been observed in one open-label randomised clinical trial. However, the increase in ear infections did not result in more ear operations/tube insertions compared to the lower dose group in the trial.

Post-marketing experience:

In addition to the above mentioned adverse drug reactions, those presented below have been spontaneously reported and are by an overall judgement considered possibly related to Norditropin® treatment. Frequencies of these adverse events cannot be estimated from the available data:

- Neoplasms benign and malignant (including cysts and polyps): Leukaemia has been reported in a small number of growth hormone deficiency patients (see section 4.4)
- Immune system disorders: Hypersensitivity (see section 4.3). Formation of antibodies directed against somatropin. The titres and binding capacities of these antibodies have been very low and have not interfered with the growth response to Norditropin® administration
- Endocrine disorders: Hypothyroidism. Decrease in serum thyroxin levels (see section 4.4)

- Metabolism and nutrition disorders: Hyperglycaemia (see section 4.4)
- Nervous system disorders: Benign intracranial hypertension (see section 4.4)
- Musculoskeletal and connective tissue disorders: Legg-Calvé-Perthes disease. Legg-Calvé-Perthes disease may occur more frequently in patients with short stature
- Investigations: Increase in blood alkaline phosphatase level.

Reporting of suspected adverse reactions
Healthcare professionals are asked to report any suspected adverse reactions to Novo Nordisk Indonesia at IDJKAgree@novonordisk.com or to BPOM (Badan Pengawas Obat dan Makanan) at e-meso.pom.go.id.

4.9 Overdose

Acute overdosage can lead to low blood glucose levels initially, followed by high blood glucose levels. These decreased glucose levels have been detected biochemically, but without clinical signs of hypoglycaemia. Long-term overdosage could result in signs and symptoms consistent with the known effects of human growth hormone excess.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Somatropin and somatropin agonists. ATC: H01AC01.

Mechanism of action

Norditropin® FlexPro contains somatropin, which is human growth hormone produced by recombinant DNA-technology. It is an anabolic peptide of 191 amino acids stabilised by two disulphide bridges with a molecular weight of approximately 22,000 Daltons.

The major effects of somatropin are stimulation of skeletal and somatic growth and pronounced influence on the body's metabolic processes.

Pharmacodynamic effects

When growth hormone deficiency is treated a normalisation of body composition takes place resulting in an increase in lean body mass and a decrease in fat mass.
Somatropin exerts most of its actions through insulin-like growth factor 1 (IGF-1), which is produced in tissues throughout the body but predominantly by the liver.
More than 90% of IGF-1 is bound to binding proteins (IGFBPs) of which IGFBP-3 is the most important.

A lipolytic and protein sparing effect of the hormone becomes of particular importance during stress.

Somatropin also increases bone turnover indicated by an increase in plasma levels of biochemical bone markers. In adults bone mass is slightly decreased during the initial months of treatment due to more pronounced bone resorption, however, bone mass increases with prolonged treatment.

Clinical efficacy and safety

In clinical trials in short children born SGA doses of 0.033 and 0.067 mg/kg/day have been used for treatment until final height. In 56 patients who were continuously treated and have reached (near) final height, the mean change from height at start of treatment was +1.90 SDS (0.033 mg/kg/day) and +2.19 SDS (0.067 mg/kg/day). Literature data from untreated SGA children without early spontaneous catch-up suggest a late growth of 0.5 SDS. Long-term safety data are still limited.

5.2 Pharmacokinetic properties

I.v. infusion of Norditropin® (33 ng/kg/min for 3 hours) to nine growth hormone deficient patients, gave the following results: serum half-life of 21.1 ± 1.7 min., metabolic clearance rate of 2.33 ± 0.58 ml/kg/min. and a distribution space of 67.6 ± 14.6 ml/kg.

S.c. injection of Norditropin SimpleXx® (Norditropin SimpleXx® is the cartridge containing the solution for injection in Norditropin® FlexPro) 2.5 mg/m^2 in 31 healthy subjects (with endogenous somatropin suppressed by continuous infusion of somatostatin) gave the following results:
Maximal concentration of human growth hormone (42 – 46 ng/ml) after approximately 4 hours. Thereafter human growth hormone declined with a half-life of approximately 2.6 hours.
In addition the different strengths of Norditropin SimpleXx® were demonstrated to be bioequivalent to each other and to Norditropin® for reconstitution after subcutaneous injection to healthy subjects.

5.3 Preclinical safety data

The general pharmacological effects on the CNS, cardiovascular and respiratory systems following administration of Norditropin SimpleXx® with and without forced degradation were investigated in mice and rats; renal function was also evaluated. The degraded product showed no difference in effect when compared with Norditropin SimpleXx® and Norditropin®. All three preparations showed the expected dose dependent decrease in urine volume and retention of sodium and chloride ions.

In rats, similar pharmacokinetics has been demonstrated between Norditropin SimpleXx® and Norditropin®. Degraded Norditropin SimpleXx® has also been demonstrated to be bioequivalent with Norditropin SimpleXx®.

Single and repeated dose toxicity and local tolerance studies of Norditropin SimpleXx® or the degraded product did not reveal any toxic effect or damage to the muscle tissue.

The toxicity of poloxamer 188 has been tested in mice, rats, rabbits, and dogs and no findings of toxicological relevance were revealed.
Poloxamer 188 was rapidly absorbed from the injection site with no significant retention of the dose at the site of injection. Poloxamer 188 was excreted primarily via the urine.

Norditropin SimpleXx® is the cartridge containing the solution for injection in Norditropin® FlexPro.

