READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

NovoRapid®
FlexTouch®/Penfill®/vial
Insulin Aspart
Solution for Injection

Read this carefully before you start taking NovoRapid® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about NovoRapid®.

Contact your doctor, Diabetes Nurse Educator or pharmacist if you have any questions about this drug.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist. If you have trouble reading this, ask a family member or a friend for help.

What is NovoRapid® used for?
• The treatment of patients with diabetes mellitus who require insulin for the control of hyperglycemia.

How does NovoRapid® work?
NovoRapid® is an insulin analogue used to treat diabetes. NovoRapid® will start to lower your blood sugar 10-20 minutes after you take it, it has a maximum effect between 1 and 3 hours and the effects last for 3-5 hours. Due to this short action NovoRapid® should normally be taken in combination with intermediate-acting or long-acting insulin preparations.

What are the ingredients in NovoRapid®?
Medicinal ingredients: The active ingredient in NovoRapid® is insulin aspart.
Non-medicinal ingredients: Glycerol; phenol; metacresol; zinc chloride; sodium chloride; disodium phosphate dihydrate; sodium hydroxide; hydrochloric acid and water for injection

NovoRapid® comes in the following doses
NovoRapid® is available from Novo Nordisk Canada in the following format:
  • NovoRapid® 10 mL vial
  • NovoRapid® FlexTouch® 3 mL prefilled pen
  • NovoRapid® Penfill® 3 mL cartridge
    (designed for use with Novo Nordisk Insulin Delivery Devices)

NovoRapid® Penfill® in use with Novo Nordisk Insulin Delivery Systems and NovoRapid® FlexTouch® is designed for use with NovoFine®, NovoFine® Plus and/or NovoTwist® needles. Novo Nordisk cannot be held responsible for malfunctions occurring as a consequence of using NovoRapid® with products that do not meet the same specifications or quality standards as NovoFine®, NovoFine® Plus and/or NovoTwist® needles.

Do not use NovoRapid® if:
  • You feel a hypoglycemic reaction (low blood sugar) coming on. (see “What are possible side effects from NovoRapid®?” for more about hypoglycemia).
  • You are allergic (hypersensitive) to insulin aspart, metacresol or any of the other ingredients in this insulin. Look out for the signs of an allergic reaction. (see “What are possible side effects from NovoRapid®?”)
  • The Penfill® or Novo Nordisk Insulin Delivery Device containing the cartridge/FlexTouch® is dropped, damaged or crushed; there is a risk of leakage of insulin.
  • The protective cap is loose or missing. Each vial has a protective, tamper proof plastic cap. If the cap is not in perfect condition when you get the vial, return the vial to your supplier.
  • The insulin has not been stored correctly or if it has been frozen. (see “How to store NovoRapid®”) The insulin does not appear water-clear and colourless.

Do not refill a NovoRapid® Penfill® cartridge.

NovoRapid® Penfill® cartridges are designed to be used with Novo Nordisk Insulin Delivery Devices, NovoFine®, NovoFine® Plus and NovoTwist® needles as part of The All In-One System®.

If you are treated with NovoRapid® Penfill® and another insulin in Penfill® cartridge, you should use two Novo Nordisk Insulin Delivery Devices, one for each type of insulin.

NovoRapid® FlexTouch® is designed to be used with, NovoFine®, NovoFine® Plus and NovoTwist® needles as part of The All In-One System®.

As a precautionary measure, you should carry a spare syringe and extra insulin in case the insulin delivery device is lost or damaged.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NovoRapid®. Talk about any health conditions or problems you may have, including if you:
  • Have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands, your doctor may decide to alter your insulin dose.
  • Drink alcohol (including wine and beer) your need for insulin may change as your blood sugar level may either rise or fall.
  • Have an infection, fever or have had an operation you may need more insulin than usual.
  • Suffer from diarrhea, vomiting or eat less than usual you may need less insulin than usual.
  • Exercise more than usual or if you want to change your usual diet.
  • Are ill: continue taking your insulin. Your need for insulin may change.
  • Go abroad: travelling over time zones may affect your insulin needs and the timing of your
injections. Consult your doctor if you are planning such travel.

- Are pregnant, or planning a pregnancy or are breastfeeding please contact your doctor for advice.
- Drive or use tools or machines: watch for signs of a hypoglycemia. Your ability to concentrate or
to react will be less during a hypoglycemic reaction. Please keep this in mind in all situations
where you might put yourself and others at risk (e.g. driving a car or operating machinery). Never
drive or use machinery if you feel a hypoglycemic reaction coming on.

