

Norditropin NordiFlex[®] 5mg, 10mg and 15mg

Somatropin (rbe)

Consumer Medicine Information

What is in this leaflet

What Norditropin NordiFlex[®] is used for 1

Using Norditropin NordiFlex[®] 2

While you or your child is using Norditropin NordiFlex[®] 2

Side effects..... 3

Storage..... 3

Product Description 3

Instructions For Use..... 5

This leaflet answers some common questions about Norditropin NordiFlex[®]. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you or your child using Norditropin NordiFlex[®] against the benefits they expect it will have.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Norditropin NordiFlex[®] is used for

Norditropin NordiFlex[®] is a pre-filled dial-a-dose pen containing Norditropin[®], a solution of human growth hormone. Norditropin[®] [also called somatropin (rbe)], is used to treat:

1. growth failure in children, which may be due to:
 - a condition called Growth Hormone Deficiency, where

the gland at the base of the brain (pituitary gland) does not make enough growth hormone

- a condition called either Small for Gestational Age (SGA) or Intrauterine Growth Retardation (IUGR), where growth failure started during the mother's pregnancy. Children with SGA/IUGR do not lack growth hormone and are therefore not treated for growth hormone deficiency. Treatment with Norditropin NordiFlex[®] promotes catch-up growth and increases final height.
 - Chronic kidney disease
 - Turner Syndrome, a genetic condition in girls
2. growth hormone deficiency in adults

You or your child may have been prescribed Norditropin NordiFlex[®] for another reason.

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

There is no evidence that Norditropin[®] is addictive.

Before using Norditropin NordiFlex[®]

When you or your child must not use it

You or your child should not use Norditropin NordiFlex[®] if you/your child:

- are allergic to phenol or any other ingredient listed in the ingredient section of this leaflet

Some of the symptoms of an allergic reaction may include:

- rash

- wheezing
- swelling of the eyelids, face or lips
- complete collapse
- have cancer or another form of active tumour
- have not finished treatment for cancer or another form of tumour
- have slow growth for reasons other than a lack of growth hormone, except where specific uses are described above
- have had a kidney transplant in the last 12 months or have had more than one episode of acute rejection (ask your doctor if unsure what this means)
- have an acute critical illness due to complications following open heart or abdominal surgery or multiple accident trauma
- have acute respiratory failure

Do not use Norditropin NordiFlex[®] if:

- it is after the expiry date (Expiry) printed on the label and carton
- the packaging is torn, shows signs of tampering or does not look quite right
- the solution is not clear and colourless, or does not look quite right

Before you or your child starts to use it

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

- diabetes
- cancer or any other kind of tumour

- impaired kidney function
- severe or recurring headaches, visual problems, nausea and vomiting. These may be symptoms of raised pressure of the fluid around the brain.
- tiredness, lethargy, muscle weakness, cramps, feeling the cold, a slow heart rate, dry and flaky skin, hair loss, a deep and husky voice and weight gain. These may be signs and symptoms of hypothyroidism (an underactive thyroid gland causing a decrease in metabolism).
- development of curvature in the spine (scoliosis) in your child

If any of the above applies, Norditropin NordiFlex® may not be suitable. Your doctor will give you advice.

Your doctor will measure your child's height and weight before he or she is prescribed Norditropin NordiFlex®. If you or your child is growth hormone deficient, your doctor will also need to measure your ability to produce growth hormone.

Taking other medicines

Tell your doctor if you or your child is taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with the growth effect of Norditropin®. These include:

- glucocorticoids
- sex steroids
- thyroid hormone

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

If you or your child is being treated with insulin, the dosage of insulin may have to be adjusted.

If you have not told your doctor about any of the above, tell them before you or your child use Norditropin NordiFlex®.

Pregnancy and breast-feeding

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

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

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

Using Norditropin NordiFlex®

How much to use

Your doctor will tell you how much Norditropin® you or your child should use. It depends on factors such as body weight and body surface area.

How and when to use it

Norditropin® is given as an injection with Norditropin NordiFlex® under the skin in the evening, 6 or 7 days per week. Injection sites should be varied as shown to you by your doctor or other health care professional. This will lessen the risk of damage to the fat and tissues under the skin (lipodystrophy).

