NovoRapid® FlexPen®

Consumer Medication Information Leaflet (RiMUP)

100 U/ml
Solution for injection in pre-filled pen
Insulin aspart

What is in this leaflet

1. What NovoRapid® is used for
2. How NovoRapid® works
3. Before you use NovoRapid®
4. How to use NovoRapid®
5. While you are using it
6. Side effects
7. Storage and Disposal of NovoRapid®
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of revision

1. What NovoRapid® is used for

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

2. How NovoRapid® works

NovoRapid® is a rapid-acting modern insulin (insulin analogue). Modern insulin products are improved versions of human insulin. NovoRapid® will start to lower your blood sugar 10–20 minutes after you take it, a maximum effect occurs between 1 and 3 hours and the effect lasts for 3–5 hours. Due to this short action, NovoRapid® should normally be used in combination with intermediate-acting or long-acting insulin preparations. Moreover NovoRapid® can be used for continuous infusion in a pump system.

3. Before you use NovoRapid®

- When you must not use it

►**If you are allergic (hypersensitive)** to insulin aspart or any of the other ingredients in NovoRapid® (see section 8. *Product Description*).
►**If you suspect hypoglycaemia (low blood sugar)** is starting (see section 4. *How to use NovoRapid®*).
►**If FlexPen® is dropped, damaged or crushed.**
►**If it has not been stored correctly** or if it has been frozen (see section 7. *Storage and Disposal of NovoRapid®*).
►**If the insulin does not appear clear and colourless.**

- Before you start to use it

►**Check the label to make sure** it is the right type of insulin.
►**Always use a new needle** for each injection to prevent contamination.
►**Needles and NovoRapid® FlexPen® must not be shared.**

- Taking other medicines

Some medicines affect the way glucose works in your body and this may influence your insulin dose. The most common medicines which may affect your insulin treatment are listed below. Tell your doctor, nurse or pharmacist if you take or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you use any medicine listed below that may affect your blood sugar level.

If you take any of the following medicines, your blood sugar level may fall (hypoglycaemia):
Oral antidiabetic medicinal products, monoamine oxidase inhibitors (MAOI), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.

If you take any of the following medicines, your blood sugar level may rise (hyperglycaemia):
Oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone and danazol.

Octreotide and lanreotide may either increase or decrease your blood sugar level.

Beta-blockers may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycaemia.

Thiazolidinediones (class of oral antidiabetic medicines used for 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 thiazolidinediones 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).

4. How to use NovoRapid®

- How much to use

Talk about your insulin dose with your doctor and nurse. Make sure you use your colour-coded NovoRapid® FlexPen® as your doctor and nurse 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.

Use in children
NovoRapid® can be used in children 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.

- When to use it

NovoRapid® is generally given immediately before a meal. When necessary, NovoRapid® can be given soon after a meal.

- How to use it

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 healthcare professional. NovoRapid® may also be given directly into a vein (intravenously) by physicians or other healthcare staff if applicable. Never inject your insulin directly into a muscle (intramuscularly).

Always vary the sites you inject within the same region to reduce the risk of developing lumps or skin pitting (see section 6. *Side effects*). 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 you inject into the waist (abdomen). You should measure your blood sugar regularly.

How to handle NovoRapid® FlexPen®

Read the included 'Instructions on how to use NovoRapid® solution for injection in FlexPen®' carefully. You must use the pen as described in the instructions on how to use NovoRapid®.

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.

- How long to use it

Continue taking NovoRapid® for as long as your doctor recommends.
Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycemia and diabetic ketoacidosis.

- If you forget to use it

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

Hyperglycaemia may also happen:
- 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 the signs mentioned above, test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.

- If you stop taking it

This could lead to severe hyperglycaemia and ketoacidosis. Do not stop taking your insulin without speaking to a doctor, who will tell you what needs to be done.

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

- If you use too much (overdose)

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

Hypoglycaemia may also happen:
- If you eat too little or miss a meal.
- If you exercise more than usual.

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 a hypoglycaemic episode is 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 hypoglycaemia have disappeared or when your blood sugar level is stabilised, continue insulin treatment.

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 hypoglycaemia to avoid getting more.

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

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

5. While you are using it

- Things you must do

Eat a meal or snack containing carbohydrates within 10 minutes of the injection to avoid hypoglycaemia.

- Things you must not do

Do not take any insulin if you feel a hypoglycaemic episode is coming on.

Always carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

Tell relevant people you have diabetes and what the consequences may be, including the risk of passing out (becoming 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.

- Things to be careful of

- ►**If you have trouble** with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- ►**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.
- ►**If you drink alcohol,** your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

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 hypoglycaemia.
- ►If you find it hard to recognize hypoglycaemia.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant, planning a pregnancy or breast-feeding, please contact your doctor for advice. NovoRapid® can be used during pregnancy and breast-feeding. Your insulin dosage may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of hypoglycaemia, is important for the health of your baby.

