

**Novo Nordisk®**

## **PATIENT INFORMATION**

### **Norditropin NordiFlex® Somatropin (rDNA origin) injection 5 mg/1.5 mL Prefilled Pen**

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Your doctor will discuss with you the benefits and risks of Norditropin NordiFlex® (pronounced Nor-dee-tro-pin Nor-dee-flex). Read all of the information in this patient guide because it contains important information for you. If you have further questions, please ask your doctor or your pharmacist. Norditropin NordiFlex has been prescribed for you and you must not pass it on to others.

#### **What is the most important information I should know about Norditropin NordiFlex?**

Store Norditropin NordiFlex in a refrigerator before use. Do not freeze it or expose it to heat.

Do not use Norditropin NordiFlex if the solution in the cartridge does not appear clear and colorless. Check this by turning the pen upside down once or twice.

Norditropin NordiFlex is for use by one person only.

Do not use Norditropin NordiFlex if you need to make more than 4 air shots before the first injection.

Your doctor may measure your height, weight and your ability to produce growth hormone before you are prescribed Norditropin NordiFlex.

#### **What is Norditropin NordiFlex?**

Norditropin® is a clear and colorless solution.

#### **Norditropin is used to treat the following:**

- children with growth failure caused by very low or no production of growth hormone
- short stature in children with Noonan syndrome
- short stature in children with Turner syndrome
- adults who do not make sufficient growth hormone

Norditropin is injected using Norditropin NordiFlex, a multi-dose disposable 1.5 mL pre-filled pen. Norditropin NordiFlex contains several doses of growth hormone solution. A dose is injected under the skin in the evening 6-7 times a week.

Norditropin NordiFlex is available in three strengths: 5 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL (i.e. with a concentration of 3.3 mg/mL, 6.7 mg/mL and 10.0 mg/mL respectively).

Throw away Norditropin NordiFlex when the cartridge is empty.

Medicines are sometimes prescribed for purposes other than those listed in a patient guide. Patients should ask their doctor about any concerns and refer to the professional labeling for additional information.

### **What does Norditropin NordiFlex contain?**

The cartridge in Norditropin NordiFlex contains human growth hormone called somatropin (so-ma-tro-pin) made through biotechnology. It is identical to the growth hormone produced in the human body.

The cartridge contains other ingredients: Histidine, Poloxamer 188, Phenol, Mannitol and Water for Injection.

### **Who should not take Norditropin NordiFlex?**

Do not use Norditropin NordiFlex if you have any of the following conditions:

- child with closed epiphyses (closed bone growth plates)
- child with Prader-Willi syndrome who is also severely obese or has significant respiratory impairment
- allergic to phenol or any other ingredients in the medicine
- had a kidney transplant
- pregnant
- breast-feeding
- active cancer or other forms of tumor
- acute critical illness due to certain types of heart or abdomen surgery, trauma or acute respiratory failure

### **What should you consider if you are pregnant or breast-feeding?**

If you become pregnant while you are receiving Norditropin NordiFlex, you are recommended to stop the treatment and discuss this with your doctor.

You are recommended not to take Norditropin NordiFlex while you are breast-feeding because somatropin might pass into your milk.

### **Be sure to tell your doctor if you:**

- have diabetes mellitus
- had cancer or other forms of tumor
- are pregnant, planning to be pregnant or breastfeeding
- had a kidney transplant

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

### **How should I take Norditropin NordiFlex?**

Carefully follow the “Instructions for Use” on the other side of this patient guide.

You should inject Norditropin NordiFlex under the skin in the evening just before bedtime. You should change the injection area so you do not harm your skin.

NovoFine® and FlexPen® disposable needles are designed to be used with Norditropin NordiFlex.

### **How much Norditropin should you take?**

Your doctor will tell you how much Norditropin you should take. In children it depends on the body weight.

General guidelines for dosages are shown below.

Children with low or no growth hormone: 0.024 to 0.034 mg/kg body weight, 6-7 times a week

Children with Noonan syndrome: Up to 0.066 mg/kg/day

**Children with Turner syndrome: Up to 0.067 mg/kg/day**

Adults: Not more than 0.004 mg/kg/day at start of therapy. Dosage may be increased as tolerated to not more than 0.016 mg/kg/day after approximately 6 weeks, or

Alternative dose for adults:

Approximately 0.2 mg/day (range, 0.15-0.30 mg/day) at start of therapy. Dosage can be increased gradually every 1-2 months by steps of approximately 0.1-0.2 mg/day, based on your doctor’s recommendations.

If you forget to take a dose, take the next dose as usual - do not double your dose.

### **What should you do if you inject too much growth hormone using Norditropin NordiFlex?**

If you inject too much growth hormone, contact your doctor.

### **How long should you continue to take Norditropin?**

Discuss with your doctor how long you should take Norditropin.

### **What should I avoid while taking Norditropin NordiFlex?**

Be sure to tell your doctor about all of the medications you are taking especially if you are taking:

- a glucocorticoid medication such as hydrocortisone or cortisone acetate
- thyroid hormone
- insulin and/or oral diabetes medicine
- drugs metabolized by the liver (for example, corticosteroids, sex steroids, anticonvulsants, cyclosporine)
- oral estrogen replacement

Adult height can be influenced if you are on Norditropin NordiFlex for growth failure and using glucocorticoids or thyroid hormone at the same time.

If you are treated with insulin and/or oral diabetes medicine, your insulin/oral diabetes medicine dose may need to be adjusted.

### **What are the possible side effects of Norditropin NordiFlex?**

The following side effects are usually mild and temporary:

- headaches
- muscle pain
- joint stiffness
- high blood sugar (hyperglycemia)
- sugar in your urine (glucosuria)
- swollen hands and feet due to fluid retention
- redness and itching in the area you inject

If you experience any of these symptoms, discuss this with your doctor.

In rare cases you may develop antibodies to growth hormone.

If you have symptoms of headaches, eyesight problems, nausea and/or vomiting, these may be symptoms of raised pressure in the brain. Contact your doctor immediately.

**Be sure to tell your doctor if you have any other side effects not mentioned here.**

### **Special warnings**

In very rare cases children treated with somatropin have experienced pain in the hip or knee or a limp. These symptoms may be caused by a slippage of the growth plate in the hip (slipped capital femoral epiphysis).

Scoliosis (curvature of the spine) can occur in children who experience rapid growth. Because growth hormone increases growth rate, patients should be monitored for progression of scoliosis.

Thyroid function tests should be performed periodically.