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

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

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

Norditropin NordiFlex® is prescribed for you or your child's personal use only. **Do not give it to anyone else.**

How long to use it

You or your child may stop using Norditropin NordiFlex® at any time. Before doing so, you should discuss this first with your doctor.

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

If you or your child misses a dose

Inject the next dose as normal the next evening. Do not inject extra to make up for the missed dose.

If you or your child uses too much (overdose)

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

You or your child should not inject more Norditropin® than the doctor has prescribed, as it may increase the risk of side effects.

Long term overdosage could result in signs and symptoms of growth hormone excess. Extreme growth hormone excess can result in overgrowth of bones and enlargement of hands and feet.

While you or your child is using Norditropin NordiFlex®

Things you must not do

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

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

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

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

Things to be careful of

Tell your doctor if you or your child are scheduled to have surgery.

If you or your child has a kidney condition, your doctor will closely monitor the kidney function (how well the kidneys are working). If there is any decrease in function, it may be necessary to stop using Norditropin®.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while using Norditropin NordiFlex®. Ask your doctor or pharmacist to answer any questions you may have.

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

- swollen hands and feet due to fluid retention
- redness and itching around the area you inject. Some patients may develop local skin reactions at the injection site which appear and disappear during treatment. If you inject too often in the same small area, damage may occur to the fat and tissues under the skin (lipodystrophy).

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

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

- convulsions
- motor problems
- joint and muscle pain
- skin rash
- headache
- curvature of the spine
- fluid retention
- hair loss.

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

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

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

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

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

In very rare cases, children treated with growth hormone have felt pain in the hip or knee, or have experienced limping. These symptoms may be caused by Legg-Calvé-Perthes disease (disease at the top of the thigh bone) or slipped capital femoral epiphysis (the end of the bone slips from the cartilage) and may not be due to the medicine.

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

If you think that you or your child are suffering from any of these symptoms or from any other side effects not mentioned here, speak to your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

Storage

Norditropin NordiFlex® must be stored between 2°C and 8°C, in a refrigerator, but not in or near the freezing compartment. Norditropin NordiFlex® must not be frozen or exposed to heat or direct light.

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

The Norditropin NordiFlex® that you are using should be stored in the refrigerator between 2°C and 8°C and used within 28 days.

Keep out of the reach of children.

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

Never use Norditropin NordiFlex® after the expiry date printed on the label and carton. The expiry date refers to the last day of that month.

Disposal

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

Product Description

What it looks like

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

Norditropin NordiFlex® is available in three strengths. The push button, pen cap and cartridge holder on the pen are colour coded according to strength: 5mg/1.5mL (yellow), 10mg/1.5mL (blue) and 15mg/1.5mL (green). Your doctor will decide which strength is suitable for you or your child.

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

Ingredients

The Norditropin[®] in Norditropin NordiFlex[®] contains the active ingredient biosynthetic human growth hormone, which is called somatropin (rbe). It is identical to the growth hormone produced in the human body. The abbreviation 'rbe' indicates the method of genetic engineering used to manufacture the growth hormone.

Other ingredients in Norditropin NordiFlex[®] are: mannitol, histidine, poloxamer, phenol, and water for injections. The quantity of each ingredient is on the label of the box.

Manufacturer

Norditropin NordiFlex[®] is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 3, 21 Solent Circuit
Baulkham Hills NSW 2153

This leaflet was prepared on 3 March 2010.

Australian Registration Numbers:

Norditropin NordiFlex[®] 5mg:

AUST R 99040

Norditropin NordiFlex[®] 10mg:

AUST R 99041

Norditropin NordiFlex[®] 15mg:

AUST R 99042

Norditropin[®], NordiCare[®] and Norditropin NordiFlex[®] are registered trademarks of Novo Nordisk Health Care AG. NovoFine[®] is a registered trademark of Novo Nordisk A/S.