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 4. *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.

6. Side effects

Like all medicines, NovoRapid® can cause side effects, although not everybody gets them.

Side effects may occur with certain frequencies, which are defined as follows:
- Very common: affects more than 1 user in 10
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000
- Very rare: affects less than 1 user in 10,000

Very common side effects
Low blood sugar (hypoglycaemia). See the advice in 'If you use too much (overdose)' under section 4. *How to use NovoRapid®.*

Uncommon side effects
Vision problems. When you first start your insulin treatment, it may disturb your vision, but the disturbance is usually temporary.

Skin changes at the injection site. If you inject insulin at the same place, the fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy) (affects 1 to 10 users in 1,000). 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. Change the injection site with each injection to help prevent these skin changes.

Signs of allergy. Reactions (pain, redness, hives, inflammation, swelling and itching) at the injection site may occur (local allergic reactions). These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor.

Seek medical advice immediately:
- ►If signs of allergy spread to other parts of your body
- ►If you suddenly feel unwell, and you start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy.

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

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.

Very rare side effects
Serious allergic reaction to NovoRapid® or one of its ingredients (called as systemic allergic reaction). See also the warning in section 3. *Before you use NovoRapid®.*

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal of NovoRapid®

- Storage

Keep out of the sight and reach of children.

Do not use NovoRapid® after the expiry date which is stated on the FlexPen® label and carton after 'Expiry'. The expiry date refers to the last day of that month.

NovoRapid® FlexPen® that is not being used is to be stored in the refrigerator at 2°C – 8°C, away from the cooling element. Do not freeze.

NovoRapid® FlexPen® that is being used or carried as a spare: You can carry your NovoRapid® FlexPen® with you and keep it at a temperature below 30°C or in a refrigerator (2°C – 8°C) for up to 4 weeks. If refrigerated, keep away from the cooling element. Do not freeze.

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

NovoRapid® must be protected from excessive heat and light.

- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

NovoRapid® comes as a clear and, colourless, solution.

Pack sizes of 1, 5 and 10 pre-filled pens of 3 ml. Not all packs may be marketed.

- Ingredients

-Active ingredient
Insulin aspart. 1 ml contains 100 U of insulin aspart. Each cartridge contains 300 U insulin aspart in 3 ml solution for injection.

-Inactive ingredients
Glycerol, phenol, metacresol, zinc chloride, disodium phosphate dihydrate, sodium chloride, hydrochloric acid/sodium hydroxide (for pH adjustment) and water for injections.

- MAL numbers

MAL20034597AZ
MAL13115137ASZ
MALXXXXXXXXASZ

9. Manufacturers

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

Novo Nordisk Produção Farmacêutica do Brasil Ltda
Avenida C, 1413, Distrito Industrial
Montes Claros - Minas Gerais
Brazil 39404-004

Novo Nordisk Production SAS
45 Avenue d'Orléans, F-28000
Chartres, France

10. Product Registration Holder

Novo Nordisk Pharma (Malaysia) Sdn. Bhd.
Menara 1 Sentrum, Level 16
No. 201 Jalan Tun Sambanthan
50470 Kuala Lumpur
Malaysia.

11. Date of revision

31/03/2021

Serial Number

NPRA (R3) 20/007

NovoRapid® FlexPen®

100 U/ml
Solution for injection in pre-filled pen
Insulin aspart

Instructions on how to use NovoRapid® solution for injection in FlexPen®.

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.

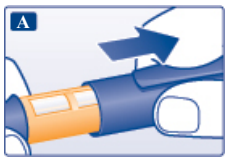
You can clean the exterior of your FlexPen® by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Do not refill your FlexPen®.

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®.

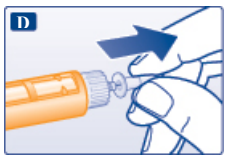


C
Pull off the big outer needle cap and keep it for later.



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.



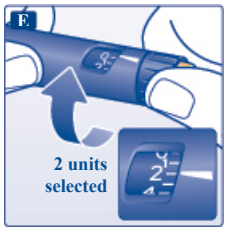
⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

⚠ 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.

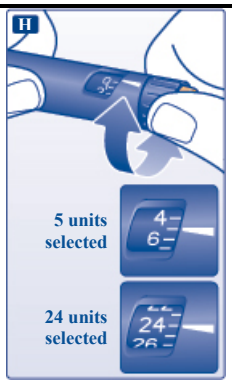
Selecting your dose

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.

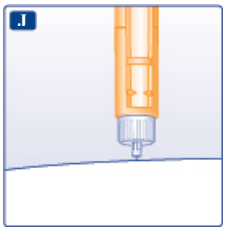
Turning the dose selector will not inject insulin.



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.

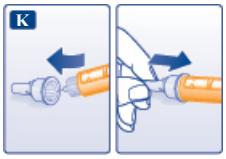
Withdraw the needle from the skin, then release the pressure on the push-button.

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.