6. Pharmaceutical particulars

6.1 List of excipients

Mannitol
Histidine
Poloxamer 188
Phenol
Water for injection
Hydrochloric acid for pH adjustment
Sodium hydroxide for pH adjustment

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

24 months
Expiry date is stated on the pen label and carton after 'Expiry'.
After first opening: Store for a maximum of 4 weeks in a refrigerator (2°C – 8°C).
Alternatively, the medicinal product may be stored for a maximum of 3 weeks below 25°C.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C) in the outer carton, in order to protect it from light. Do not freeze.
Do not store close to any cooling elements.
For storage conditions after first opening of the medicinal product, see section 6.3.
Do not freeze.

When in use, always replace the pen cap on the Norditropin® FlexPro pre-filled pen after each injection. Always use a new needle for each injection.
The needle must not be screwed onto the pre-filled pen when it is not in use.

6.5 Nature and contents of container

Norditropin® FlexPro 5 mg/1.5 ml is a multidose disposable pre-filled pen, which consists of a cartridge (Type I colourless glass) permanently sealed in a pen-injector made of plastic components and metal springs. The cartridge is closed at the bottom with a rubber stopper (Type I rubber closures) shaped as a plunger and at the top with a laminated rubber stopper (Type I rubber closures) shaped as a disc and sealed with an aluminium cap. The push button on the pen-injector is coloured orange. Pack size of 1 pre-filled pen.

The pre-filled pen is packed in a carton.

HARUS DENGAN RESEP DOKTER
Reg. No.: DKIXXXXXXXXXXX

6.6 Special precautions for disposal and other handling

Norditropin® FlexPro is a pre-filled pen designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm.

Norditropin® FlexPro 5 mg/1.5 ml delivers a maximum of 2.0 mg somatropin per dose, in increments of 0.025 mg somatropin.

To ensure proper dosing and avoid injection of air, check the growth hormone flow before the first injection. Do not use Norditropin® FlexPro if a drop of growth hormone does not appear at the needle tip. A dose is selected by turning the dose selector, until the desired dose appears at the window of the housing. If the wrong dose is selected, the dose can be corrected by turning the dose selector the opposite way. The push button is pressed to inject the dose.

Norditropin® FlexPro should not be shaken vigorously at any time.

Do not use Norditropin® FlexPro if the growth hormone solution for injection is cloudy or discoloured. Check this by turning the pen upside down once or twice.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Manufactured by:
Novo Nordisk A/S
Hallas Allé
DK-4400 Kalundborg
Denmark

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

Registered by:
PT Beta Pharmacon
Karawang – Indonesia

Distributed by:
PT Anugrah Argon Medica
Indonesia

Based on approval date: ……

Front page information:

Norditropin®
FlexPro
5 mg/1.5 ml
somatropin

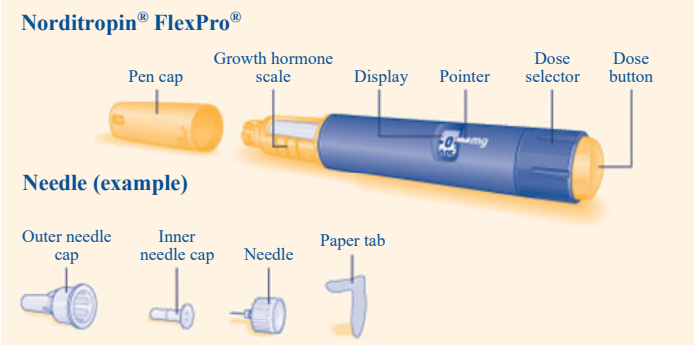
Instructions on how to use Norditropin® FlexPro

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



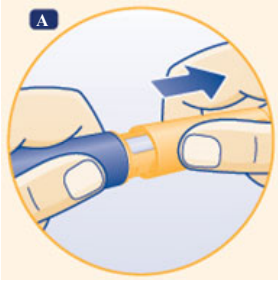
Your Norditropin® FlexPro pen is a pre-filled growth hormone pen. Norditropin® FlexPro contains 5 mg human growth hormone solution and delivers doses from 0.025 mg to 2.0 mg, in increments of 0.025 mg. Norditropin® FlexPro is designed to be used with NovoFine® or NovoTwist® disposable needles up to a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

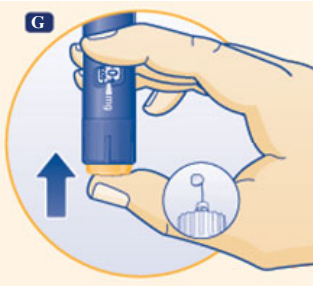
F Hold the pen with the needle pointing up.

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.

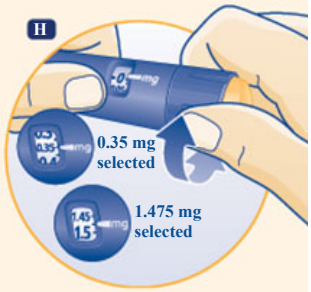


⚠ Always make sure that a drop appears at the needle tip before you inject your first dose with each new pen.

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.

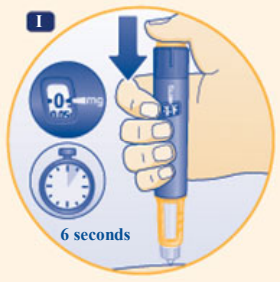
Injecting your dose
Make sure that you receive your full dose by using the right injection technique.

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.

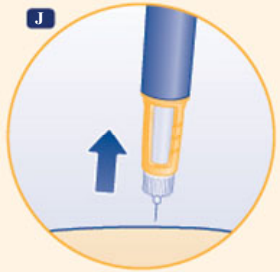
Leave the needle under the skin for at least **6 seconds** to make sure that you get your full dose.

