**Insulin aspart NovoRapid 100 units/mL solution for injection in a vial**

Insulin aspart

**What is NovoRapid and what is it used for?**NovoRapid is a modern insulin (insulin analogue) with a rapid-acting effect. Modern insulin products are improved versions of human insulin.

NovoRapid is used to lower high blood sugar levels in adults, adolescents, and children aged 1 year and older with diabetes mellitus (diabetes). Diabetes is a condition in which your body does not produce enough insulin to control your blood sugar. Treatment with NovoRapid helps prevent complications from diabetes.

NovoRapid begins to lower your blood sugar 10-20 minutes after injection. The maximum effect occurs 1-3 hours after injection, and the effect lasts for 3-5 hours. Due to its short duration of action, NovoRapid is usually administered in combination with medium- or long-acting insulin preparations. Additionally, NovoRapid can be used for continuous infusion with an insulin pump system.

**When should you not use this medication or be extra cautious?**

**When should you not use this medication?**

* If you are allergic to any of the substances in this medication. You can find these substances in Section 6 (Contents of the package and other information).
* If you suspect the onset of hypoglycemia (low blood sugar) (see 'a) Overview of serious and very common side effects' in Section 4).
* If the protective cap is loose or missing. Each vial has an abuse-resistant plastic protective cap. If it is not completely intact when you receive the vial, you should return it to your supplier.
* If the vial has not been stored correctly or has been frozen (see Section 5, 'How should you store this medication?').
* If the insulin is not clear and colorless.

if any of the above points apply to you, do not use NovoRapid. Contact your doctor, nurse, or pharmacist for advice.

Before using NovoRapid:

* Check the label to ensure that you have the correct type of insulin.
* Remove the protective cap.
* Always use a new needle for each injection to prevent contamination.
* Needles and syringes should not be shared with others.

**When should you be extra cautious with this medication?**

Certain conditions and activities can affect your insulin requirements. Contact your doctor if:

* You have kidney or liver problems or issues with your adrenal glands, pituitary gland, or thyroid.
* You engage in physical activity more than usual or if you want to change your usual diet, as this can affect your blood sugar levels.
* You are ill; continue using the insulin and consult your doctor.
* You are traveling abroad; due to time differences between countries, it may be necessary to adjust the amount of insulin you use and the timing of your injections.

**Children and adolescents up to 18 years:** Do not use this medication in children under 1 year of age, as no clinical studies have been conducted in this age group.

**Are you taking any other medications?**If you are taking other medications in addition to NovoRapid, have taken them recently, or may take other medications in the near future, please inform your doctor, nurse, or pharmacist.

Some medications can affect your blood sugar levels, which may require adjustments to your insulin dose. The most common medications that may affect your insulin treatment are listed below.

Your blood sugar levels may decrease (hypoglycemia) when using:

* Other medications for the treatment of diabetes
* Monoamine oxidase inhibitors (MAO inhibitors) (for the treatment of depression)
* Beta-blockers (for the treatment of high blood pressure)
* Angiotensin-converting enzyme (ACE) inhibitors (for the treatment of certain heart conditions or high blood pressure)
* Salicylates (for pain relief and reducing fever)
* Anabolic steroids (such as testosterone)
* Sulfonamides (for the treatment of infections).

Your blood sugar levels may increase (hyperglycemia) when using:

* Oral contraceptives (the 'pill' for contraception)
* Thiazides (for the treatment of high blood pressure or excessive fluid retention)
* • Glucocorticoids (such as cortisone, for the treatment of inflammation)
* Thyroid hormones (for the treatment of thyroid disorders)
* Sympathomimetics (such as epinephrine [adrenaline] or salbutamol, terbutaline for the treatment of asthma)
* Growth hormone (medication for stimulating skeletal and body growth with a pronounced effect on metabolic processes in the body)
* Danazol (medication that affects ovulation).

Octreotide and lanreotide (used to treat acromegaly, a rare hormonal disorder that typically occurs in middle-aged adults and is caused by the pituitary gland producing too much growth hormone) can increase or decrease your blood sugar levels.

Beta-blockers (used to treat high blood pressure) can weaken or completely suppress the early warning signs that help you recognize low blood sugar.

Pioglitazone (tablets used to treat type 2 diabetes)

Some patients with long-standing type 2 diabetes and a history of heart disease or stroke who were treated with pioglitazone and insulin developed heart failure. Inform your doctor immediately if you experience symptoms of heart failure such as unusual shortness of breath or rapid weight gain or local swelling (edema).

If you have taken any of the medications listed here, please inform your doctor, nurse, or pharmacist.

**What to consider with alcohol?**

Drinking alcohol can change your insulin requirements because it can cause your blood sugar levels to rise or fall. Careful monitoring is recommended.