Discuss with your doctor whether you should drive or use machines at all, if you have a lot of
hypoglycemic reactions or if you find it hard to recognize hypoglycemia.

Before you travel, check with your doctor or pharmacist on the availability of NovoRapid® in other
countries. If possible, bring enough NovoRapid® with you on your trip.

Thiazolidinediones (class of oral antidiabetic drugs) used together with insulin may increase risk of
oedema and heart failure. Inform your doctor as soon as possible if you experience localised swelling
(oedema) or signs of heart failure such as unusual shortness of breath.

Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you
are on potassium lowering drugs or losing potassium (e.g. diarrhea).

NovoRapid® has a rapid onset of effect therefore if hypoglycemia occurs, you may experience it earlier
after an injection when compared to soluble human insulin.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins,
minerals, natural supplements or alternative medicines.

The following may interact with NovoRapid®:
Some medicines affect the way glucose works in your body and this may influence your insulin dose.
Listed below are the most common medicines, which may affect your insulin treatment. Tell your doctor,
Diabetes Nurse Educator or pharmacist if you are taking or have recently taken any other medicines,
including medicines obtained without a prescription. In particular, you should tell your doctor if you are
using any medicine as mentioned below that affects your blood sugar level.

If you take any of the medicines below, your blood sugar level may fall (hypoglycemia)
- Other medicines for the treatment of diabetes
- Monoamine oxidase inhibitors (MAOI) (used to treat depression)
- Beta-blockers (used to treat high blood pressure)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high
blood pressure)
- Salicylates (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 (hyperglycemia)
- 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 epinephrine [adrenaline], or salbutamol, terbutaline used to treat
asthma)
• Growth hormone (medicine for stimulation of skeletal and somatic growth and pronounced influence on the body’s metabolic processes)
• Danazol (medicine acting on ovulation)

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 a hypoglycemia.

**How to take NovoRapid®?**

NovoRapid® is for injection under the skin (subcutaneously).

NovoRapid® 10 mL vial is also for continuous infusion in a pump system. NovoRapid® may also be given intravenously by healthcare professionals under close supervision by a doctor.

Always vary the site you inject within the same region, to avoid lumps (see ‘What are possible side effects from using NovoRapid®?’). The best places to give yourself an injection are: the front of your thighs; the front of your waist (abdomen); or the upper arm. Your insulin will work more quickly if you inject around the waist.

You should always measure your blood glucose regularly.

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Do not change your insulin unless your doctor tells you to. Follow their advice carefully. This leaflet is a general guide only.

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.

Due to the faster onset of action, NovoRapid® should be given close to a meal (start of the meal should be no more than 5-10 minutes after the injection). When necessary, NovoRapid® can be given soon after a meal, instead of before the meal.

**Before using NovoRapid®**

• Check the label to make sure you have the right type of insulin.
• Remove the protective cap [vial].
• Always check the Penfill® cartridge, including the rubber stopper (plunger). Don’t use it if any damage is seen or if there is a gap between the rubber stopper and the white barcode label. Take it back to your supplier or call Novo Nordisk Canada at 1-800-465-4334 for assistance. See your Novo Nordisk Insulin Delivery Device manual for further instructions.
• Always use a new needle for each injection to prevent contamination [Penfill® / FlexTouch®].
• Do not share your NovoRapid® FlexTouch® /Penfill® in a Novo Nordisk Insulin Delivery Device with another person, even if the needle is changed. Do not reuse or share needles with another person including family members. You may give another person an infection or get an infection from them.

**If you use only one type of insulin [vial]**

• 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.

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 [vial]

- Just before use, roll the long-acting (cloudy) insulin between your hands until the liquid is uniformly white and cloudy.
- 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.
- 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.
- 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.
- Always mix NovoRapid® and long-acting insulin in the same order.

How to inject this insulin [vial]

- Pinch your skin between two fingers, push the needle into the skin fold and inject the insulin under the skin.

Keep the needle under your skin for at least 6 seconds to make sure you have injected all the insulin.

For use in an infusion pump system [vial]:

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 using NovoRapid® in a pump system you must receive comprehensive instructions in its 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 wash your hands and the skin around the area where the needle is inserted so as 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 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 a possible malfunction of the insulin pump, you should 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.