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.



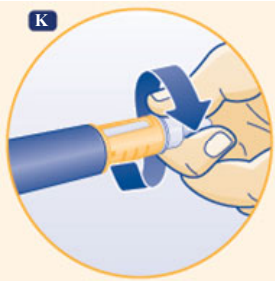
⚠ Never use the pen clicks to count the number of mg you inject. Only the display and pointer will indicate the exact number of mg.

⚠ 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 6.3 and 6.4 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**

Brosur kemasan: Informasi untuk pengguna

Norditropin® FlexPro 5 mg/1,5 ml
larutan injeksi dalam pena yang sudah terisi
somatropin

Bacalah seluruh brosur ini dengan teliti sebelum Anda mulai menggunakan obat ini karena brosur ini berisi informasi yang penting untuk Anda.
- Simpan brosur ini. Anda mungkin perlu membacanya kembali
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda
- Obat ini telah diresepkan hanya untuk Anda. Jangan memberikannya kepada orang lain. Obat ini mungkin membahayakan mereka, meskipun jika mereka memiliki tanda – tanda sakit yang sama dengan Anda
- Jika Anda mengalami efek samping apapun, bicarakan dengan dokter atau apoteker Anda. Termasuk kemungkinan efek samping apapun yang tidak tercantum dalam brosur ini. Lihat bagian 4.

Apa yang terdapat dalam brosur ini

1. Apa itu Norditropin® FlexPro dan untuk apa kegunaannya

Norditropin® FlexPro mengandung hormon pertumbuhan manusia biosintetik yang disebut somatropin 5 mg/1,5 ml yang identik dengan hormon pertumbuhan yang diproduksi secara alami di dalam tubuh. Anak – anak memerlukan hormon pertumbuhan untuk membantu mereka tumbuh, tetapi orang dewasa juga memerlukannya untuk kesehatan mereka secara umum.

Norditropin® FlexPro digunakan untuk mengobati kegagalan pertumbuhan pada anak – anak
- Jika mereka tidak memiliki atau memiliki produksi hormon pertumbuhan yang sangat rendah (defisiensi hormon pertumbuhan)
- Jika mereka memiliki sindrom Turner (gangguan genetik yang mungkin memengaruhi pertumbuhan)
- Jika mereka mengalami penurunan fungsi ginjal
- Jika tinggi mereka pendek dan terlahir kecil pada usia kehamilan (*small for gestational age* / SGA).

Norditropin® FlexPro digunakan sebagai pengganti hormon pertumbuhan pada orang dewasa

Pada orang dewasa Norditropin® FlexPro digunakan untuk menggantikan hormon pertumbuhan jika produksi hormon pertumbuhan mereka telah menurun sejak masa kanak-kanak atau telah hilang ketika usia dewasa karena tumor, pengobatan tumor, atau penyakit yang memengaruhi kelenjar yang memproduksi hormon pertumbuhan. Jika Anda pernah dirawat karena defisiensi hormon pertumbuhan selama masa kanak-kanak, maka Anda akan diperiksa ulang setelah masa pertumbuhan selesai. Jika defisiensi hormon pertumbuhan ditemukan, maka Anda seharusnya melanjutkan pengobatan.

2. Apa yang Anda perlu ketahui sebelum Anda menggunakan Norditropin® FlexPro

Jangan menggunakan Norditropin® FlexPro
- Jika Anda **alergi** terhadap somatropin, fenol, atau zat lainnya dalam obat ini (tercantum di bagian 6)
- Jika Anda pernah menjalani **transplantasi ginjal**
- Jika Anda memiliki **tumor aktif (kanker).** Tumor harus tidak aktif dan Anda harus telah menyelesaikan pengobatan antitumor sebelum Anda memulai pengobatan dengan Norditropin® FlexPro
- Jika Anda memiliki **penyakit kritis akut** misalnya operasi jantung terbuka, operasi perut, trauma kecelakaan multipel atau gagal pernapasan akut
- Jika Anda telah berhenti tumbuh (epifisis tertutup) dan Anda tidak mengalami defisiensi hormon pertumbuhan.

Peringatan dan pencegahan
Bicarakan dengan dokter atau apoteker Anda sebelum menggunakan Norditropin® FlexPro
- Jika Anda memiliki **diabetes**
- Jika Anda pernah memiliki **kanker** atau jenis **tumor** lainnya
- Jika Anda berulangkali mengalami **sakit kepala, gangguan penglihatan, mual** atau jika **muntah** terjadi
- Jika Anda memiliki kelainan fungsi **tiroid**
- Peningkatan kelengkungan tulang belakang ke samping (skoliosis) mungkin berkembang pada anak mana pun selama pertumbuhan yang cepat. Selama pengobatan dengan Norditropin® FlexPro, dokter Anda akan memeriksa Anda (atau anak Anda) untuk tanda-tanda skoliosis
- Jika Anda berjalan dengan pincang atau jika Anda mulai pincang selama pengobatan hormon pertumbuhan, Anda seharusnya menginformasikan dokter Anda
- Jika Anda berusia **di atas 60 tahun,** atau telah mendapatkan pengobatan somatropin sebagai orang dewasa selama lebih dari 5 tahun, karena pengalamannya terbatas
- Jika Anda memiliki **penyakit ginjal,** karena fungsi ginjal Anda seharusnya dipantau oleh dokter Anda
- Jika Anda menjalani **terapi pengganti dengan glukokortikoid,** Anda seharusnya berkonsultasi dengan dokter Anda secara teratur, karena Anda mungkin memerlukan penyesuaian dosis glukokortikoid Anda.
- Norditropin® FlexPro mungkin menyebabkan peradangan pankreas, yang menyebabkan nyeri parah di perut dan punggung. Hubungi dokter Anda jika Anda atau anak Anda mengalami nyeri perut setelah mengonsumsi Norditropin® FlexPro.

