PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

NovoRapid® 100 U/mL solution for injection/infusion

Insulin aspart.

Sugar free.

Read all of this leaflet carefully before you start using NovoRapid®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NovoRapid® has been prescribed for you personally and you should not share your NovoRapid® with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NovoRapid® is and what is it used for

NovoRapid® is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above. Diabetes is a disease where your body does not produce enough insulin to control the level of your blood sugar. Treatment with NovoRapid® helps to prevent complications from your diabetes.

NovoRapid® will start to lower your blood sugar 10 – 20 minutes after you have injected.

Maximum effect occurs between 1 and 3 hours and the effect last for 3 – 5 hours. Due to this short action, NovoRapid® should be injected in combination with intermediate-acting or long-acting insulin preparations. Moreover NovoRapid® can be used for continuous infusion in a pump system.

2. What you need to know before you use NovoRapid®

You should not use NovoRapid®:

- If are allergic (hypersensitive) to insulin aspart or any of the other ingredients in NovoRapid® listed in section 6.
- If you suspect hypoglycaemia (low blood sugar) is starting.
- If it has not been stored correctly or if it has been frozen.
- If the insulin does not appear clear and colourless.

Before using NovoRapid®

- Check the label to make sure it is the right type of insulin.
- **Vial:** Remove the protective cap.
- **Penfill®:** Always check the cartridge, including the rubber stopper. Do not use it if any damage is seen or if there is a gap between the rubber stopper and the white label band.

Take it back to your supplier. See your delivery system manual for further instructions.

- **Penfill®/FlexPen®:** Always use a new needle for each injection to prevent contamination.
- **Penfill®/FlexPen®:** Needles and NovoRapid® Penfill®/FlexPen® must not be shared.

Warnings and precautions

Take special care with NovoRapid®

Medical examination/follow-up:

- If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid gland.
- If you exercise more than usual or if you want to change your usual diet, as this may affect your blood sugar level.
- If you are ill, carry on taking your insulin and consult your doctor.
- If you are going abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travelling.

Skin changes at the injection site

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area (see section 3**, How to use NovoRapid®**). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Children and adolescents

Do not give this medicine to children below 1 year of age since no clinical studies have been carried out in children below the age of 1 year.

Other medicines and NovoRapid®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

If you take any of the medicines below, your blood sugar level may fall (hypoglycaemia):

- Other medicines for the treatment of diabetes.
- Monoamine oxidase inhibitors (used to treat depression).
- Beta-blockers (used to treat high blood pressure) such as propranolol.
- Angiotensin converting enzyme (ACE) inhibitors, ARBs (Angiotensin Receptor Blockers) - used to treat certain heart conditions or high blood pressure.
- Aspirin (used to relieve pain and lower fever).
- Anabolic steroids (such as testosterone).
- Sulphonamides (used to treat infections).

If you take any of the medicines below, your blood sugar level may rise (hyperglycaemia):

- Oral contraceptives (birth control pills).
- Thiazides (used to treat high blood pressure or excessive fluid retention).
- Glucocorticoids (such as ‘cortisone’ used to treat inflammation).
- Thyroid hormones (used to treat thyroid gland disorders).
- Sympathomimetics (such as adrenaline [epinephrine], salbutamol or terbutaline to treat asthma).
- Growth hormone (medicine for stimulation of growth that influences the body’s metabolic processes).
- Danazol (medicine acting on ovulation).

Conditions which need supervision:

- Octreotide and lanreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level.
- Beta-blockers (used to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognise low blood sugar.

Pioglitazone (class of oral antidiabetic medicines used for the treatment of type 2 diabetes mellitus):

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with pioglitazone in combination with insulin may develop heart failure. Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

NovoRapid® with alcohol

If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using NovoRapid®.

NovoRapid® can be used during pregnancy and breastfeeding. Your insulin dosage may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of low blood sugar, is important for your health and the health of your baby.

Driving and using machines

If your blood sugar is low or high, your concentration and ability to react might be affected, and therefore also your ability to drive or operate a machine.

Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car:

- If you have frequent low blood sugar.
- If you find it hard to recognise low blood sugar.

NovoRapid® has a rapid effect therefore if low blood sugar occurs you may experience it earlier after an injection when compared to soluble human insulin.

