Introduction

This package contains one FlexPro® PenMate® autoinsertion accessory, a case for storage and this user Please read this user manual carefully before using your

FlexPro® PenMate® (called PenMate® in the rest of this user manual). The instructions contain information about using, storing and cleaning your PenMate®, and you should read the instructions even if you have used other Novo Nordisk delivery systems before.

PenMate® is designed to help you inject growth hormone by hiding the needle during the injection with Norditropin® FlexPro® 5, 10 or 15 mg/1.5 ml.

Norditropin® FlexPro® is a pre-filled growth hormone pen for single patient use, only. Norditropin® FlexPro® designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm. Do not use your pen or PenMate® without training from your doctor or nurse. Read the Norditropin® FlexPro® 5, 10 or 15 mg/1.5 ml user manual before using PenMate® The illustrations in this user manual show PenMate®

used with Norditropin® FlexPro® 5 mg/1.5 ml. Important information and additional information are

clearly marked by the symbols you see below:

Pay special attention to these notes as they are

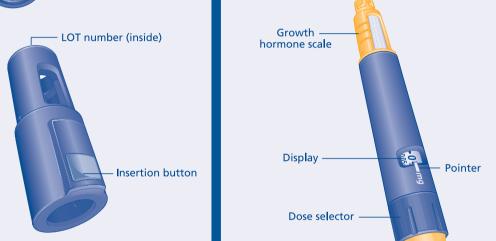
△ Important information

important for safe use of your pen or PenMate®.

 Additional information Helpful information when using your pen and

FlexPro® PenMate®





(example)

Dose button -

Norditropin® FlexPro® 5 mg/1.5 ml

Pen cap

Needle (example) Paper needle cap needle cap Needle

⚠ Important information

Read this important information before you start using your PenMate®

- PenMate® should only be used in combination with Norditropin® FlexPro® 5, 10 or 15 mg/1.5 ml. • If your PenMate® becomes lost or damaged, you ca
- still use your Norditropin® FlexPro® pen without
- PenMate® is for single patient use, only. Never share your pen. PenMate® or your needles with other people. It might lead to cross-infection. • Always keep your pen. PenMate® and needles out of
- reach of others, especially children. Caregivers must be very careful when handling used needles - to reduce the risk of needle injury and cross-infection.

Pen table

Use the pen table below to get a quick overview of all Norditropin® FlexPro® pens and how they differ in terms of growth hormone strength, colour, minimum and maximum doses.

lorditropin® lexPro®	5 mg/ 1.5 ml	10 mg/ 1.5 ml	15 mg/ 1.5 ml
Colour code			
⁄lin. dose	02 mg	O mg	22 -mg
	0.025 mg	0.05 mg	0.1 mg
Лах. dose	2.0-mg	4.0 mg	608 em-
	2.0 mg	4.0 mg	8.0 mg

Preparing your PenMate®

Before you prepare your PenMate®, always 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 PenMate®



B Pull off the pen cap. You **B** will not need it with your 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.





Take a new disposable needle and tear off the



Pull off the outer needle

After injection, you will

remove the needle from

G Pull off the inner needle G

cap and throw it away.

If you try to put it back

on, vou may accidental

stick vourself with the

hormone may appear at

The needle is covered by two caps. You must

Always use a new needle for each injection. This

vou will not inject any growth hormone.

Always discard a bent or damaged needle

remove both caps. If you forget to remove both caps

reduces the risk of contamination, infection, leakage

of growth hormone, blocked needles and inaccurate

A drop of growth

the needle tip. This is

normal

need it to correctly

cap and save it.

the pen.



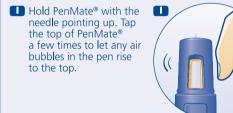
Checking the growth hormone flow with each new pen

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.

Turn the dose selector to select the **minimum** dose, 0.025, 0.05 or 0.1 mg, depending on which pen you are using. See Pen table.



needle pointing up. Tap the top of PenMate® a few times to let any air bubbles in the pen rise to the top.



Press the dose button until the figure 0 in the display lines up with the pointer and a drop of arowth hormone appears at the needle If no drop appears,

> repeat steps H to J up to 6 times. If no drop appears after these new attempts, change the needle and repeat steps H to J once more. Do not use the pen if

a drop of growth

hormone still does not

K Check that the figure 0 in the display lines up with the pointer. Select or adjust the dose you need by turning the dose selector forward or backward until the right

Selecting your dose

number of mg lines up with the pointer. When the pen contains less than the maximum

Use the dose selector on your Norditropin®

dose, depending on which pen you are using

FlexPro® pen to select up to 2.0, 4.0 or 8.0 mg per

dose (2.0, 4.0 or 8.0 mg depending on which per you are using), the dose selector stops at the number of mg left.

(i) The dose selector clicks differently when turned forward, backward or past the number of mg left.