Obat-obatan lain dan Norditropin® FlexPro

Beritahu dokter atau apoteker Anda jika Anda sedang menggunakan, baru saja atau mungkin menggunakan obat – obatan lain.
Secara khusus, informasikan dokter Anda jika Anda sedang atau baru saja mengonsumsi obat-obatan berikut. Dokter Anda mungkin perlu menyesuaikan dosis Norditropin® FlexPro atau obat - obatan lain tersebut:

- **Glukokortikoid** - tinggi badan dewasa Anda mungkin terpengaruh jika Anda menggunakan Norditropin® FlexPro dan glukokortikoid di waktu yang bersamaan
- **Cyclosporine** (imunosupresif) - karena dosis Anda mungkin perlu disesuaikan
- **Insulin** - karena dosis Anda mungkin perlu disesuaikan
- Hormon **tiroid** - karena dosis Anda mungkin perlu disesuaikan
- **Gonadotropin** (hormon perangsang gonad) - karena dosis Anda mungkin perlu disesuaikan
- **Antikonvulsan** - karena dosis Anda mungkin perlu disesuaikan
- **Estrogen** oral atau hormon seks lainnya.

Kehamilan dan menyusui
Produk yang mengandung somatropin tidak direkomendasikan untuk wanita dengan potensi melahirkan yang tidak menggunakan kontrasepsi.

- **Kehamilan –** Hentikan pengobatan dan beritahu dokter Anda jika Anda hamil ketika Anda menggunakan Norditropin® FlexPro.
- **Menyusui –** Jangan menggunakan Norditropin® FlexPro ketika Anda sedang menyusui karena somatropin mungkin masuk ke dalam ASI Anda.

Mengemudi dan menggunakan mesin
Norditropin® FlexPro tidak memengaruhi penggunaan mesin apapun atau kemampuan untuk mengemudi dengan aman.

Norditropin® mengandung natrium
Norditropin® mengandung kurang dari 1 mmol natrium (23 mg) per 1,5 ml, sehingga pada dasarnya ‘bebas natrium’.

3. Bagaimana cara menggunakan Norditropin® FlexPro

Selalu gunakan obat ini sama dengan yang dokter Anda telah beritahukan kepada Anda. Periksa dengan dokter atau apoteker Anda jika Anda tidak yakin.

Dosis yang direkomendasikan
Dosis untuk anak – anak tergantung pada berat badan dan luas permukaan tubuh mereka. Selanjutnya, dosis tergantung pada tinggi badan, berat badan, jenis kelamin dan sensitivitas hormon pertumbuhan Anda dan akan disesuaikan hingga Anda mendapatkan dosis yang tepat.

- **Anak – anak dengan produksi hormon pertumbuhan yang rendah atau defisiensi hormon pertumbuhan:**
  Dosis umumnya adalah 0,025 hingga 0,035 mg per kg berat badan per hari atau 0,7 hingga 1,0 mg per m² luas permukaan tubuh per hari
- **Anak – anak dengan sindrom Turner:**

Dosis umumnya adalah 0,045 hingga 0,067 mg per kg berat badan per hari atau 1,3 hingga 2,0 mg per m² luas permukaan tubuh per hari

- **Anak – anak dengan penyakit ginjal:**
  Dosis umumnya adalah 0,050 mg per kg berat badan per hari atau 1,4 mg per m² luas permukaan tubuh per hari
- **Anak – anak yang terlahir kecil pada usia kehamilan (*small for gestational age* / SGA):**
  Dosis umumnya adalah 0,033 hingga 0,067 mg per kg berat badan per hari atau 1,0 hingga 2,0 mg per m² luas permukaan tubuh per hari
- **Orang dewasa dengan produksi hormon pertumbuhan yang rendah atau defisiensi hormon pertumbuhan:**
  Jika defisiensi hormon pertumbuhan Anda berlanjut setelah selesainya pertumbuhan, pengobatan seharusnya dilanjutkan. Dosis awal umumnya adalah 0,2 hingga 0,5 mg per hari. Dosis akan disesuaikan hingga Anda mendapatkan dosis yang tepat. Jika defisiensi hormon pertumbuhan Anda dimulai pada masa dewasa, dosis awal biasa adalah 0,1 hingga 0,3 mg per hari. Dokter Anda akan meningkatkan dosis ini setiap bulan hingga Anda mendapatkan dosis yang Anda perlukan. Dosis maksimum umumnya adalah 1,0 mg per hari.

Kapan menggunakan Norditropin® FlexPro
Suntikkan dosis harian Anda ke dalam kulit setiap malam sebelum tidur.

Bagaimana cara menggunakan Norditropin® FlexPro
Larutan hormon pertumbuhan Norditropin® FlexPro tersedia dalam pena multidosis sekali pakai yang sudah terisi 1,5 ml.
Instruksi lengkap tentang bagaimana cara menggunakan pena Norditropin® FlexPro dicantumkan di halaman sebaliknya. Hal instruksional utamanya adalah sebagai berikut:

- Periksa larutan sebelum digunakan dengan membalikkan pena satu atau dua kali. Jangan menggunakan pena jika larutan keruh atau berubah warna
- Norditropin® FlexPro dirancang untuk digunakan dengan jarum sekali pakai NovoFine® atau NovoTwist® dengan panjang hingga 8 mm
- Selalu gunakan jarum baru untuk setiap penyuntikan
- Variasikan area penyuntikan agar tidak membahayakan kulit Anda
- Untuk memastikan Anda mendapatkan dosis yang tepat dan tidak menyuntikkan udara, periksa aliran hormon pertumbuhan sebelum penyuntikan pertama dari pena Norditropin® FlexPro baru. Jangan menggunakan pena jika satu tetesan larutan hormon pertumbuhan tidak muncul di ujung jarum
- Jangan berbagi pena Norditropin® FlexPro Anda dengan orang lain.