NovoRapid® contains sodium

NovoRapid® contains less than 1 mmoL sodium (23 mg) per 1 mL, i.e. NovoRapid® is essentially 'sodium-free'.

3. How to use NovoRapid®

Do not share medicines prescribed for you with any other person.

Dosage and when to take your insulin

Always use NovoRapid® and adjust your dose exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with NovoRapid® will last. If you have the impression that the effect of NovoRapid® is too strong or too weak, tell your doctor or pharmacist.

NovoRapid® is generally taken immediately before a meal. Eat a meal or snack containing carbohydrates within 10 minutes of the injection to avoid low blood sugar. When necessary, NovoRapid® can be given soon after a meal.

Penfill®:

Make sure to use NovoRapid® Penfill® as your doctor or other health care providers have told you and follow their advice carefully.

FlexPen®/FlexTouch®:

Make sure to use the colour-coded NovoRapid® FlexPen®/ FlexTouch® as your doctor or other health care providers have told you and follow their advice carefully.

If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor. Do not change your insulin unless your doctor tells you to.

Due to the shorter duration of the effect, NovoRapid® has a lower risk of causing hypoglycaemia during the night.

Do not use NovoRapid®:

Vial:

- If the protective cap is loose or missing. Each vial has a protective, tamper-proof plastic cap. If it is not in perfect condition when you get the vial, return the vial to your supplier.

Penfill®:

- If the cartridge or the device containing the cartridge is dropped, damaged or crushed.

FlexPen®/FlexTouch®:

- If FlexPen®/FlexTouch® is dropped, damaged or crushed.

Use in children and adolescents

NovoRapid® can be used in adolescents and children aged 1 year and above instead of soluble human insulin when a rapid onset effect is preferred. For example, when it is difficult to dose the child in relation to meals.

Use in special populations

If you have reduced kidney or liver function, or if you are above 65 years of age, you need to check your blood sugar more regularly and discuss changes in your insulin dose with your doctor.

How and where to inject

NovoRapid® is for injection under the skin (subcutaneously) or for continuous infusion in a pump system. Administration in a pump system will require a comprehensive instruction by your health care provider. NovoRapid® may also be given directly into a vein (intravenously) by health care providers under close supervision by a doctor.

Never inject your insulin directly into a muscle (intramuscular).

Always vary the sites you inject within the same region to reduce the risk of developing lumps or skin pitting.

The best places to give yourself an injection are: the front of your waist (abdomen), the upper arm or the front of your thighs. The insulin will work more quickly if injected around the waist. You should measure your blood sugar regularly.

***10 mL Vial*:** Please see Appendix 1 Vial instructions for use.

Penfill®: Please see Appendix 2 Penfill® instructions for use.

FlexPen®: Please see Appendix 3 FlexPen® instructions for use.

FlexTouch®: Please see Appendix 4 FlexTouch® instructions for use.

FlexPen®: How to handle NovoRapid® FlexPen®/FlexTouch®

Read the included NovoRapid® FlexPen®/FlexTouch® instructions for use carefully. You must use the pen as described in the instructions for use.

For use in an infusion pump system

NovoRapid® should never be mixed with any other insulin when used in a pump.

Follow the instructions and recommendations from your doctor regarding the use of NovoRapid® in a pump. Before use of NovoRapid® in the pump system, you must have received a comprehensive instruction in the use and information about any actions to be taken in case of illness, too high or too low blood sugar or failure of the pump system.

- Before inserting the needle, use soap and water to clean your hands and the skin where the needle is inserted to avoid any infection at the infusion site.
- When you fill a new reservoir, be certain not to leave large air bubbles in either the syringe or the tubing.
- Changing of the infusion set (tubing and needle) must be done according to the instructions in the product information supplied with the infusion set.

To get the benefit of insulin infusion, and to detect possible malfunction of the insulin pump, it is recommended that you measure your blood sugar level regularly.

What to do in case of pump system failure

You should always have alternative insulin available for injection under the skin in case of pump system failure.

If you inject more NovoRapid® than you should

If you take too much insulin, your blood sugar gets too low (this is called hypoglycaemia).

This may also happen:

- If you eat too little or miss a meal.
- If you exercise more than usual.
- Inject too much insulin.
- Drink alcohol (see **NovoRapid® with alcohol** in section 2).