**Pregnancy and breastfeeding**Are you pregnant, think you might be pregnant, or planning to become pregnant? Please consult your doctor before using this medication. NovoRapid can be used during pregnancy. Your insulin dose may need to be adjusted during pregnancy and after childbirth. Careful control of your diabetes, particularly the prevention of hypoglycemia, is important for the health of your baby.

There are no restrictions on using NovoRapid while breastfeeding.

Consult your doctor, nurse, or pharmacist for advice before using this medication if you are pregnant or breastfeeding.

**Driving and using machinery**

* Discuss with your doctor whether you are allowed to drive a vehicle or operate machinery:
* If you frequently experience hypoglycemia.
* If you have difficulty recognizing hypoglycemia.

Low or high blood sugar can affect your concentration and reaction abilities, as well as your ability to drive a vehicle or operate machinery. Remember that you may put yourself or others at risk.

Due to the rapid effect of NovoRapid, hypoglycemia may occur earlier after an injection compared to soluble human insulin.

Important information about some of the ingredients in NovoRapid

NovoRapid contains less than 1 mmol of sodium (23 mg) per dose and is considered virtually "sodium-free."

**How to use this medication?**Dose and when to administer your insulin

Always use your insulin and adjust your dose exactly as instructed by your doctor. If you are unsure about the correct usage, please contact your doctor, nurse, or pharmacist.

NovoRapid is generally administered immediately before a meal. Consume a meal or snack within 10 minutes after administration to prevent low blood sugar. If necessary, NovoRapid can be administered shortly after the meal. See 'How and where to inject' below for information.

Do not change your insulin unless instructed to do so by your doctor. If your doctor has switched you from another type or brand of insulin, your dose may need to be adjusted by your doctor.

**Use in children and adolescents up to 18 years:** NovoRapid can be used in young people and children from 1 year of age instead of soluble human insulin when a rapid effect is preferred, for example, when dosing is challenging in relation to meals.

**Use in special patient groups:** If you have reduced kidney or liver function or if you are older than 65 years, you should monitor your blood sugar more frequently and discuss any changes in your insulin dose with your doctor.

**How and where to inject:** NovoRapid should be injected subcutaneously (under the skin) or can be administered via continuous infusion using an insulin pump system. Administration with an insulin pump system requires detailed instruction by medical personnel. Never inject directly into a vein (intravenously) or muscle (intramuscularly). If necessary, NovoRapid can be administered directly into a vein, but this should only be done by doctors or other medical personnel.

Change the injection site within the specific area of skin you are using for each injection. This can reduce the risk of developing lumps or indentations in the skin (see Section 4, 'Possible side effects'). The best places to inject yourself are the front of the abdomen, the upper arm, or the front of your thighs. Insulin works faster when injected into the abdomen. Always monitor your blood sugar regularly.

**How to use this medication:**

**When using only one type of insulin:**

1. Draw air into a syringe, the same amount as the prescribed insulin dose. Inject the air into the vial.
2. Turn the vial with the syringe upside down and draw the appropriate amount of insulin into the syringe. Remove the needle from the vial. Expel any air from the syringe and check the dosage.
3. When mixing two types of insulin:
4. Just before use, roll the vial containing the long-acting (milky) insulin between your hands until the liquid appears uniformly white and cloudy.
5. Draw into a syringe the same amount of air as the prescribed dose of long-acting insulin. Inject the air into the vial containing the long-acting insulin and remove the needle from the vial.
6. Draw into a syringe the same amount of air as the prescribed dose of NovoRapid.
7. Inject the air into the vial containing NovoRapid.
8. Turn the vial with the syringe upside down and draw the prescribed amount of NovoRapid into the syringe.
9. Expel any air from the syringe and check the dosage. Remove air from the syringe and check if the dose is correct.
10. Insert the needle into the vial containing the long-acting insulin.
11. Turn the vial with the syringe upside down and draw the prescribed amount of long-acting insulin into the syringe.
12. Expel any air from the syringe and check the dosage. Inject the mixture immediately.

NovoRapid and long-acting insulin should always be mixed in the same order.

**How to inject NovoRapid:**

* Inject the insulin under the skin. Inject in the manner recommended by your doctor or nurse.
* Keep the needle under the skin for at least 6 seconds to ensure the full dose is injected.
* Discard the needle after each injection.

**For use in an insulin pump system:**

If NovoRapid is used in a pump, it should never be mixed with any other insulin. Follow your doctor's instructions and recommendations regarding the use of NovoRapid in a pump.

1. Before using NovoRapid in a pump, you must receive comprehensive instructions on pump usage. You should also receive information on what to do in case of illness, high or low blood sugar, or if the pump is not working properly.
2. Before inserting the needle, wash your hands and the insertion site with water and soap to prevent infection at the infusion site.
3. When filling a new reservoir, ensure that no large air bubbles remain in the syringe or tubing.
4. Infusion set (tubing and needle) changes should be done according to the instructions provided with the infusion set.