© 2010

Novo Nordisk A/S
2880 Bagsvaerd, Denmark

For further information call the NordiCare[®] Hotline on 1800 632 362.

www.novonordisk.com.au

Norditropin NordiFlex[®] 5mg, 10mg and 15mg

Somatropin (rbe)

Instructions For Use

Introduction

Norditropin NordiFlex[®] is a multi-dose injection pen pre-filled with human growth hormone solution for injection. Norditropin NordiFlex[®] is available in three strengths, the push button, pen cap and cartridge holder on the pen is colour coded according to strength:

Norditropin NordiFlex[®] 5mg (yellow) allows you to dial doses from 0.025 to 1.5mg.

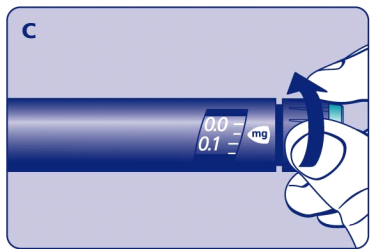
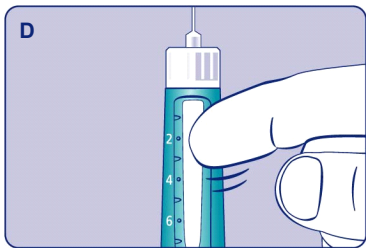
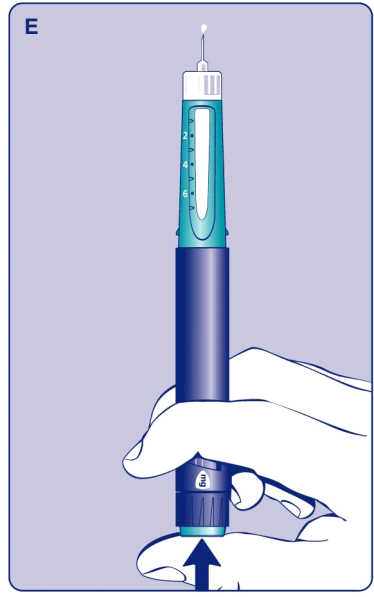
Norditropin NordiFlex[®] 10mg (blue) allows you to dial doses from 0.050 to 3.0mg.

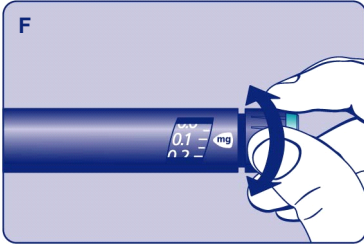
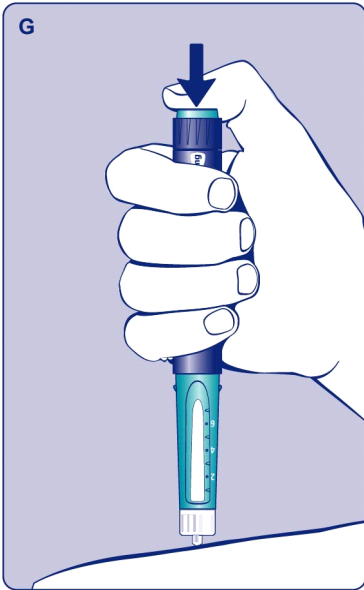
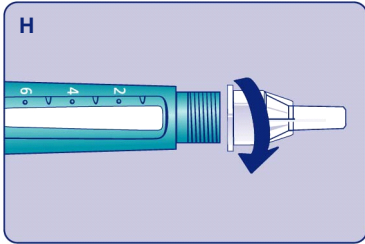
Norditropin NordiFlex[®] 15mg (green) allows you to dial doses from 0.075 to 4.5mg.

Read all of the following instructions carefully before using Norditropin NordiFlex[®].

Note: Norditropin NordiFlex[®] 10mg is pictured.