Patients with Turner syndrome have an increased risk of ear or hearing disorders. They should be carefully evaluated for middle ear infection (otitis media) and other ear disorders.

Skin lesions should be checked carefully for any cancerous changes.

The following tumors have been reported in patients treated with somatropin: Leukemia in children, relapse of brain tumors in children and adults. However, there is no evidence that somatropin is responsible for causing these diseases.

Talk to your doctor if you think you have any of these conditions.

**How to store Norditropin NordiFlex?**

Store unused Norditropin NordiFlex in a refrigerator (2°C - 8°C/36°F - 46°F). Do not freeze or expose it to heat. Avoid direct light.

After the initial injection, Norditropin NordiFlex 5 mg/1.5 mL may be **EITHER** stored in the refrigerator (2-8°C/36-46°F) and use within 4 weeks **OR** may be stored for up to 3 weeks at not more than 25°C (77°F). Discard unused portion.

Do not use Norditropin NordiFlex which has been frozen or exposed to temperatures higher than 25°C (77°F).

Always use a new NovoFine needle for each injection. Do not keep the needle screwed onto the Norditropin NordiFlex when you are not using it.

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

Never use Norditropin NordiFlex after the expiration date printed on the pen and on the carton.

Date of issue:

*Novo Nordisk<sup>®</sup>, Norditropin<sup>®</sup>, Norditropin NordiFlex<sup>®</sup>, NovoFine<sup>®</sup> and FlexPen<sup>®</sup> are registered trademarks of Novo Nordisk A/S.*

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Novo Nordisk Inc.

US Patent Nos. 6,235,004; 6,004,297 and other patents pending.

For assistance or further information, write to:

Novo Nordisk Inc.

100 College Road West

Princeton, NJ 08540, USA

1-888-NOVO-444

[www.norditropin-us.com](http://www.norditropin-us.com)

Manufactured by:

Novo Nordisk A/S

DK-2880 Bagsvaerd, Denmark

**Novo Nordisk<sup>®</sup>**

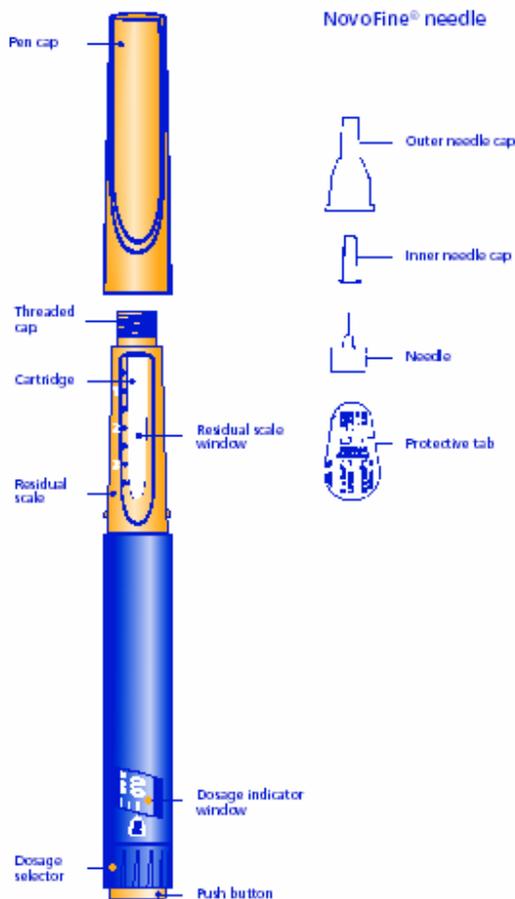
## INSTRUCTIONS FOR USE

### Norditropin NordiFlex<sup>®</sup> Somatropin (rDNA origin) injection 5 mg/1.5 mL Prefilled Pen

#### Using the disposable Norditropin NordiFlex<sup>®</sup> 5 mg/1.5 mL Prefilled Pen

Norditropin NordiFlex 5 mg/1.5 mL is a multi-dose, disposable, prefilled pen with liquid growth hormone able to deliver doses from 0.025 to 1.5 mg. The dose can be adjusted in increments of 0.025 mg. Your doctor will determine the correct dose for you. Norditropin NordiFlex prefilled pen is designed to be used with NovoFine<sup>®</sup> and FlexPen<sup>®</sup> disposable needles (sold separately). Norditropin NordiFlex prefilled pen is not recommended for people who are blind or have trouble seeing unless they have the help of a sighted individual trained to use Norditropin NordiFlex.

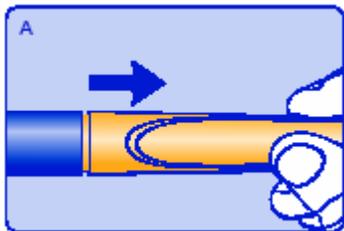
*Please read these instructions carefully before using this pen*



## 1 Preparing Norditropin NordiFlex 5 mg/1.5 mL for injection

**A.** Pull off the pen cap and check if the growth hormone solution is clear and colorless by turning Norditropin NordiFlex upside down once or twice and view the solution through the residual scale window. **DO NOT use Norditropin NordiFlex if the growth hormone solution is cloudy or contains particles. Use it only if it is clear and colorless.**

Wash hands well and wipe the front rubber stopper on the threaded plastic cap with an alcohol swab.



**B.** Place the NovoFine disposable needle onto Norditropin NordiFlex immediately before use. Remove the protective tab from the disposable needle and screw the needle tightly onto Norditropin NordiFlex. Pull off the outer and inner needle caps. Never place a disposable needle on your Norditropin NordiFlex until you are ready to give an injection. Remove the needle immediately after use. If the needle is not removed, some growth hormone may be expelled from Norditropin NordiFlex.



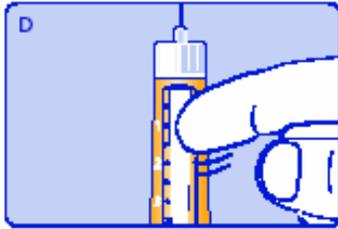
**C. Do an air shot before starting a new Norditropin NordiFlex as follows:**

Small amounts of air may collect in the needle and cartridge. To avoid injecting air and ensure proper dosing, set the dosage selector to 0.025 mg. Each line between labeled dosages is 0.025 mg.