The warning signs of a hypoglycaemia may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

If you feel changes of low blood sugar coming on, take a high sugar snack and then measure your blood sugar. If your blood sugar is too low, eat glucose tablets or another high sugar snack (sweets, biscuits, fruit juice), then rest. Always carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

When the symptoms of low blood sugar have disappeared or when your blood sugar level is stabilised, continue insulin treatment.

Tell relevant people you have diabetes and what the consequences may be, including the risk of passing out (become unconscious) due to a hypoglycaemia.

Tell relevant people that if you pass out, they must turn you on your side and get medical help straight away. They must not give you any food or drink. It could choke you.

You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon, you will need glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Contact your doctor or an emergency ward after an injection of glucagon:

you need to find the reason for your low blood sugar to avoid getting more.

- If prolonged severe low blood sugar is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a low blood sugar that makes you pass out, or a lot of low blood sugar episodes, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

If you forget to inject NovoRapid®

If you forget to take your insulin, your blood sugar may get too high (this is called hyperglycaemia). This may also happen:

- Have not injected enough insulin.
- Forget to inject your insulin or stop taking insulin.
- If you repeatedly take less insulin than you need.
- If you get an infection or a fever.
- If you eat more than usual.
- If you exercise less than usual.

The warning signs appear gradually. They include increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed, dry skin; dry mouth and a fruity (acetone) smell of the breath. These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar).

If you do not treat it, this could lead to diabetic coma and eventually death. If you get any of these signs mentioned above, test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.

Do not take a double dose to make up for forgotten individual doses.

If you stop injecting NovoRapid®

Inadequate dosing or discontinuation of treatment may, especially in Type 1 diabetes (insulin-dependent diabetes mellitus), lead to high blood sugar levels (hyperglycaemia) and a metabolic state resulting from a profound lack of insulin (diabetic ketoacidosis).

This could lead to severe hyperglycaemia and ketoacidosis.

Do not stop taking your NovoRapid® injection without speaking to your doctor, who will tell you what needs to be done.

If you have any further questions on the use of NovoRapid®, ask your doctor or pharmacist.

4. Possible side effects

NovoRapid® can have side effects.

Not all side effects reported for NovoRapid® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NovoRapid®, please consult your health care provider for advice.

Serious and common side effects

Serious allergic reactions

If any of the following happens, stop using NovoRapid® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- rash or itching.
- if you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have a rapid heartbeat; feel dizzy.
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NovoRapid®. You may need urgent medical attention or hospitalisation.

Low blood sugar (hypoglycaemia)

The most frequently reported side effect is hypoglycaemia. This means your blood sugar level is too low, this is a serious side effect. What to do **i**f your if your blood sugar is too low; please refer to section 3 **If you inject more NovoRapid® than you should.**

Skin changes at the injection site (Lipodystrophy)

If you inject insulin too often at the same place, the fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy) (may affect up to 1 in 100 people). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Changing the site with each injection may help to reduce the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or other health care providers. These reactions can become more severe, or they may change the absorption of your insulin, if you inject in such a site.

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

Uncommon side effects

Signs of allergy

Reactions (pain, redness, hives, inflammation, swelling and itching) at the injection site may occur (local allergic reactions). These reactions usually disappear after a few weeks of taking your NovoRapid®. If they don’t disappear, or if they spread throughout your body, see your doctor.

Vision problems

When you first start NovoRapid® treatment, it may disturb your vision (blurred vision), but the disturbance is usually temporary**.**

Swollen joints

When you start NovoRapid® treatment, water retention may cause swelling around your ankles and other joints. Usually this soon disappears**.** If not, talk to your doctor.

Diabetic retinopathy *(an eye disease related to diabetes, which can lead to loss of vision)*

If you have diabetic retinopathy and your blood sugar level improves very fast, the retinopathy may get worse. Ask your doctor about this.

Rare side effects

Painful neuropathy *(pain due to nerve damage)*

If your blood sugar level improves very fast, you may get nerve related pain, this is called acute painful neuropathy and is usually transient.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of NovoRapid®.

5. How to store NovoRapid®

NovoRapid® Vials (10 mL), FlexPens®, FlexTouch® and Penfills®

Before opening: Store in a refrigerator (2 ºC – 8 ºC). Do not freeze.