Berapa lama Anda akan memerlukan pengobatan

- Anak – anak dengan kegagalan pertumbuhan karena sindrom Turner, penyakit ginjal atau SGA: Dokter Anda akan merekomendasikan Anda untuk melanjutkan pengobatan hingga Anda berhenti tumbuh.
- Anak – anak atau remaja yang defisiensi hormon pertumbuhan: Dokter Anda akan merekomendasikan Anda untuk melanjutkan pengobatan hingga dewasa.

Jangan berhenti menggunakan Norditropin® FlexPro tanpa mendiskusikannya dengan dokter Anda terlebih dahulu.

Jika Anda menggunakan lebih banyak Norditropin® FlexPro dari yang seharusnya
Beritahu dokter Anda jika Anda menyuntikkan terlalu banyak somatropin. Overdosis jangka panjang dapat menyebabkan pertumbuhan yang abnormal dan fitur wajah menjadi kasar.

Jika Anda lupa menggunakan Norditropin® FlexPro
Suntikkan dosis berikutnya seperti biasa, di waktu normal. **Jangan menyuntikkan dosis ganda** untuk mengganti dosis yang terlewat.

Jika Anda berhenti menggunakan Norditropin® FlexPro
Jangan berhenti menggunakan Norditropin® FlexPro tanpa mendiskusikannya dengan dokter Anda terlebih dahulu.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

4. Efek samping yang mungkin dirasakan

Seperti semua obat-obatan, obat ini dapat menyebabkan efek samping meskipun tidak semua orang mengalami efek samping.

Efek yang terjadi pada anak – anak dan orang dewasa (frekuensi tidak diketahui):
- **Ruam, mengi, pembengkakan kelopak mata, wajah atau bibir, kolaps total.** Hal tersebut mungkin merupakan tanda – tanda reaksi alergi
- **Sakit kepala, gangguan penglihatan, rasa mual** dan **muntah**. Hal tersebut mungkin tanda – tanda peningkatan tekanan di otak
- Kadar serum **tiroksin** mungkin turun
- **Hiperglikemia** (peningkatan kadar gula darah).

Jika Anda mengalami salah satu dari efek tersebut, segera temui dokter. Hentikan penggunaan Norditropin® FlexPro hingga dokter Anda mengatakan Anda dapat melanjutkan pengobatan.

Pembentukan antibodi langsung terhadap somatropin jarang ditemukan selama terapi Norditropin®.
Peningkatan kadar enzim hati telah dilaporkan.
Kasus leukemia dan kekambuhan tumor otak juga telah dilaporkan pada pasien yang diobati dengan somatropin (zat aktif di Norditropin® FlexPro), meskipun tidak ada bukti bahwa somatropin adalah penyebabnya.

Jika Anda merasa mengalami salah satu dari penyakit tersebut, bicarakan dengan dokter Anda.

Efek samping tambahan pada anak – anak
Tidak umum (mungkin memengaruhi hingga 1 dari 100 anak - anak):
- **Sakit kepala**
- **Kemerahan,** gatal dan nyeri di area penyuntikan
- **Pembesaran payudara** (gynaecomastia).

Jarang (mungkin memengaruhi hingga 1 dari 1.000 anak - anak):
- **Ruam**
- Nyeri **otot** dan sendi
- **Pembengkakan tangan** dan kaki karena retensi cairan.

Dalam kasus yang jarang terjadi, anak – anak yang menggunakan Norditropin® FlexPro telah mengalami nyeri pinggul dan lutut atau mulai pincang. Gejala - gejala ini mungkin disebabkan oleh penyakit yang memengaruhi bagian atas tulang paha (penyakit Legg-Calvé) atau karena ujung tulang telah terlepas dari tulang rawan (*slipped capital femoral epiphysis*) dan mungkin bukan karena Norditropin® FlexPro.

Pada anak-anak dengan **sindrom Turner**, beberapa kasus **pertumbuhan tangan dan kaki yang meningkat** dibandingkan dengan tinggi badan telah ditemukan dalam uji klinis.

Uji klinis pada anak – anak dengan sindrom Turner telah menunjukkan bahwa dosis tinggi Norditropin® mungkin dapat meningkatkan risiko terkena infeksi telinga.

Jika salah satu dari efek samping tersebut menjadi serius, atau jika Anda mengalami efek samping apapun yang tidak tercantum dalam brosur ini, beritahu dokter atau apoteker Anda, karena dosis mungkin perlu dikurangi.

Efek samping tambahan pada orang dewasa
Sangat umum (mungkin memengaruhi lebih dari 1 dari 10 orang dewasa):
- **Pembengkakan tangan** dan kaki karena retensi cairan.

Umum (mungkin memengaruhi hingga 1 dari 10 orang dewasa):
- **Sakit kepala**
- Perasaan **merayap di kulit** (formikasi) dan mati rasa atau nyeri terutama di jari
- **Nyeri sendi** dan kekakuan; nyeri otot.