**Dial 0.025 mg**

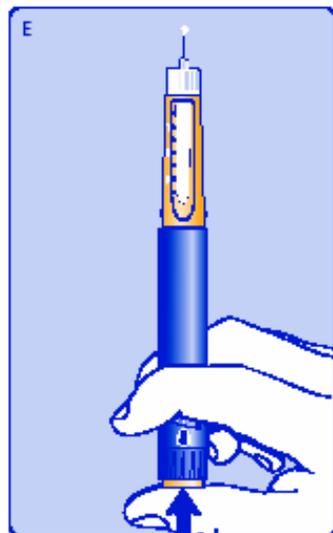


**D.** Hold Norditropin NordiFlex with the needle pointing up, tap the cartridge gently with your finger a few times to raise any air bubbles to the top of the cartridge.



**E.** Still holding Norditropin NordiFlex with the needle up, press the push button all the way in. A drop of growth hormone should appear at the needle tip. If not, repeat the procedure, no more than 4 times.

*If a drop of growth hormone still does not appear, call 1-888-NOVO-444 for help.*



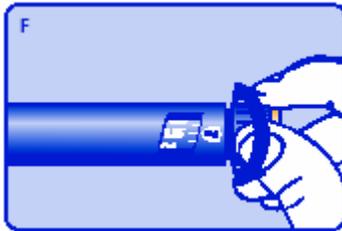
## 2 Setting the dose

**F.** Check that the dose selector is set at **0.0**. Dial the number of mg that you need to inject. The dose can be changed up or down by turning the dose selector in either direction. When dialing back, be careful not to press the push button as growth hormone liquid will come out.

**DO NOT use the clicking sound as a guide for selecting dose.**

The numbers on the residual scale can be used to estimate the mg left in the cartridge. **DO NOT use these numbers to measure the growth hormone dose.**

**You cannot set a dose higher than the number of mg left in the cartridge.** Use a new Norditropin NordiFlex pen to inject the remaining amount of your dose. Be sure to remember the dose already received with the first dose. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.4 mg. You will need to inject an additional 0.2 mg with a new Norditropin NordiFlex pen.

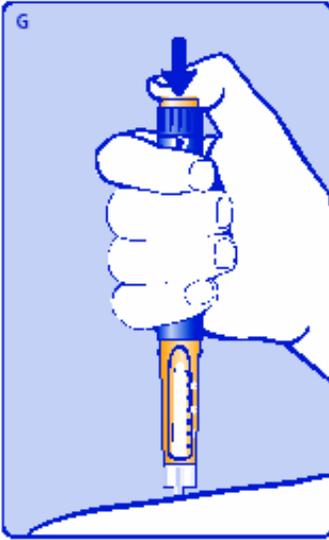


## 3 Giving the injection

Use the injection procedure recommended by your doctor or healthcare professional.

**G.** This product is for subcutaneous use only. Insert the needle under the skin and deliver the dose by pressing the push button all the way in. Press the push button only when injecting.

After the injection, the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle is removed from the skin. This will ensure that the full dose has been delivered. Vary the injection site using the injection procedure recommended by your doctor.



#### 4 Removing the needle

**H.** After the injection, remove the needle **without recapping** and dispose of it in a puncture-resistant container. Used needles should be placed in sharps container (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.

*It is important that you use a new needle for each injection. Healthcare professionals, relatives and other caregivers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle stick injuries.*

When the cartridge is empty, throw away Norditropin NordiFlex without the needle attached.

#### 5 Maintenance

Norditropin NordiFlex should be handled with care. Protect Norditropin NordiFlex from dust, dirt, and direct sunlight.

You can clean the outside of Norditropin NordiFlex by wiping it with a soft cloth moistened with water. Do not soak Norditropin NordiFlex in alcohol, wash, or lubricate it.

## 6 Important Notes

- Store unused Norditropin NordiFlex pens in a refrigerator (2°C - 8°C/36°F - 46°F). After the initial injection, Norditropin NordiFlex 5 mg/1.5 mL may be **EITHER** stored in the refrigerator (2-8°C/36-46°F) and use within 4 weeks **OR** may be stored for up to 3 weeks at not more than 25°C (77°F).
- Remember to perform an air shot before starting a new Norditropin NordiFlex or before the injection if you dropped or knocked the pen against a hard surface. See diagrams **C**, **D** and **E**.
- If you need to perform more than 4 air shots before the first use of Norditropin NordiFlex to get a droplet of growth hormone at the needle tip, **DO NOT** use Norditropin NordiFlex. *Call 1-888-NOVO-444 for help.*
- Take care not to drop Norditropin NordiFlex or knock it against a hard surface.
- **DO NOT** leave Norditropin NordiFlex in a car or other location where it can get too hot or too cold.
- Always have a spare Norditropin NordiFlex disposable pen in order to avoid running out of this product.
- Norditropin NordiFlex is designed to be used with NovoFine and FlexPen disposable needles.
- **NEVER** place a needle on Norditropin NordiFlex until you are ready to use it. Remove the needle right after use without recapping.
- **Throw away used needles properly, so people will not be harmed.**
- Throw away the used Norditropin NordiFlex, without the needle attached.
- To avoid spread of disease, do not let anyone else use your Norditropin NordiFlex, even if you attach a new needle.
- Keep Norditropin NordiFlex out of the reach of children.
- **Novo Nordisk is not responsible for harm due to using Norditropin NordiFlex with products that are not recommended by Novo Nordisk.**

## 7 Warranty

If your Norditropin NordiFlex is defective in materials or workmanship, Novo Nordisk Inc. will replace it at no charge if you mail the defective unit, postage prepaid to:

Novo Nordisk Inc.  
Product Safety  
100 College Road West  
Princeton, NJ 08540, USA

8-2084-31-001-x

**Novo Nordisk®**

## **PATIENT INFORMATION**

### **Norditropin NordiFlex® Somatropin (rDNA origin) injection 10 mg/1.5 mL Prefilled Pen**

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#### **What is the most important information I should know about Norditropin NordiFlex?**

Store Norditropin NordiFlex in a refrigerator before use. Do not freeze it or expose it to heat.

Do not use Norditropin NordiFlex if the solution in the cartridge does not appear clear and colorless. Check this by turning the pen upside down once or twice.

Norditropin NordiFlex is for use by one person only.

Do not use Norditropin NordiFlex if you need to make more than 4 air shots before the first injection.

Your doctor may measure your height, weight and your ability to produce growth hormone before you are prescribed Norditropin NordiFlex.

#### **What is Norditropin NordiFlex?**

Norditropin® is a clear and colorless solution.

Norditropin is used to treat the following:

- children with growth failure caused by very low or no production of growth hormone
- short stature in children with Noonan syndrome
- short stature in children with Turner syndrome
- adults who do not make sufficient growth hormone

Norditropin is injected using Norditropin NordiFlex, a multi-dose disposable 1.5 mL pre-filled pen. Norditropin NordiFlex contains several doses of growth hormone solution. A dose is injected under the skin in the evening 6-7 times a week.