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

 $oldsymbol{\Lambda}$ Never use the growth hormone scale to measure

A 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.

how much growth hormone to inject. Only the display and pointer will indicate the exact number

KK

novo nordisk

The CE mark on a medical device

FlexPro® and Norditropin® are

Novo Nordisk Health Care AG.

Novo Nordisk A/S. Denmark

Date of issue: 2019/05

Novo Nordisk A/S

DK-2880 Bagsværd Denmark

© 2019

Novo Allé

registered trademarks owned by

PenMate®, NovoFine® and NovoTwist®

are registered trademarks owned by

indicates that the product conforms

with the requirements in the Medical Device Regulations (EU) 2017/745.

Activating your PenMate®

Use your PenMate® to insert the needle automatically into your skin.

■ To activate your PenMate®, grip both Norditropin® FlexPro® without touching the needle, insertion button or dose button. Hold PenMate® firmly

and pull the pen out until you hear and feel it click into place.

Never press the insertion button before you are

Never turn the dose selector when activating your

PenMate®, as you may end up injecting a wrong

vourself with the needle.

ready to inject your dose. You may accidentally stick

The needle is now hidden in PenMate®.



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

M Hold PenMate® against vour skin. Press the insertion button until you hear a click and the needle is inserted automatically.



N To inject, press the dose button 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 su that you get your full

You can let go off the dose button while you



A Never use the pen clicks to count the number of mo vou inject. Only the display and pointer will indicate the exact number of mg.

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



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.

the skin.

Remove the needle from



Q Put the PenMate® cap back on after every use. If growth hormone is exposed to direct light, its effect may be



have removed it from the needle. You may accidentally stick yourself with the needle.

needles and inaccurate dosing.

⚠ If you lose your PenMate® cap, contact your supplier to get a new one. Until you get a new PenMate® cap, you can use your Norditropin® FlexPro® pen and pen cap without your PenMate®, or you can use your PenMate® with the pen attached and keep them protected from direct light.

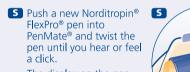


Reuse your PenMate® by simply replacing your Norditropin® FlexPro® pen once it is empty.

R When your Norditropin® R FlexPro® pen is empty. twist it and gently pull it out of PenMate®.

FlexPro®

Throw away the empty pen without a needle on as instructed by your doctor or nurse, or your local authorities.



The display on the pen will align with the insertion button on your PenMate®



What to do when Norditropin^o FlexPro® is nearly empty

You can use the growth hormone scale on your

much growth hormone is left in the pen.

vou are using:

You can use the dose selector on the pen to see exactly

how much growth hormone is left - if the pen contains

If you need more growth hormone than you have left in

less than 2.0, 4.0 or 8.0 mg, depending on which pen

up with the pointer shows how many mg are left.

vour pen, vou can use a new pen or split vour dose

between your current pen and a new pen.

Norditropin® FlexPro® pen to see approximately how

Turn the dose selector until it stops. The figure that lines

- Do not try to refill your pen it is pré-filled.

- PenMate® store it as described in the insert in your Norditropin® FlexPro® pack.
- the case supplied when not in use. The expected lifetime of your PenMate® is 5 years of normal use.
- The case can also hold four extra NovoFine® or NovoTwist® disposable needles.

Cleaning and maintenance

- Do not try to wash, soak or lubricate your PenMate®
- Clean off dirt and dust with a dry soft brush.

Disposal

 If you are going to throw away your PenMate[®], do so as advised by your local authorities. PenMate® does not contain substances harmful to the

environment.

Warranty

 PenMate® must only be used according to the instructions provided in this user manual. The manufacturer cannot be held responsible for any problems with PenMate® if these instructions have not been followed

If you find that your PenMate® or case is faulty. Novo Nordisk will replace it if you return it to your supplier for inspection within five years of receiving it and you enclose the receipt you were given when you purchased your PenMate®.

If you need the LOT number of your PenMate®, it is located as shown in the picture of FlexPro® PenMate® iust after the *Introduction* in this user manual.

For customers in the European Union; if your doctor and/or you believe you had a serious incident caused by using PenMate®, make sure to report it to Novo Nordisk and to your national authority.



User manual Please read this user manual carefully before using your

FlexPro® PenMate®

FlexPro® PenMate®







A Never put the inner needle cap back on once you

Always store the pen in PenMate® without a needle attached. This reduces the risk of contamination. infection, leakage of growth hormone, blocked

Caring for your PenMate® and Norditropin® FlexPro® pen

Treat your PenMate® and Norditropin® FlexPro® pen with Storage and handling

• Do not drop your PenMate® or pen or knock them

- against hard surfaces. If you do drop them or suspect that something is wrong with them, always screw a new disposable needle onto the pen and check the arowth hormone flow before you inject.
- Do not try to repair or pull apart your PenMate® or
- Do not expose your PenMate® or pen to dust, dirt.
- liquid, direct light or extreme temperatures.
- When your Norditropin® FlexPro® pen is inserted in
- Store your PenMate® and Norditropin® FlexPro® pen in

- or pen. If necessary, clean them with a mild detergent on a moistened cloth