Tidak umum (mungkin memengaruhi hingga 1 dari 100 orang dewasa):
- **Diabetes tipe 2**
- **Sindrom carpal tunnel;** kesemutan dan nyeri di jari dan tangan
- **Gatal** (dapat intens) dan nyeri di area penyuntikan
- **Kekakuan otot**
- **Pembesaran payudara** (gynaecomastia).

Pelaporan efek samping
Jika Anda mengalami efek samping apapun selama atau setelah penggunaan obat, bicarakan dengan dokter atau apoteker Anda. Termasuk kemungkinan efek samping apapun yang tidak tercantum dalam brosur ini. Anda juga dapat melaporkan efek samping tersebut secara langsung ke Novo Nordisk Indonesia melalui IDJKAgree@novonordisk.com. Dengan melaporkan efek samping, Anda dapat membantu menyediakan informasi lebih lanjut mengenai keamanan obat ini.

5. Bagaimana cara menyimpan Norditropin® FlexPro

Jauhkan obat ini dari pandangan dan jangkauan anak – anak.

Jangan menggunakan obat ini setelah tanggal kadaluwarsa yang tercantum di kemasan setelah 'Expiry'. Tanggal kadaluwarsa mengacu di hari terakhir bulan tersebut.

Simpan pena Norditropin® FlexPro **yang belum digunakan** di lemari pendingin (2°C - 8°C) di dalam karton, untuk melindunginya dari cahaya. Jangan dibekukan atau terpapar panas. Jangan disimpan di dekat elemen pendingin apapun.

Ketika menggunakan Norditropin® FlexPro 5 mg/1,5 ml Anda dapat:
- Menyimpannya hingga 4 minggu di lemari pendingin (2°C - 8°C), **atau**
- Menyimpannya hingga 3 minggu di suhu ruang (di bawah 25°C).

Jangan menggunakan pena Norditropin® FlexPro jika telah dibekukan atau terpapar suhu yang berlebihan.

Jangan menggunakan pena Norditropin® FlexPro jika larutan hormon pertumbuhan keruh atau berubah warna.

Selalu simpan Norditropin® FlexPro tanpa jarum terpasang.
Selalu tutup pena Norditropin® FlexPro sepenuhnya ketika Anda tidak menggunakannya.
Selalu gunakan jarum baru untuk setiap penyuntikan.

Jangan membuang obat apapun melalui limbah pembuangan air atau limbah rumah tangga. Tanyakan ke apoteker Anda bagaimana membuang obat – obatan yang sudah tidak Anda gunakan. Hal tersebut akan membantu melindungi lingkungan.

6. Isi kemasan dan informasi lainnya

Apa kandungan Norditropin® FlexPro
- Zat aktifnya adalah somatropin
- Zat tambahan lainnya adalah manitol, histidine, poloxamer 188, fenol, air untuk injeksi, asam hidroklorida dan natrium hidroksida.

Seperti apa Norditropin® FlexPro dan isi kemasannya
Norditropin® FlexPro adalah larutan injeksi yang jernih dan tidak berwarna dalam pena multidosis sekali pakai yang sudah terisi 1,5 ml.

1 ml larutan mengandung 3,3 mg somatropin.
1 mg somatropin setara dengan 3 IU somatropin.

Kemasan isi 1 pena yang sudah terisi.

HARUS DENGAN RESEP DOKTER
Reg. No.: DKIXXXXXXXXXXXX

Diproduksi oleh:
Novo Nordisk A/S
Hallas Allé

DK-4400 Kalundborg
Denmark

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

Didaftarkan oleh:
PT Beta Pharmacon
Karawang - Indonesia

Didistribusikan oleh:
PT Anugrah Argon Medica
Indonesia

Berdasarkan persetujuan tanggal: …….

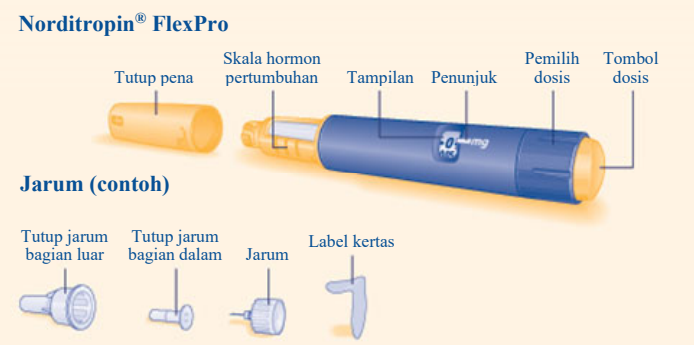
Informasi di halaman depan :

Norditropin®
FlexPro
5 mg/1,5 ml
somatropin

Norditropin® dan FlexPro adalah merek dagang yang dimiliki oleh Novo Nordisk Health Care AG, Swiss.
NovoFine® dan NovoTwist® adalah merek dagang yang dimiliki oleh Novo Nordisk A/S, Denmark.

Instruksi bagaimana cara menggunakan Norditropin® FlexPro
Bacalah instruksi ini dengan teliti sebelum menggunakan pena Norditropin® FlexPro Anda.
Mulailah dengan memeriksa nama, kekuatan, dan label berwarna pena Norditropin® FlexPro Anda untuk memastikan bahwa pena tersebut mengandung kekuatan hormon pertumbuhan yang Anda perlukan.