<ul style="list-style-type: none"> • NovoFine® needles (8mm 30 G or smaller) are designed to be used with Norditropin NordiFlex®. • Only use the injection pen if the growth hormone solution inside is clear and colourless. • Always check the flow ('prime' the pen) before the first injection from a new pen – see Step 3. • You can use the dose selector to dial your dose - your doctor will decide the correct dose for you. • Do not share your Norditropin NordiFlex® pen with anyone else. 	<p style="text-align: right;">NovoFine® disposable needle</p> <p>Pen Cap</p> <p>Cartridge</p> <p>Residual scale window</p> <p>Residual scale</p> <p>Dosage indicator window</p> <p>Dosage selector</p> <p>Push button</p> <p>Outer needle cap</p> <p>Inner needle cap</p> <p>Needle</p> <p>Protective paper tap</p>
<p>1. Check the solution</p> <ul style="list-style-type: none"> • Pull off the pen cap [A] • Check the solution inside the pen by turning it upside down once or twice • Only use the Norditropin NordiFlex® pen if the solution inside is clear and colourless. 	<p>A</p>
<p>2. Attach the needle</p> <ul style="list-style-type: none"> • Always use a new disposable needle for each injection in order to receive the correct dose and prevent contamination • Take a new needle and 	<p>B</p>

<p>remove the protective paper tab</p> <ul style="list-style-type: none"> • Screw the needle securely onto your Norditropin NordiFlex[®] pen [B]. <p>The needle has two needle caps. You need to remove them both:</p> <ul style="list-style-type: none"> • Pull off the outer needle cap and keep it to dispose of the used needle later • Remove the inner needle cap by pulling on the central tip and throw it away. 	
<p>3. Check the flow</p> <ul style="list-style-type: none"> • Before you use a new pen for the first time, you need to check the flow (called 'priming' the pen) to make sure you get the proper dose and do not inject any air: For Norditropin NordiFlex[®] 5mg: dial 0.025mg For Norditropin NordiFlex[®] 10mg: dial 0.050mg For Norditropin NordiFlex[®] 15mg: dial 0.075mg 	
<ul style="list-style-type: none"> • Hold your Norditropin NordiFlex[®] pen with the needle pointing upwards and tap the cartridge gently with your finger a few times [D] 	
<ul style="list-style-type: none"> • Holding your Norditropin NordiFlex[®] pen with the needle upwards, press the push button at the bottom of the pen all the way in [E] • Repeat steps C to E until a drop of growth hormone solution appears at the needle tip • Do not use the Norditropin NordiFlex[®] pen if a drop of solution does not appear • Always check the flow (prime the pen) before the first injection from a new Norditropin NordiFlex[®] pen. Check the flow again if your pen has been dropped or knocked against a hard surface, or if you are not sure that it is working properly. 	

<p>4. Dial the dose</p> <ul style="list-style-type: none"> • Check that the dosage selector is set at 0.0. Dial the number of mg your doctor has recommended for you [F] • The dose can be increased or decreased by turning the dosage selector in either direction. When dialing back, be careful not to press the push button as growth hormone will come out. You cannot set a dose larger than the amount of solution left in the pen. 	
<p>5. Inject the solution</p> <ul style="list-style-type: none"> • Use the injection method that has been recommended to you • Vary the area you inject so you do not harm your skin • Insert the needle into your skin. Deliver the dose by pressing the push button all the way in. Be careful only to press the push button when injecting [G] • After the injection keep the needle under the skin for at least 6 seconds and then withdraw it. Keep the push button fully depressed until the needle is removed from the skin. This ensures that you get the full dose. 	
<p>6. Remove the needle</p> <ul style="list-style-type: none"> • Replace the outer needle cap and unscrew the needle. Throw it away carefully [H] • Always use a new needle for each injection and always remove a used needle immediately after each injection. If you do not remove it straight away, air may get into the cartridge, which may mean you get the wrong dose next time • <i>Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle penetration</i> 	

<ul style="list-style-type: none"> • Ask your pharmacist how to dispose of used needles and empty Norditropin NordiFlex[®] pens. 	
<p>7. Maintenance</p> <ul style="list-style-type: none"> • Look after your Norditropin NordiFlex[®] pen so that it continues to work accurately and safely. Protect your pen from dust, dirt and direct sunlight and any situation where it might be damaged • You can clean the outside of your pen by wiping it with cotton wool moistened with alcohol. Do not soak Norditropin NordiFlex[®] in alcohol, or wash or lubricate it as this may damage it. 	