In-use storage

NovoRapid® Penfill®/ NovoRapid® Vials

During use or when carried as a spare: Store at or below 30 ºC for up to 4 weeks. Do not expose to heat and sunlight. Do not store cartridges/Penfill®, in use in the refrigerator (between 2 ºC and 8 ºC).

Vials: Discard any unused portion after 4 weeks of use.

NovoRapid® FlexPen® and NovoRapid® FlexTouch®

During use or when carried as a spare: Store at or below 30 ºC for up to 4 weeks. Do not expose to heat and sunlight. Can be stored in the refrigerator (2 ºC – 8 ºC) for up to 4 weeks.

Store all medicines out of reach of children.

Do not use NovoRapid® if you notice that the solution is not clear, colourless and aqueous.

Do not use after the expiry date stated on the vial/cartridge label and carton.

Return all unused and or expired NovoRapid® to your nearest pharmacy.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NovoRapid® contains

NovoRapid® contains insulin aspart 100 U/mL. One unit of insulin aspart corresponds to 6 nmol, 0,035 mg salt-free anhydrous insulin aspart (produced in *Saccharomyces cerevisiae* by recombinant DNA technology.

The other ingredients are glycerol, zinc chloride, disodium phosphate dihydrate, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

The following preservatives are included: phenol 0,15 % *m/v* and metacresol 0,172 % *m/v*.

What NovoRapid® looks like and contents of the pack

NovoRapid® is a clear, colourless and aqueous solution.

NovoRapid® single vial:

10 mL solution in a colourless type 1 glass vial, closed with a rubber disc and protective tamper-proof plastic cap. Pack size: 1 vial in an outer carton.

NovoRapid® 3 mL Penfill®:

3 mL solution in colourless type I glass Penfill® cartridges with a plunger (bromobutyl) and a rubber closure. Pack size: 5 x 3 mL cartridges in an outer carton.

NovoRapid® 3 mL FlexPen®:

3 mL solution in colourless type I glass Penfill® cartridges with a plunger (bromobutyl) and a rubber closure contained in a disposable pen. Pack size: 5 x 3 mL pre-filled pens in an outer carton.

NovoRapid® 3 mL FlexTouch®:

3 mL solution in colourless type I glass Penfill® cartridges with a plunger (bromobutyl) and a rubber closure contained in a disposable pen. Pack size: 5 x 3 mL pre-filled pens in an outer carton.

Holder of certificate of registration

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Appendix 1 – 10 mL Vial instructions for use

How to inject NovoRapid®

If you use only one type of insulin:

1. Draw into the syringe the same amount of air as the dose of insulin you are going to inject. Inject the air into the vial.
2. Turn the vial and syringe upside down and draw the correct insulin dose into the syringe. Pull the needle out of the vial. Then expel the air from the syringe and check that the dose is correct.

If you have to mix two types of insulin:

3. Just before use, roll the long-acting (cloudy) insulin between your hands until the liquid is uniformly white and cloudy.
4. Draw into the syringe the same amount of air as the dose of long-acting insulin. Inject the air into the vial containing long-acting insulin and pull out the needle.
5. Draw into the syringe the same amount of air as the dose of NovoRapid®. Inject the air into the vial containing NovoRapid®. Turn the vial and syringe upside down and draw up the prescribed dose of NovoRapid®. Expel any air from the syringe and check that the dose is correct.
6. Push the needle into the vial of long-acting insulin, turn the vial and syringe upside down and draw out the dose you have been prescribed. Expel any air from the syringe and check the dose.

   Inject the mixture immediately.
7. Always mix NovoRapid® and long-acting insulin in the same sequence.

How to inject this insulin

- Inject the insulin under the skin. Use the injection technique advised by your doctor or diabetes nurse.
- Keep the needle under your skin for at least 6 seconds to make sure you have injected all the insulin.
- Discard the needle after each injection.