Norditropin NordiFlex is available in three strengths: 5 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL (i.e. with a concentration of 3.3 mg/mL, 6.7 mg/mL and 10.0 mg/mL respectively).

Throw away Norditropin NordiFlex when the cartridge is empty.

Medicines are sometimes prescribed for purposes other than those listed in a patient guide. Patients should ask their doctor about any concerns and refer to the professional labeling for additional information.

### **What does Norditropin NordiFlex contain?**

The cartridge in Norditropin NordiFlex contains human growth hormone called somatropin (so-ma-tro-pin) made through biotechnology. It is identical to the growth hormone produced in the human body.

The cartridge contains other ingredients: Histidine, Poloxamer 188, Phenol, Mannitol and Water for Injection.

### **Who should not take Norditropin NordiFlex?**

Do not use Norditropin NordiFlex if you have any of the following conditions:

- child with closed epiphyses (closed bone growth plates)
- child with Prader-Willi syndrome who is also severely obese or has significant respiratory impairment
- allergic to phenol or any other ingredients in the medicine
- had a kidney transplant
- pregnant
- breast-feeding
- active cancer or other forms of tumor
- acute critical illness due to certain types of heart or abdomen surgery, trauma or acute respiratory failure

### **What should you consider if you are pregnant or breast-feeding?**

If you become pregnant while you are receiving Norditropin NordiFlex, you are recommended to stop the treatment and discuss this with your doctor.

You are recommended not to take Norditropin NordiFlex while you are breast-feeding because somatropin might pass into your milk.

### **Be sure to tell your doctor if you:**

- have diabetes mellitus
- had cancer or other forms of tumor
- are pregnant, planning to be pregnant or breastfeeding
- had a kidney transplant

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

### **How should I take Norditropin NordiFlex?**

Carefully follow the “Instructions for Use” on the other side of this patient guide.

You should inject Norditropin NordiFlex under the skin in the evening just before bedtime. You should change the injection area so you do not harm your skin.

NovoFine<sup>®</sup> and FlexPen<sup>®</sup> disposable needles are designed to be used with Norditropin NordiFlex.

### **How much Norditropin should you take?**

Your doctor will tell you how much Norditropin you should take. In children it depends on the body weight.

General guidelines for dosages are shown below.

Children with low or no growth hormone: 0.024 to 0.034 mg/kg body weight, 6-7 times a week

Children with Noonan syndrome: Up to 0.066 mg/kg/day

**Children with Turner syndrome: Up to 0.067 mg/kg/day**

Adults: Not more than 0.004 mg/kg/day at start of therapy. Dosage may be increased as tolerated to not more than 0.016 mg/kg/day after approximately 6 weeks, or

Alternative dose for adults:

Approximately 0.2 mg/day (range 0.15-0.30 mg/day) at start of therapy. Dosage can be increased gradually every 1-2 months by steps of approximately 0.1-0.2 mg/day, based on your doctor's recommendations.

If you forget to take a dose, take the next dose as usual - do not double your dose.

### **What should you do if you inject too much growth hormone using Norditropin NordiFlex?**

If you inject too much growth hormone, contact your doctor.

### **How long should you continue to take Norditropin?**

Discuss with your doctor how long you should take Norditropin.

### **What should I avoid while taking Norditropin NordiFlex?**

Be sure to tell your doctor about all of the medications you are taking especially if you are taking:

- a glucocorticoid medication such as hydrocortisone or cortisone acetate
- thyroid hormone
- insulin and/or oral diabetes medicine
- drugs metabolized by the liver (for example, corticosteroids, sex steroids, anticonvulsants, cyclosporine)
- oral estrogen replacement

Adult height can be influenced if you are on Norditropin NordiFlex for growth failure and using glucocorticoids or thyroid hormone at the same time.

If you are treated with insulin and/or oral diabetes medicine, your insulin/oral diabetes medicine dose may need to be adjusted.

### **What are the possible side effects of Norditropin NordiFlex?**

The following side effects are usually mild and temporary:

- headaches
- muscle pain
- joint stiffness
- high blood sugar (hyperglycemia)
- sugar in your urine (glucosuria)
- swollen hands and feet due to fluid retention
- redness and itching in the area you inject

If you experience any of these symptoms, discuss this with your doctor.

In rare cases you may develop antibodies to growth hormone.

If you have symptoms of headaches, eyesight problems, nausea and/or vomiting, these may be symptoms of raised pressure in the brain. Contact your doctor immediately.

**Be sure to tell your doctor if you have any other side effects not mentioned here.**

### **Special warnings**

In very rare cases children treated with somatropin have experienced pain in the hip or knee or a limp. These symptoms may be caused by a slippage of the growth plate in the hip (slipped capital femoral epiphysis).

Scoliosis (curvature of the spine) can occur in children who experience rapid growth. Because growth hormone increases growth rate, patients should be monitored for progression of scoliosis.

Thyroid function tests should be performed periodically.

Patients with Turner syndrome have an increased risk of ear or hearing disorders. They should be carefully evaluated for middle ear infection (otitis media) and other ear disorders.

Skin lesions should be checked carefully for any cancerous changes.

The following tumors have been reported in patients treated with somatropin: Leukemia in children, relapse of brain tumors in children and adults. However, there is no evidence that somatropin is responsible for causing these diseases.

Talk to your doctor if you think you have any of these conditions.

### **How to store Norditropin NordiFlex?**

Store unused Norditropin NordiFlex in a refrigerator (2°C - 8°C/36°F - 46°F). Do not freeze or expose it to heat. Avoid direct light.

After the initial injection, Norditropin NordiFlex 10 mg/1.5 mL may be **EITHER** stored in the refrigerator (2 -8°C/36 - 46°F) and use within 4 weeks **OR** may be stored for up to 3 weeks at not more than 25°C (77°F). Discard unused portion.

Do not use Norditropin NordiFlex which has been frozen or exposed to temperatures higher than 25°C (77°F).

Always use a new NovoFine needle for each injection. Do not keep the needle screwed onto Norditropin NordiFlex when you are not using it.

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

Never use Norditropin NordiFlex after the expiration date printed on the pen and on the carton.

Date of issue:

*Novo Nordisk<sup>®</sup>, Norditropin<sup>®</sup>, Norditropin NordiFlex<sup>®</sup>, NovoFine<sup>®</sup> and FlexPen<sup>®</sup> are registered trademarks of Novo Nordisk A/S.*

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US Patent Nos. 6,235,004; 6,004,297 and other patents pending.