How to inject this insulin [Penfill®]

- Inject the insulin under the skin. Use the injection technique advised by your doctor or Diabetes Nurse Educator and described in your Novo Nordisk Insulin Delivery Device Manual.
- Keep the needle under your skin for at least six 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 discard the needle. Otherwise, the liquid may leak out when the temperature changes.

How to inject this insulin

Please read these instructions carefully before using your NovoRapid® FlexTouch® pen. Use the
coloured label to make sure that your FlexTouch® pen contains the type of insulin you need.

Your NovoRapid® FlexTouch® pen is an easy-to-use prefilled insulin pen with a light-touch dose button. NovoRapid® FlexTouch® contains 300 units of insulin and delivers doses from 1-80 units, in increments of 1 unit. NovoRapid® FlexTouch® is designed to be used with NovoFine®, NovoFine® Plus and/or NovoTwist® disposable needles up to a length of 8 mm.
Do not share your NovoRapid® FlexTouch® with another person, even if the needle is changed. You may give another person an infection, or get an infection from them.
A Pull off the pen cap.

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

C Screw the needle straight onto the pen. Make sure the needle is on tight.
D Pull off the outer needle cap and save it.
You will need it after the injection, to safely 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 hurt 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 to help ensure sterility and prevent blocked needles. Do not reuse or share needles with another person including family members.

Never bend or damage the 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.

E Turn the dose selector to select 2 units.
**F** Hold the pen with the needle pointing up. Tap the top of the pen a few times to let any air bubbles rise to the top.

**G** Press the dose button with your thumb until the display returns to zero. The figure 0 lines up with the pointer. A drop of insulin will appear at the needle tip.

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

Do not use the pen if a drop of insulin still does not appear.
Always make sure that a drop appears at the needle tip before you inject.

**Selecting your dose**

Use the dose selector on your NovoRapid® FlexTouch® pen to ensure exact and easy dose selection. You can select up to 80 units per dose.

H 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 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 display stops at the number of units left.

**How much insulin is left?**
You can use the insulin scale to see approximately how much insulin is left in the pen. You can use the display to see exactly how much insulin is left – if the pen contains less than 80 units: Turn the dose selector until the display stops. The figure that lines up with the pointer shows how many units are left.

Never use the pen clicks to count the number of units you select. Only the display and pointer will indicate the exact number of units.

Never use the insulin scale to measure how much insulin to inject. Only the display and pointer will indicate the exact number of units.

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

Insert the needle into your skin as your doctor or Diabetes Nurse Educator has shown you. Make sure you can see the display. Press the dose button until the display returns to zero. The figure 0 lines up with the pointer and you may hear or feel a click.

After the display has returned to zero, leave the needle under the skin for at least six seconds to make sure that you get your full dose.

![Image of needle insertion](image)

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 remove and dispose of the needle after each injection to prevent blocked needles. If the needle is blocked, you will **not** receive your full dose.

**K** 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, Diabetes Nurse Educator or local authorities.

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

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

Never put the inner needle cap back on once you have removed it from the needle. This reduces the risk of hurting yourself with the needle.

Always store the pen without a needle attached. This prevents contamination, infection and leakage of insulin and ensures accurate dosing.
Caring for your NovoRapid® FlexTouch® pen
Your NovoRapid® FlexTouch® pen is accurate and safe to use. However, you must take care of it:

- Do not drop your pen or knock it against hard surfaces. If you do drop it or suspect that something is wrong with it, always screw on a new disposable needle and check the insulin flow before you inject.
- Do not try to refill your pen – it is prefilled.
- Do not try to repair your pen or pull it apart.
- Do not expose your pen to dust, dirt or any kind of liquid.
- Do not try to wash, soak or lubricate your pen. If necessary, clean it with a mild detergent on a moistened cloth.
- Always carry an extra NovoRapid® FlexTouch® in case you lose or damage your current pen. Also carry new disposable needles.
- Always keep your pen and needles out of reach of others, especially children.
- Needles and NovoRapid® FlexTouch® must not be shared. Caregivers should be most careful when handling used needles to avoid hurting themselves.
Overdose

Causes of a hypoglycemia:
You get a hypoglycemia if your blood sugar gets too low. This might happen:

- If you take too much insulin.
- If you eat too little or miss a meal.
- If you exercise more than usual.