Appendix 2 - Penfill® instructions for use

How to inject this insulin

- Inject the insulin under the skin. Use the injection technique advised by your doctor or diabetes nurse and as described in your delivery system manual.
- Keep the needle under your skin for at least 6 seconds. Keep the push button fully depressed until the needle has been withdrawn. This will ensure correct delivery and limit possible flow of blood into the needle or insulin reservoir.
- After each injection be sure to remove and discard the needle and store NovoRapid® without the needle attached. Otherwise the liquid may leak out, which can cause inaccurate dosing.
- Do not refill the cartridge.
- NovoRapid® Penfill® is designed to be used with Novo Nordisk insulin delivery systems and NovoFine® or NovoTwist® needles.
- If you are treated with NovoRapid® Penfill® and another insulin Penfill® cartridge, you should use two insulin delivery systems, one for each type of insulin.
- As a precautionary measure, always carry a spare insulin delivery device in case your Penfill® is lost or damaged.

Delivery of dosage using NovoPen:

- Use the injection technique advised by the healthcare practioner.
- With NovoPen it is possible to select a dose larger than the number of units remaining in the Penfill. For your convenience the cartridge holder has marks which show the approximate dose remaining in the Penfill.
- Do not dial up more than what is available.
- Do not initiate injection if the rubber piston can be seen in the small inspection windows as the glass ball needs room to resuspend the insulin.
- When a dosage greater than the insulin remaining in the cartridge is required, the following options can be exercised:

i) The dosage remaining in the current Penfill can be administered. A new Penfill is then inserted according to the manufacturer's instructions, and the balance of the required dosage is administered from the new Penfill

or

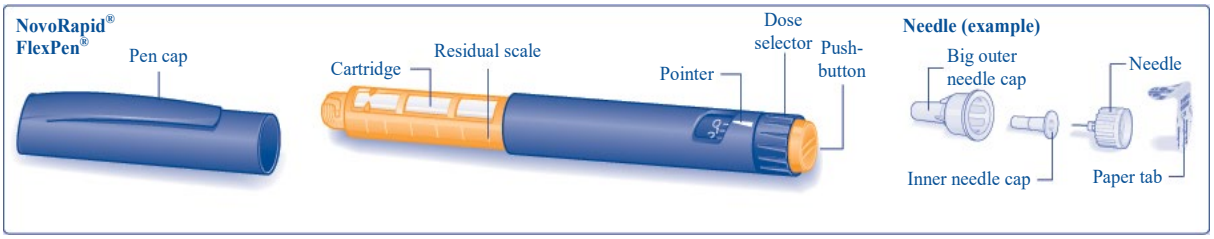
ii) The current Penfill can be discarded. A new Penfill is then inserted according to the manufacturer's instructions and the full dosage is administered from the new Penfill.

To avoid possible transmission of disease, Penfill is for single person use only.

Appendix 3 - FlexPen® instructions for use

Read the following instructions carefully before using your FlexPen®. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

Your FlexPen® is a pre-filled dial-a-dose insulin pen. You can select doses from 1 to 60 units in increments of 1 unit. FlexPen® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm. As a precautionary measure, always carry a spare insulin delivery device in case your FlexPen® is lost or damaged.



Caring for your pen

Your FlexPen® must be handled with care.

If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

You can clean the exterior of your FlexPen® by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Do not refill your FlexPen®. Once empty, it must be disposed of.

Preparing your NovoRapid® FlexPen®

Check the name and coloured label of your pen to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take the wrong type of insulin, your blood sugar level may get too high or too low.

A

Pull off the pen cap.

B

Remove the paper tab from a new disposable needle.

Screw the needle straight and tightly onto your FlexPen®.

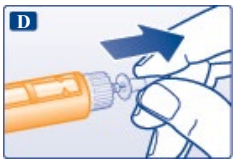
C

Pull off the big outer needle cap and keep it for later.

D

Pull off the inner needle cap and dispose of it.

Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.



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

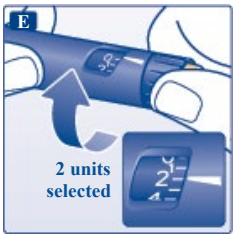
⚠ Be careful not to bend or damage the needle before use.

Checking the insulin flow

Prior to each injection small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:

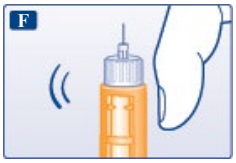
E

Turn the dose selector to select 2 units.



F

Hold your FlexPen® with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.



G

Keeping the needle upwards, press the push-button all the way in. The dose selector returns to 0.

A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times.

If a drop of insulin still does not appear, the pen is defective, and you must use a new one.