For assistance or further information, write to:

Novo Nordisk Inc.

100 College Road West

Princeton, NJ 08540, USA

1-888-NOVO-444

[www.norditropin-us.com](http://www.norditropin-us.com)

Manufactured by:

Novo Nordisk A/S

DK-2880 Bagsvaerd, Denmark

**Novo Nordisk<sup>®</sup>**

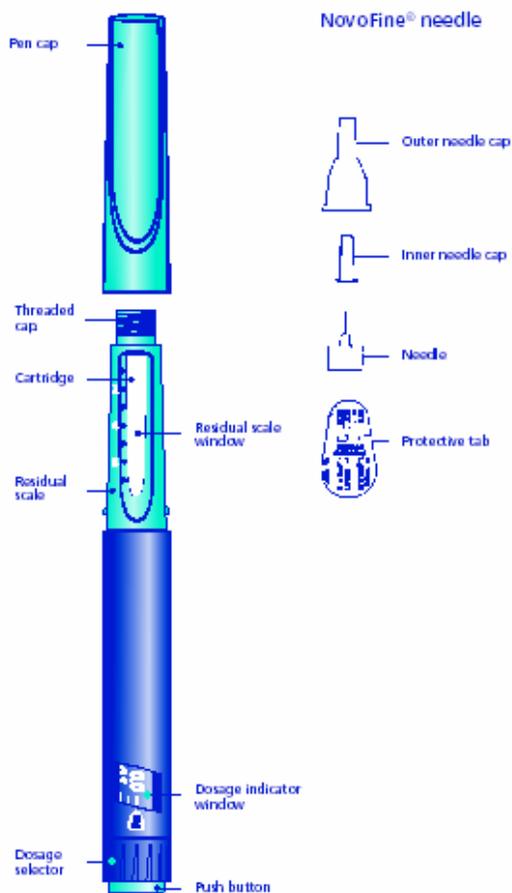
## INSTRUCTIONS FOR USE

### Norditropin NordiFlex<sup>®</sup> Somatotropin (rDNA origin) injection 10 mg/1.5 mL Prefilled Pen

#### Using the disposable Norditropin NordiFlex<sup>®</sup> 10 mg/1.5 mL Prefilled Pen

Norditropin NordiFlex 10 mg/1.5 mL is a multi-dose, disposable, pre-filled pen with liquid growth hormone able to deliver doses from 0.05 to 3.0 mg. The dose can be adjusted in increments of 0.05 mg. Your doctor will determine the correct dose for you. Norditropin NordiFlex prefilled pen is designed to be used with NovoFine<sup>®</sup> and FlexPen<sup>®</sup> disposable needles (sold separately). Norditropin NordiFlex prefilled pen is not recommended for people who are blind or have trouble seeing unless they have the help of a sighted individual trained to use Norditropin NordiFlex.

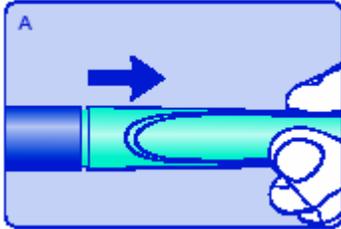
*Please read these instructions carefully before using this pen*



## 1 Preparing Norditropin NordiFlex 10 mg/1.5 mL for injection

**A.** . Pull off the pen cap and check if the growth hormone solution is clear and colorless by turning Norditropin NordiFlex upside down once or twice and view the solution through the residual scale window. **DO NOT use Norditropin NordiFlex if the growth hormone solution is cloudy or contains particles. Use it only if it is clear and colorless.**

Wash hands well and wipe the front rubber stopper on the threaded plastic cap with an alcohol swab.



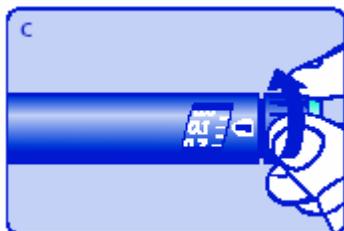
**B.** Place the NovoFine disposable needle onto Norditropin NordiFlex immediately before use. Remove the protective tab from the disposable needle and screw the needle tightly onto Norditropin NordiFlex. Pull off the outer and inner needle caps. Never place a disposable needle on your Norditropin NordiFlex until you are ready to give an injection. Remove the needle immediately after use. If the needle is not removed, some growth hormone may be expelled from Norditropin NordiFlex.



**C. Do an air shot before starting a new Norditropin NordiFlex as follows:**

Small amounts of air may collect in the needle and cartridge. To avoid injecting air and ensure proper dosing, set the dosage selector to 0.05 mg. Each line between labeled dosages is 0.05 mg.

**Dial 0.05 mg**

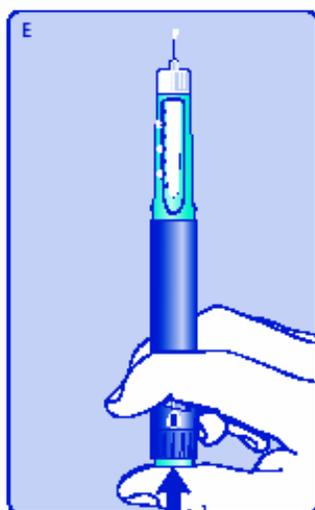


**D.** Hold Norditropin NordiFlex with the needle pointing up, tap the cartridge gently with your finger a few times to raise any air bubbles to the top of the cartridge.



**E.** Still holding Norditropin NordiFlex with the needle up, press the push button all the way in. A drop of growth hormone should appear at the needle tip. If not, repeat the procedure, no more than 4 times.

*If a drop of growth hormone still does not appear, call 1-888-NOVO-444 for help.*



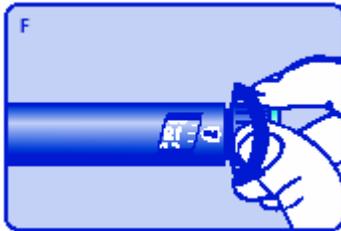
## 2 Setting the dose

**F.** Check that the dose selector is set at **0.0**. Dial the number of mg that you need to inject. The dose can be changed up or down by turning the dose selector in either direction. When dialing back, be careful not to press the push button as growth hormone liquid will come out.