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

If you get any of these signs: eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest. Don't take any insulin if you feel a hypoglycemia coming on. Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must turn you on your side and get medical help right away. They must not give you anything to eat or drink as it could choke you.

- If severe hypoglycemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a hypoglycemia that makes you pass out, or if you get a lot of hypoglycemias, talk to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

Using glucagon
You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon you will need to eat 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 hospital emergency after an injection of glucagon: you need to find the reason for your hypoglycemia in order to avoid getting more.

Causes of a hyperglycemia:
You get a hyperglycemia if your blood sugar gets too high. This might happen:

- If you forget to take insulin.
- If you repeatedly take less insulin than you need.
- 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; a dry mouth and a fruity (acetone) smelling breath.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

If you think you have taken too much NovoRapid®, contact your healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.
If you get any of these signs: test your blood sugar level; test your urine for ketones if you can; then seek medical advice right away.

**What are possible side effects from using NovoRapid®?**

Like all medicines, NovoRapid® can cause side effects, although not everybody gets them. The most common side effect is low blood sugar (hypoglycemia). See the advice in ‘How to take NovoRapid®?’.

**Less commonly reported side effects** (1 to 10 users in 1000)

**Signs of allergy**

Hives and rash may occur.

**Seek medical advice immediately**

- If the above signs of allergy appear or
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty breathing; have a rapid heart beat; feel dizzy.

You may have a very rare serious allergic reaction to NovoRapid® or one of its ingredients (called a generalized allergic reaction). See also the warning in ‘Do not use NovoRapid® if’.

**Vision problems**

When you first start your insulin treatment it may disturb your vision, but the disturbance is usually temporary.

**Changes at the injection site** (lipodystrophy)

If you inject yourself too often at the same site, fatty tissue under the skin at this injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Changing the site with each injection may help to prevent such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or Diabetes Nurse Educator because these reactions can become more severe, or they may change the absorption of your insulin at this site.

**Swollen joints**

When you start taking insulin, water retention may cause swelling around your ankles and other joints. This soon disappears.

**Diabetic retinopathy** (eye background changes)

If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

**Rarely reported side effects** (less than 1 user in 10,000)

**Painful neuropathy** (nerve related pain)

If your blood glucose levels improve very fast you may get nerve related pain. This is called acute painful neuropathy and is usually transient.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist.
How to store NovoRapid®?

Keep out of the reach and sight of children.

NovoRapid® [vial] that is not being used is to be stored in the refrigerator between 2°C-10°C, in the original package, not in or too near the freezer section or cooling element. Do not freeze.

Always keep the vial in the outer carton when you're not using it in order to protect it from light.

NovoRapid® [Penfill®/FlexTouch®] that is not being used is to be stored in the refrigerator between 2°C to 10°C, not in or too near the freezer section or cooling element. Do not freeze.

NovoRapid® [vial/Penfill®/FlexTouch®] that is being used or is about to be used is not to be kept in the refrigerator. You can carry it with you and keep it at room temperature (not above 30°C) for up to 4 weeks.

Always keep the Penfill® cartridge in the outer carton when not using it, in order to protect it from light.

Always keep the pen cap on your FlexTouch® when you are not using it, in order to protect it from light.

NovoRapid® should be protected from excessive heat and sunlight.

Do not use NovoRapid® after the expiry date printed on the label and carton.

NovoRapid® should not be disposed of in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

What NovoRapid® looks like and package content

NovoRapid® comes as a water-clear, colourless, aqueous solution in packages of one 10 mL vial per carton.
NovoRapid® Penfill® comes as a water-clear, colourless, aqueous solution in packages of 5 cartridges of 3 mL per carton.

NovoRapid® FlexTouch® comes as a water-clear, colourless, aqueous solution in packages of 1 or 5 prefilled pens of 3 mL per carton.

1 mL contains 100 U (units) of insulin aspart.
1 vial contains 10 mL of insulin aspart equivalent to 1000 U.
1 Penfill® cartridge contains 3 mL of insulin aspart equivalent to 300 U.
1 prefilled pen contains 3 mL insulin aspart equivalent to 300 U.

If you want more information about NovoRapid®:
This document plus the full Product Monograph, prepared for healthcare professionals can be obtained by contacting the sponsor, Novo Nordisk Canada, at 1-800-465-4334.

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Novo Nordisk A/S

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