⚠ Always make sure that a drop appears at the needle tip before you inject. This makes sure that the insulin flows. If no drop appears, you will not inject any insulin, even though the dose selector may move. This may indicate a blocked or damaged needle.

⚠ Always check the flow before you inject. If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.

Selecting your dose

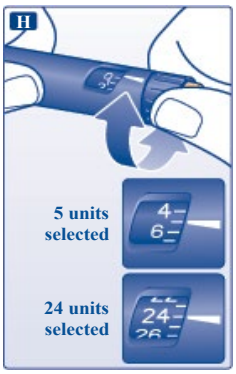
Check that the dose selector is set at 0.

H

Turn the dose selector to select the number of units you need to inject

The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.

You cannot select a dose larger than the number of units left in the cartridge.



⚠ Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.

⚠ Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

Insert the needle into your skin. Use the injection technique shown by your doctor or nurse.

I

Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.

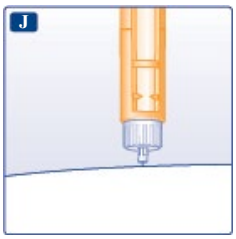
Turning the dose selector will not inject insulin.

J

Keep the push-button fully depressed and let the needle remain under the skin for at least 6 seconds. This will make sure you get the full dose.

Withdraw the needle from the skin, then release the pressure on the push-button.

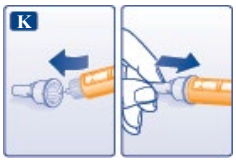
Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.



K

Lead the needle into the big outer needle cap without touching it. When the needle is covered, carefully push the big outer needle cap completely on and then unscrew the needle.

Dispose of it carefully and put the pen cap back on.



⚠ Always remove the needle after each injection and store your FlexPen® without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Further important information

⚠ Caregivers must be very careful when handling used needles - to reduce the risk of needle sticks and cross-infection.

⚠ Dispose of your used FlexPen® carefully without the needle attached.

⚠ Never share your pen or your needles with other people. It might lead to cross-infection.

⚠ Never share your pen with other people. Your medicine might be harmful to their health.

⚠ Always keep your pen and needles out of sight and reach of others, especially children.

Appendix 4 – FlexTouch instructions for use

Instructions on how to use NovoRapid® 100 U/mL solution for injection in pre-filled pen (FlexTouch®)

Please read these instructions carefully before using your FlexTouch® pre-filled pen. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

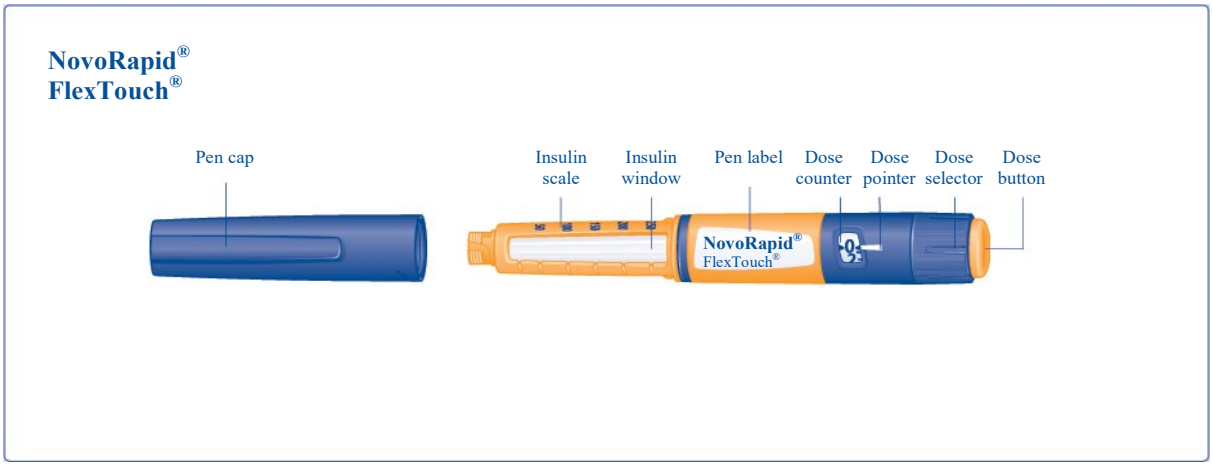
Do not use the pen without proper training from your doctor or nurse.