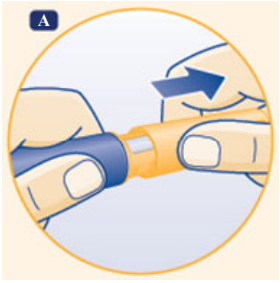
Bacalah untuk mempelajari tentang:
Mempersiapkan pena Norditropin® FlexPro Anda
Memeriksa aliran hormon pertumbuhan dengan setiap pena baru
Memilih dosis Anda
Menyuntikkan dosis Anda
Pemeliharaan pena Norditropin® FlexPro Anda
Informasi penting



Pena Norditropin® FlexPro Anda is a pena injeksi yang sudah terisi hormon pertumbuhan. Norditropin® FlexPro mengandung 5 mg larutan hormon pertumbuhan manusia dan memberikan dosis dari 0,025 mg hingga 2,0 mg, dengan kenaikan 0,025 mg. Norditropin® FlexPro dirancang untuk digunakan dengan jarum sekali pakai NovoFine® atau NovoTwist® dengan panjang hingga 8 mm.

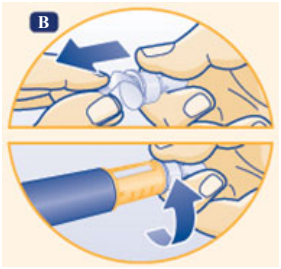
Mempersiapkan pena Norditropin® FlexPro Anda
Periksa nama, kekuatan dan label warna pena Norditropin® FlexPro Anda untuk memastikan bahwa pena tersebut mengandung kekuatan hormon pertumbuhan yang Anda perlukan.

A Cabut tutup pena.



Periksa bahwa larutan hormon pertumbuhan di dalam pena jernih dan tidak berwarna dengan cara membalikkan pena satu atau dua kali. Jika larutan terlihat tidak jernih atau keruh, jangan menggunakan pena.

B Ambil jarum sekali pakai yang baru. Lepaskan label kertas dan putar jarum lurus ke pena. Pastikan jarum terpasang dengan kencang.

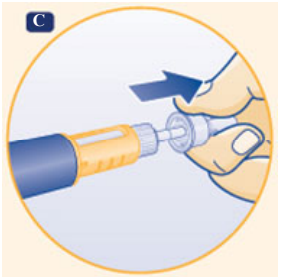


Selalu gunakan jarum baru untuk setiap penyuntikan**.** Hal tersebut mengurangi risiko kontaminasi, infeksi, kebocoran hormon pertumbugan, jarum tersumbat dan dosis yang tidak akurat.

Jangan pernah membengkokkan atau merusak jarum

C Cabut tutup jarum bagian luar dan simpan.

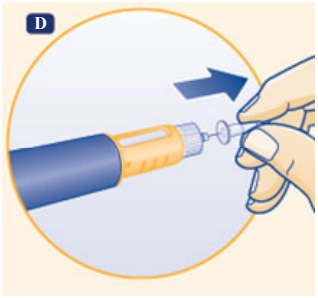
Setelah penyuntikan, Anda akan memerlukannya untuk melepaskan jarum dengan benar dari pena.



D Cabut tutup jarum bagian dalam dan buang.

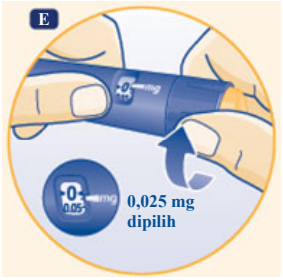
Jika Anda mencoba memasangnya kembali, Anda mungkin tidak sengaja tertusuk jarum.

Setetes hormon pertumbuhan mungkin muncul di ujung jarum. Hal tersebut normal.

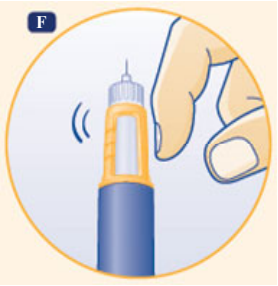


Memeriksa aliran hormon pertumbuhan dengan setiap pena baru
Pastikan Anda menerima dosis penuh dengan memeriksa aliran hormon pertumbuhan sebelum Anda memilih dan menyuntikkan dosis pertama dengan setiap pena baru.

E Putar pemilih dosis untuk memilih dosis **minimum** 0,025 mg.

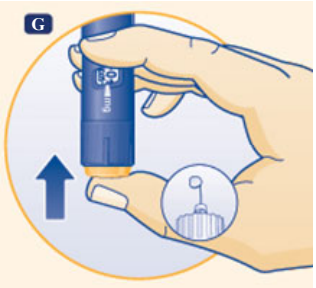


F Pegang pena dengan jarum mengarah ke atas.



ketuk bagian atas pena beberapa kali agar gelembung udara naik ke atas.

G Tekan tombol dosis hingga angka 0 di tampilan sejajar dengan penunjuk dan setetes hormon pertumbuhan muncul di ujung jarum.



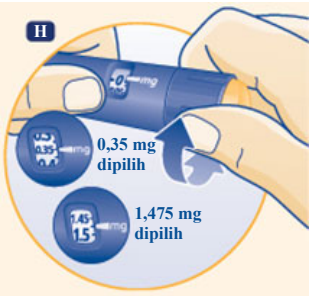
Jika tidak ada tetesan yang muncul, ulangi langkah E hingga G hingga 6 kali. Jika tetap tidak ada tetesan, ganti jarum dan ulangi langkah E hingga G sekali lagi.

Jangan menggunakan pena jika tetesan hormon pertumbuhan tetap tidak muncul.

Selalu pastikan bahwa tetesan muncul di ujung jarum sebelum Anda menyuntikkan dosis pertama Anda dengan setiap pena baru.

Memilih dosis Anda
Gunakan pemilih dosis pada pena Norditropin® FlexPro Anda untuk memilih hingga 2,0 mg per dosis.

H Pilih atau atur dosis yang Anda perlukan dengan memutar pemilih dosis ke depan atau ke belakang hingga angka yang tepat sejajar dengan penunjuk.