**DO NOT use the clicking sound as a guide for selecting dose.**

The numbers on the residual scale can be used to estimate the mg left in the cartridge. **DO NOT use these numbers to measure the growth hormone dose.**

**You cannot set a dose higher than the number of mg left in the cartridge.** Use a new Norditropin NordiFlex pen to inject the remaining amount of your dose. Be sure to remember the dose already received with the first dose. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.4 mg. You will need to inject an additional 0.2 mg with a new Norditropin NordiFlex pen.



## 3 Giving the injection

Use the injection procedure recommended by your doctor or healthcare professional.

**G.** This product is for subcutaneous use only. Insert the needle under the skin and deliver the dose by pressing the push button all the way in. Press the push button only when injecting.

After the injection, the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle is removed from the skin. This will ensure that the full dose has been delivered. Vary the injection site using the injection procedure recommended by your doctor.



#### 4 Removing the needle

**H.** After the injection, remove the needle **without recapping** and dispose of it in a puncture-resistant container. Used needles should be placed in sharps container (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.

*It is important that you use a new needle for each injection. Healthcare professionals, relatives and other caregivers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle stick injuries.*

When the cartridge is empty, throw away Norditropin NordiFlex without the needle attached.

#### 5 Maintenance

Norditropin NordiFlex should be handled with care. Protect Norditropin NordiFlex from dust, dirt, and direct sunlight.

You can clean the outside of Norditropin NordiFlex by wiping it with a soft cloth moistened with water. Do not soak Norditropin NordiFlex in alcohol, wash, or lubricate it.

## 6 Important Notes

- Store unused Norditropin NordiFlex pens in a refrigerator (2°C - 8°C/36°F - 46°F). After the initial injection, Norditropin NordiFlex 10 mg/1.5 mL may be **EITHER** stored in the refrigerator (2-8°C/36-46°F) and use within 4 weeks **OR** may be stored for up to 3 weeks at not more than 25°C (77°F).
- Remember to perform an air shot before starting a new Norditropin NordiFlex or before the injection if you dropped or knocked the pen against a hard surface. See diagrams **C**, **D** and **E**.
- If you need to perform more than 4 air shots before the first use of Norditropin NordiFlex to get a droplet of growth hormone at the needle tip, **DO NOT** use Norditropin NordiFlex. *Call 1-888-NOVO-444 for help.*
- Take care not to drop Norditropin NordiFlex or knock it against a hard surface.
- **DO NOT** leave Norditropin NordiFlex in a car or other location where it can get too hot or too cold.
- Always have a spare Norditropin NordiFlex disposable pen in order to avoid running out of this product.
- Norditropin NordiFlex is designed to be used with NovoFine and FlexPen disposable needles.
- **NEVER** place a needle on Norditropin NordiFlex until you are ready to use it. Remove the needle right after use without recapping.
- **Throw away used needles properly, so people will not be harmed.**
- Throw away the used Norditropin NordiFlex, without the needle attached.
- To avoid spread of disease, do not let anyone else use your Norditropin NordiFlex, even if you attach a new needle.
- Keep Norditropin NordiFlex out of the reach of children.
- **Novo Nordisk is not responsible for harm due to using Norditropin NordiFlex with products that are not recommended by Novo Nordisk.**

## 7 Warranty

If your Norditropin NordiFlex is defective in materials or workmanship, Novo Nordisk Inc. will replace it at no charge if you mail the defective unit, postage prepaid to:

Novo Nordisk Inc.  
Product Safety  
100 College Road West  
Princeton, NJ 08540, USA

8-2085-31-001-x

**Novo Nordisk®**

## **PATIENT INFORMATION**

### **Norditropin NordiFlex® Somatropin (rDNA origin) injection 15 mg/1.5 mL Prefilled Pen**

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Your doctor will discuss with you the benefits and risks of Norditropin NordiFlex® (pronounced Nor-dee-tro-pin Nor-dee-flex). Read all of the information in this patient guide because it contains important information for you. If you have further questions, please ask your doctor or your pharmacist. Norditropin NordiFlex has been prescribed for you and you must not pass it on to others.

#### **What is the most important information I should know about Norditropin NordiFlex?**

Store Norditropin NordiFlex in a refrigerator before use. Do not freeze it or expose it to heat.

Do not use Norditropin NordiFlex if the solution in the cartridge does not appear clear and colorless. Check this by turning the pen upside down once or twice.

Norditropin NordiFlex is for use by one person only.

Do not use Norditropin NordiFlex if you need to make more than 4 air shots before the first injection.

Your doctor may measure your height, weight and your ability to produce growth hormone before you are prescribed Norditropin NordiFlex.

#### **What is Norditropin NordiFlex?**

Norditropin® is a clear and colorless solution.

Norditropin is used to treat the following:

- children with growth failure caused by very low or no production of growth hormone
- short stature in children with Noonan syndrome
- short stature in children with Turner syndrome
- adults who do not make sufficient growth hormone

Norditropin is injected using Norditropin NordiFlex, a multi-dose disposable 1.5 mL pre-filled pen. Norditropin NordiFlex contains several doses of growth hormone solution. A dose is injected under the skin in the evening 6-7 times a week.

Norditropin NordiFlex is available in three strengths: 5 mg/1.5 mL, 10 mg/1.5 mL and 15 mg/1.5 mL (i.e. with a concentration of 3.3 mg/mL, 6.7 mg/mL and 10.0 mg/mL respectively).

Throw away Norditropin NordiFlex when the cartridge is empty.

Medicines are sometimes prescribed for purposes other than those listed in a patient guide. Patients should ask their doctor about any concerns and refer to the professional labeling for additional information.

### **What does Norditropin NordiFlex contain?**

The cartridge in Norditropin NordiFlex contains human growth hormone called somatropin (so-ma-tro-pin) made through biotechnology. It is identical to the growth hormone produced in the human body.

The cartridge contains other ingredients: Histidine, Poloxamer 188, Phenol, Mannitol and Water for Injection.

### **Who should not take Norditropin NordiFlex?**

Do not use Norditropin NordiFlex if you have any of the following conditions:

- child with closed epiphyses (closed bone growth plates)
- child with Prader-Willi syndrome who is also severely obese or has significant respiratory impairment
- allergic to phenol or any other ingredients in the medicine
- had a kidney transplant
- pregnant
- breast-feeding
- active cancer or other forms of tumor
- acute critical illness due to certain types of heart or abdomen surgery, trauma or acute respiratory failure

### **What should you consider if you are pregnant or breast-feeding?**

If you become pregnant while you are receiving Norditropin NordiFlex, you are recommended to stop the treatment and discuss this with your doctor.

You are recommended not to take Norditropin NordiFlex while you are breast-feeding because somatropin might pass into your milk.