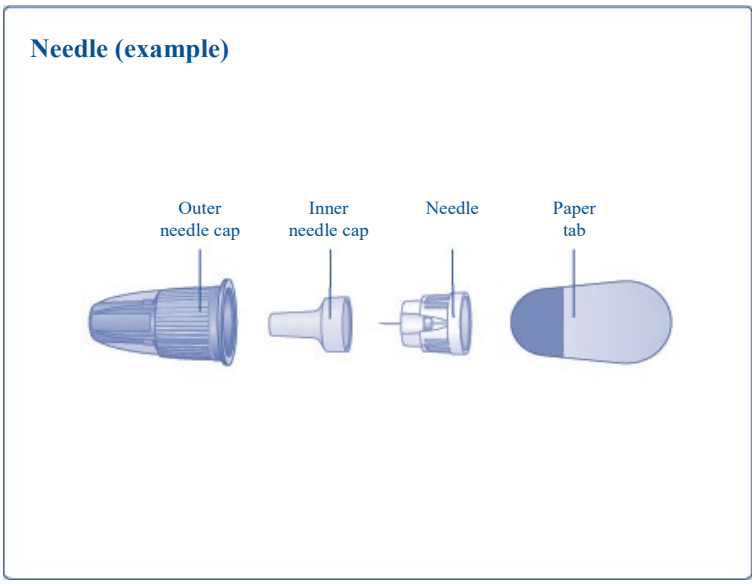
Start by checking your pen to **make sure that it contains NovoRapid® 100 U/mL**, then look at the illustrations to the right to get to know the different parts of your pen and needle.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the FlexTouch® pre-filled pen.

Your NovoRapid® FlexTouch® pen is a pre-filled insulin pen. NovoRapid® FlexTouch® contains 300 units of insulin and delivers doses from 1 to 80 units, in increments of 1 unit.

NovoRapid® FlexTouch® is designed to be used with **NovoFine® or NovoTwist®** single-use disposable needles up to a length of 8 mm.



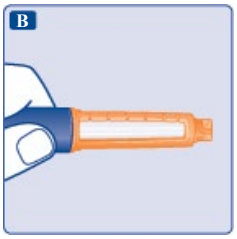


Preparing your NovoRapid® FlexTouch® pen

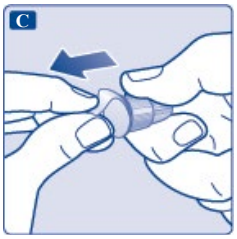
Check the name and coloured label on your NovoRapid® FlexTouch® pen to make sure that it contains the type of insulin you need. This is especially important if you take more than one type of insulin. If you take a wrong type of insulin, your blood sugar level may get too high or too low.

A. Pull off the pen cap.

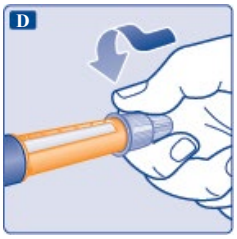
B. Check that the insulin in your pen is clear and colourless. Look through the insulin window. If the insulin looks cloudy, do not use the pen.



C. Take a new disposable needle, and tear off the paper tab.



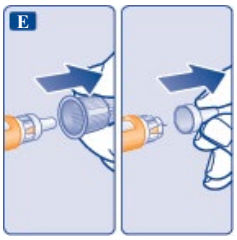
D. Screw the needle straight onto the pen. Make sure the needle is on tight.



E. Pull off the outer needle cap and save it. You will need it after the injection to correctly remove the needle from the pen.

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 insulin may appear at the needle tip. This is normal.



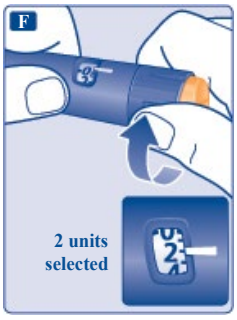
⚠ **Always use a new needle for each injection.** This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

⚠ **Never use a bent or damaged needle.**

Checking the insulin flow

Make sure that you receive your full dose by always checking the insulin flow before you select and inject your dose.

F. Turn the dose selector to select 2 units.



G. 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.

H. Press the dose button with your thumb until the dose counter returns to 0. The 0 must line up with the dose pointer. A drop of insulin will appear at the needle tip.