Ketika pena mengandung kurang dari 2,0 mg, pemilih dosis berhenti pada angka mg yang tersisa.

Pemilih dosis berbunyi klik berbeda ketika diputar ke depan, ke belakang atau melewati jumlah mg yang tersisa.

Berapa banyak hormon pertumbuhan yang tersisa?
Anda bisa menggunakan skala hormon pertumbuhan untuk melihat perkiraan berapa banyak hormon pertumbuhan yang tersisa di pena.

Anda bisa menggunakan pemilih dosis untuk melihat dengan tepat berapa banyak hormon pertumbuhan yang tersisa – jika pena mengandung kurang dari 2,0 mg: Putar pemilih dosis sampai berhenti. Angka yang sejajar dengan penunjuk menunjukkan berapa mg yang tersisa.

Jika Anda memerlukan hormon pertumbuhan lebih banyak dari yang tersisa di pena Anda, Anda dapat menggunakan pena baru atau membagi dosis Anda antara pena Anda saat ini digunakan dan pena baru.

Jangan menggunakan bunyi klik pena untuk menghitung jumlah mg yang Anda pilih. Hanya tampilan dan penunjuk yang mengindikasikan jumlah mg dengan tepat.

Jangan menggunakan skala hormon pertumbuhan untuk mengukur berapa banyak hormon pertumbuhan yang disuntikkan. Hanya tampilan dan penunjuk yang mengindikasikan jumlah mg dengan tepat.

Menyuntikkan dosis Anda
Pastikan Anda mendapatkan dosis penuh Anda dengan melakukan teknik penyuntikan yang benar.

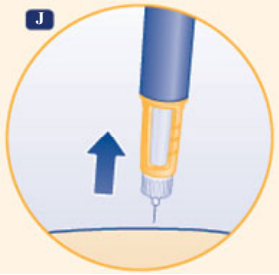
I Masukkan jarum ke dalam kulit Anda seperti yang dokter atau perawat Anda tunjukkan kepada Anda. Tekan tombol dosis untuk menyuntikkan sampai angka 0 di tampilan sejajar dengan penunjuk.

Ketika Anda melakukan hal tersebut, Anda mungkin mendengar atau merasakan klik.

Diamkan jarum di dalam kulit setidaknya selama **6 detik** untuk memastikan Anda mendapatkan dosis penuh Anda.

Anda bisa melepas tombol dosis sambil Anda menunggu.

J Lepaskan jarum dari kulit.

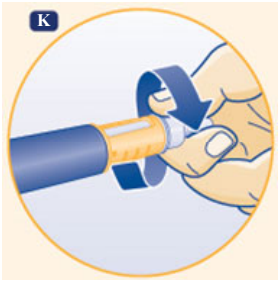


Setelahnya, Anda mungkin melihat tetesan hormon pertumbuhan di ujung jarum. Hal tersebut normal dan tidak memiliki efek terhadap dosis yang Anda baru saja dapatkan.

Jangan menggunakan klik pena untuk menghitung mg yang Anda suntikkan. Hanya tampilan dan penunjuk yang mengindikasikan jumlah mg yang tepat.

Jangan menyentuh tampilan saat Anda menyuntikkan, karena hal tersebut dapat menghambat penyuntikan.

K Pasang kembali tutup jarum bagian luar di jarum dengan hati-hati tanpa menyentuh jarum. Lepaskan jarum dan buang dengan hati-hati seperti yang diinstruksikan oleh dokter atau perawat Anda.



Pasang kembali tutup pena setelah setiap penggunaan.

Ketika pena kosong, buang pena tanpa jarum seperti yang disarankan oleh dokter atau perawat Anda dan pihak berwenang setempat.

Jangan memasang kembali tutup jarum bagian dalam setelah Anda melepasnya dari jarum. Anda mungkin tidak sengaja tertusuk jarum.

Selalu simpan pena tanpa jarum terpasang. Hal tersebut mengurangi risiko kontaminasi, infeksi, kebocoran hormon pertumbuhan, jarum yang terhambat dan dosis yang tidak akurat.

Pemeliharaan pena Norditropin® FlexPro Anda

Rawatlah pena Norditropin® FlexPro Anda:

- Jangan menjatuhkan atau membenturkan pena Anda ke permukaan yang keras. Jika Anda menjatuhkannya atau mencurigai ada masalah, selalu pasang jarum sekali pakai yang baru dan periksa aliran hormon pertumbuhan sebelum Anda menyuntikkannya.
- Jangan mencoba mengisi ulang pena Anda – pena sudah terisi.
- Jangan mencoba memperbaiki atau memisahkan bagian pena Anda.
- Jangan memaparkan pena Anda ke debu, kotoran, cairan atau sinar langsung.
- Jangan mencoba mencuci, merendam atau melumasi pena Anda. Jika perlu bersihkan dengan deterjen lembut di kain yang lembab.
- Jangan membekukan pena Anda atau menyimpannya di dekat elemen pendingin, misalnya di lemari pendingin. Lihat bagian 6.3 dan 6.4 untuk informasi bagaimana menyimpan pena Anda.

Informasi penting

- Selalu simpan pena dan jarum Anda jauh dari jangkauan orang lain, terutama anak-anak.
- **Jangan berbagi** pena atau jarum Anda dengan orang lain. Hal tersebut dapat mengakibatkan infeksi silang.
- Perawat **harus berhati-hati ketikan menangani jarum bekas** – untuk mengurangi risiko tertusuk jarum dan infeksi silang.

Informasi penting

Berikan perhatian khusus di catatan ini karena catatan tersebut penting untuk

keselamatan penggunaan pena.

Informasi tambahan