### **Be sure to tell your doctor if you:**

- have diabetes mellitus
- had cancer or other forms of tumor
- are pregnant, planning to be pregnant or breastfeeding
- had a kidney transplant

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

### **How should I take Norditropin NordiFlex?**

Carefully follow the “Instructions for Use” on the other side of this patient guide.

You should inject Norditropin NordiFlex under the skin in the evening just before bedtime. You should change the injection area so you do not harm your skin.

NovoFine<sup>®</sup> and FlexPen<sup>®</sup> disposable needles are designed to be used with Norditropin NordiFlex.

### **How much Norditropin should you take?**

Your doctor will tell you how much Norditropin you should take. In children it depends on the body weight.

General guidelines for dosages are shown below.

Children with low or no growth hormone: 0.024 to 0.034 mg/kg body weight, 6-7 times a week

Children with Noonan syndrome: Up to 0.066 mg/kg/day

**Children with Turner syndrome: Up to 0.067 mg/kg/day**

Adults: Not more than 0.004 mg/kg/day at start of therapy. Dosage may be increased as tolerated to not more than 0.016 mg/kg/day after approximately 6 weeks, or

Alternative dose for adults:

Approximately 0.2 mg/day (range, 0.15-0.30 mg/day) at start of therapy. Dosage can be increased gradually every 1-2 months by steps of approximately 0.1-0.2 mg/day, based on your doctor's recommendations.

If you forget to take a dose, take the next dose as usual - do not double your dose.

### **What should you do if you inject too much growth hormone using Norditropin NordiFlex?**

If you inject too much growth hormone, contact your doctor.

### **How long should you continue to take Norditropin?**

Discuss with your doctor how long you should take Norditropin.

### **What should I avoid while taking Norditropin NordiFlex?**

Be sure to tell your doctor about all of the medications you are taking especially if you are taking:

- a glucocorticoid medication such as hydrocortisone or cortisone acetate
- thyroid hormone
- insulin and/or oral diabetes medicine
- drugs metabolized by the liver (for example, corticosteroids, sex steroids, anticonvulsants, cyclosporine)
- oral estrogen replacement

Adult height can be influenced if you are on Norditropin NordiFlex for growth failure and using glucocorticoids or thyroid hormone at the same time.

If you are treated with insulin and/or oral diabetes medicine, your insulin/oral diabetes medicine dose may need to be adjusted.

### **What are the possible side effects of Norditropin NordiFlex?**

The following side effects are usually mild and temporary:

- headaches
- muscle pain
- joint stiffness
- high blood sugar (hyperglycemia)
- sugar in your urine (glucosuria)
- swollen hands and feet due to fluid retention
- redness and itching in the area you inject

If you experience any of these symptoms, discuss this with your doctor.

In rare cases you may develop antibodies to growth hormone.

If you have symptoms of headaches, eyesight problems, nausea and/or vomiting, these may be symptoms of raised pressure in the brain. Contact your doctor immediately.

**Be sure to tell your doctor if you have any other side effects not mentioned here.**

### **Special warnings**

In very rare cases children treated with somatropin have experienced pain in the hip or knee or a limp. These symptoms may be caused by a slippage of the growth plate in the hip (slipped capital femoral epiphysis).

Scoliosis (curvature of the spine) can occur in children who experience rapid growth. Because growth hormone increases growth rate, patients should be monitored for progression of scoliosis.

Thyroid function tests should be performed periodically.

Patients with Turner syndrome have an increased risk of ear or hearing disorders. They should be carefully evaluated for middle ear infection (otitis media) and other ear disorders.

Skin lesions should be checked carefully for any cancerous changes.

The following tumors have been reported in patients treated with somatropin: Leukemia in children, relapse of brain tumors in children and adults. However, there is no evidence that somatropin is responsible for causing these diseases.

Version 4

Talk to your doctor if you think you have any of these conditions.

### **How to store Norditropin NordiFlex?**

Store unused Norditropin NordiFlex in a refrigerator (2°C - 8°C/36°F - 46°F). Do not freeze or expose it to heat. Avoid direct light.

After the initial injection, Norditropin NordiFlex 15 mg/1.5 mL must be kept in a refrigerator and used within 4 weeks. Discard unused portion after 4 weeks.

Do not use Norditropin NordiFlex which has been frozen or exposed to temperatures higher than 25°C (77°F).

Always use a new NovoFine needle for each injection. Do not keep the needle screwed onto Norditropin NordiFlex when you are not using it.

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

Never use Norditropin NordiFlex after the expiration date printed on the pen and on the carton.

Date of issue:

*Novo Nordisk<sup>®</sup>, Norditropin<sup>®</sup>, Norditropin NordiFlex<sup>®</sup>, NovoFine<sup>®</sup> and FlexPen<sup>®</sup> are registered trademarks of Novo Nordisk A/S.*

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Novo Nordisk Inc.

US Patent Nos. 6,235,004; 6,004,297 and other patents pending.

For assistance or further information, write to:

Novo Nordisk Inc.

100 College Road West

Princeton, NJ 08540, USA

1-888-NOVO-444

[www.norditropin-us.com](http://www.norditropin-us.com)

Manufactured by:

Novo Nordisk A/S

DK-2880 Bagsvaerd, Denmark

**Novo Nordisk<sup>®</sup>**

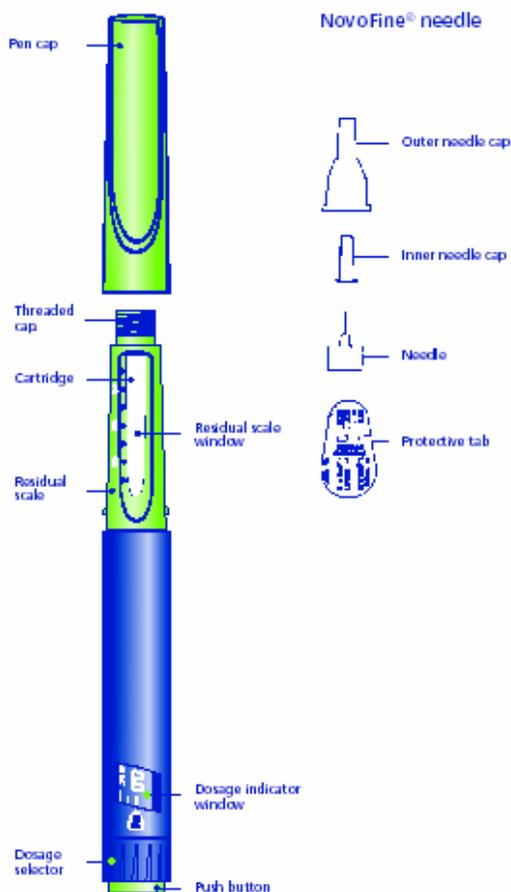
## INSTRUCTIONS FOR USE

### Norditropin NordiFlex<sup>®</sup> Somatotropin (rDNA origin) injection 15 mg/1.5 mL Prefilled Pen

#### Using the disposable Norditropin NordiFlex<sup>®</sup> 15 mg/1.5 mL Prefilled Pen

Norditropin NordiFlex 15 mg/1.5 mL is a multi-dose, disposable, prefilled pen with liquid growth hormone able to deliver doses from 0.075 to 4.5 mg. The dose can be adjusted in increments of 0.075 mg. Your doctor will determine the correct dose for you. Norditropin NordiFlex prefilled pen is designed to be used with NovoFine<sup>®</sup> and FlexPen<sup>®</sup> disposable needles (sold separately). Norditropin NordiFlex prefilled pen is not recommended for people who are blind or have trouble seeing unless they have the help of a sighted individual trained to use Norditropin NordiFlex.

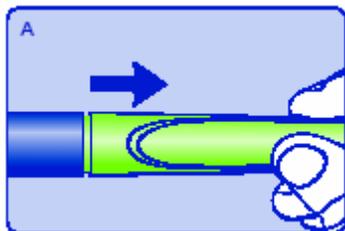
*Please read these instructions carefully before using this pen*



## 1 Preparing Norditropin NordiFlex 15 mg/1.5 mL for injection

**A.** Pull off the pen cap and check if the growth hormone solution is clear and colorless by turning the Norditropin NordiFlex upside down once or twice and view the solution through the residual scale window. **DO NOT use Norditropin NordiFlex if the growth hormone solution is cloudy or contains particles. Use it only if it is clear and colorless.**

Wash hands well and wipe the front rubber stopper on the threaded plastic cap with an alcohol swab.



**B.** Place the NovoFine disposable needle onto Norditropin NordiFlex immediately before use. Remove the protective tab from the disposable needle and screw the needle tightly onto Norditropin NordiFlex. Pull off the outer and inner needle caps. Never place a disposable needle on your Norditropin NordiFlex until you are ready to give an injection. Remove the needle immediately after use. If the needle is not removed, some growth hormone may be expelled from Norditropin NordiFlex.



**C. Do an air shot before starting a new Norditropin NordiFlex as follows:**

Small amounts of air may collect in the needle and cartridge. To avoid injecting air and ensure proper dosing, set the dosage selector to 0.075 mg. Each line between labeled dosages is 0.075 mg.

**Dial 0.075 mg**

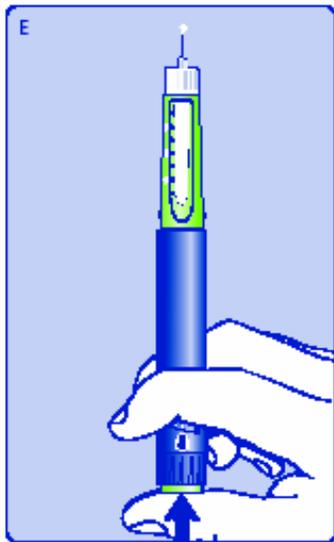


**D.** Hold Norditropin NordiFlex with the needle pointing up, tap the cartridge gently with your finger a few times to raise any air bubbles to the top of the cartridge.



**E.** Still holding Norditropin NordiFlex with the needle up, press the push button all the way in. A drop of growth hormone should appear at the needle tip. If not, repeat the procedure, no more than 4 times.

*If a drop of growth hormone still does not appear, call 1-888-NOVO-444 for help.*



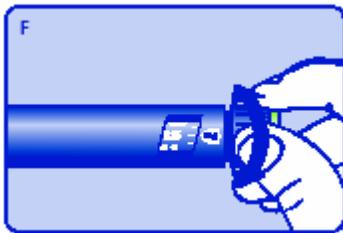
## 2 Setting the dose

**F.** Check that the dose selector is set at **0.0**. Dial the number of mg that you need to inject. The dose can be changed up or down by turning the dose selector in either direction. When dialing back, be careful not to press the push button as growth hormone liquid will come out.

**DO NOT use the clicking sound as a guide for selecting dose.**

The numbers on the residual scale can be used to estimate the mg left in the cartridge. **DO NOT use these numbers to measure the growth hormone dose.**

**You cannot set a dose higher than the number of mg left in the cartridge.** Use a new Norditropin NordiFlex pen to inject the remaining amount of your dose. Be sure to remember the dose already received with the first dose. For example, if your dose is 0.6 mg and you can only set the dose selector to 0.3 mg. You will need to inject an additional 0.3 mg with a new Norditropin NordiFlex pen.

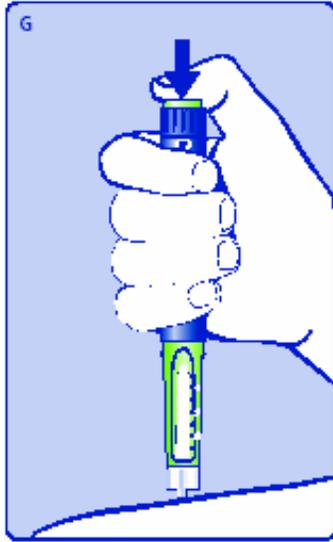


## 3 Giving the injection

Use the injection procedure recommended by your doctor or healthcare professional.

**G.** This product is for subcutaneous use only. Insert the needle under the skin and deliver the dose by pressing the push button all the way in. Press the push button only when injecting.

After the injection, the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle is removed from the skin. This will ensure that the full dose has been delivered. Vary the injection site using the injection procedure recommended by your doctor.



#### 4 Removing the needle

**H.** After the injection, remove the needle **without recapping** and dispose of it in a puncture-resistant container. Used needles should be placed in sharps container (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.

*It is important that you use a new needle for each injection. Healthcare professionals, relatives and other caregivers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle stick injuries.*

When the cartridge is empty, throw away Norditropin NordiFlex without the needle attached.

#### 5 Maintenance

Norditropin NordiFlex should be handled with care. Protect Norditropin NordiFlex from dust, dirt, and direct sunlight.

You can clean the outside of Norditropin NordiFlex by wiping it with a soft cloth moistened with water. Do not soak Norditropin NordiFlex in alcohol, wash, or lubricate it.