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

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

⚠ **Always make sure that a drop appears** at the needle tip before you inject. This makes sure that the insulin flows. If no drop appears, you will **not** inject any insulin, even though the dose counter may move. This may indicate a blocked or damaged needle.

⚠ **Always check the flow before you inject.** If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.

Selecting your dose

Use the dose selector on your NovoRapid® FlexTouch® pen to select your dose. You can select up to 80 units per dose.

I. Select the dose you need. You can turn the dose selector forwards or backwards. Stop when the right number of units lines up with the dose pointer.

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

When the pen contains less than 80 units, the dose counter stops at the number of units left.

Always use the dose counter and the dose pointer to see how many units you have selected before injecting the insulin.

Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low.

Do not use the insulin scale, it only shows approximately how much insulin is left in your pen.

How much insulin is left?

The **insulin scale** shows you **approximately** how much insulin is left in your pen.

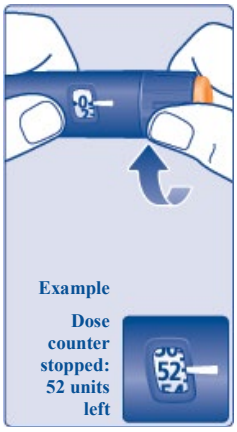
To see precisely how much insulin is left, use the dose counter:

Turn the dose selector until the **dose counter stops**. If it shows 80, **at least 80** units are left in your pen.

If it shows **less than 80**, the number shown is the number of units left in your pen.

Turn the dose selector back until the dose counter shows 0.

If you need more insulin than the units left in your pen, you can split your dose between two pens.



⚠ **Be very careful to calculate correctly if splitting your dose.**

If in doubt, take the full dose with a new pen. If you split the dose wrong, you will inject too little or too much insulin, which can lead to too high or too low blood sugar level.

Injecting your dose

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

J. Insert the needle into your skin as your doctor or nurse has shown you. Make sure you can see the dose counter. Do not touch the dose counter with your fingers. This could interrupt the injection.

Press the dose button until the dose counter returns to 0. The 0 must line up with the dose pointer. You may then hear or feel a click.

After the dose counter has returned to 0, leave the needle under the skin for **at least 6 seconds** to make sure that you get your full dose.

K. Remove the needle from the skin.

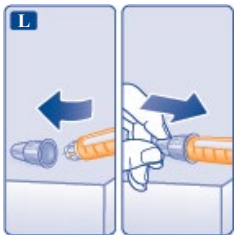
After that, you may see a drop of insulin at the needle tip. This is normal and has no effect on the dose you just received.

Always dispose of the needle after each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing. If the needle is blocked, you will **not** inject any insulin.

L. Lead the needle tip into the outer needle cap on a flat surface. Do not touch the needle or the cap.

Once the needle is covered, carefully push the outer needle cap completely on and then unscrew the needle. Dispose of it carefully, and put the pen cap back on after every use.

When the pen is empty, throw it away without a needle on as instructed by your doctor, nurse or local authorities.



- **Always watch the dose counter to know how many units you inject.**

  The dose counter will show the exact number of units. Do not count the pen clicks.

  Hold the dose button down until the dose counter returns to 0 after the injection. If the dose counter stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.

- **Never try to put the inner needle cap back on the needle.** You may stick yourself with the needle.

- **Always remove the needle after each injection** and store your pen without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Caring for your pen

Treat your pen with care. Rough handling or misuse may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

- **Do not leave the pen in a car** or other place where it can get too hot or too cold.
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** If necessary, clean it with mild detergent on a moistened cloth.
- **Do not drop your pen** or knock it against hard surfaces.

  If you drop it or suspect a problem, attach a new needle and check the insulin flow before you inject.
- **Do not try to refill your pen.** Once empty, it must be disposed of.
- **Do not try to repair your pen** or pull it apart.

⚠ Important information

- **Always keep your pen with you.**
- **Always carry an extra pen and new needles** with you, in case of loss or damage.
- Always keep your pen and needles **out of sight and reach of others**, especially children.
- **Never share** your pen or your needles with other people. It might lead to cross- infection.
- **Never share** your pen with other people. Your medicine might be harmful to their health.
- Caregivers must **be very careful when handling used needles** – to reduce the risk of needle injury and cross-infection.