To fully benefit from insulin infusion and to detect any malfunction of the pump, it is recommended to regularly monitor your blood sugar levels.

**What to do if the pump system is not working or malfunctioning?**You should always have an alternative method of insulin delivery, such as subcutaneous injection, in case the pump is not functioning properly.

**What to do if you have used too much of this medication?**If you have used too much insulin, your blood sugar will become too low (hypoglycemia). See 'a) Overview of serious and very common side effects' in

**What to do if you forget to use this medication?**If you forget to use your insulin, your blood sugar may become too high (hyperglycemia). Do not stop using your insulin without contacting a doctor who will advise you on what to do. It may lead to very high blood sugar (severe hyperglycemia) and ketoacidosis. See 'c) Consequences of diabetes' in

**Possible side effects**Like all medications, this medication can have side effects, although not everyone gets them.

**a) Overview of serious and very common side effects**

**Low blood sugar (hypoglycemia) is a very common side effect. It can occur in more than 1 in 10 people.**

**Low blood sugar may occur if you:**

* inject too much insulin;
* eat too little or skip a meal;
* engage in more physical activity than usual;
* consume alcohol (see 'What to consider with alcohol?'

Symptoms indicating low blood sugar include cold sweat, cool pale skin, headache, rapid heartbeat, nausea, excessive hunger, temporary visual disturbances, drowsiness, unusual tiredness and weakness, nervousness or tremors, feelings of anxiety, confusion, difficulty concentrating.

Severe low blood sugar can lead to unconsciousness. When a prolonged severe low blood sugar remains untreated, it can result in brain damage (temporary or permanent) or even death. You may regain consciousness faster if someone who knows how to use the hormone glucagon gives you an injection of glucagon. If you receive glucagon, once you regain consciousness, you should eat glucose or a sugary snack. If you do not respond to glucagon treatment, you will need to go to the hospital for treatment.

**What to do if you experience low blood sugar:**

* When your blood sugar is too low, eat glucose tablets or consume another sugary snack (e.g., candies, cookies, fruit juice). If possible, measure your blood sugar and then rest. Always make sure to carry glucose tablets or sugary snacks with you in case you need them.
* Once the symptoms of low blood sugar have disappeared or when your blood sugar has stabilized, continue with your usual insulin treatment.
* Consult a doctor if your blood sugar is so low that you have fainted, if you needed an injection of glucagon, or if you frequently experience low blood sugar. You may need to adjust the amount or timing of your insulin, food, or physical activity.

Inform relevant people in your surroundings that you have diabetes and what the consequences may be, including the risk of fainting (losing consciousness) due to low blood sugar. Inform them that if you faint, they should lay you on your side and immediately seek medical help. They should not give you anything to eat or drink. You could choke.

Serious allergic reactions to NovoRapid or any of the ingredients in the medication (referred to as a 'systemic allergic reaction') are a very rare side effect but can be potentially life-threatening. This side effect can occur in less than 1 in 10,000 people.

**Call for immediate medical help if:**

* allergic reactions spread to other parts of your body;
* you suddenly feel unwell and start sweating, experiencing nausea (vomiting), breathing difficulties, rapid heartbeat, or dizziness.
* If you notice any of these symptoms, seek immediate medical help.

**b) List of other side effects**

**Common side effects**

**May occur in less than 1 in 100 people.**

Symptoms of allergy: localized hypersensitivity reactions (pain, redness, hives, inflammation, bruising, swelling, and itching) may occur at the injection site. They usually disappear after a few weeks of insulin use. If they do not disappear or spread to your body, discuss this immediately with your doctor. See also 'Serious allergic reactions' above.

Vision problems: when starting your insulin treatment, your vision may be affected, but this side effect is usually temporary.

Changes at the injection site (lipodystrophy): the fatty tissue under the skin at the injection site may decrease (lipoatrophy) or thicken (lipohypertrophy). By choosing a different injection site within the same area, the chances of such skin changes decrease. If you develop indentations or thickening of the skin at the injection site, contact your doctor or nurse. These reactions can worsen or alter the absorption of your insulin if you continue injecting in these areas.

Joint swelling: when starting insulin treatment, swelling may occur around the ankles and other joints due to fluid retention in the body. Normally, this symptom disappears quickly. If it does not, discuss it with your doctor.

Diabetic retinopathy (an eye condition related to diabetes that can lead to impaired vision): if you have diabetic retinopathy and your blood sugar level improves very rapidly, the retinopathy may worsen. Discuss it with your doctor.

**Rare side effects**

**May occur in less than 1 in 1,000 people.**

Painful neuropathy (pain caused by nerve damage): when your blood sugar level improves very rapidly, you may experience nerve-related pain, known as acute painful neuropathy, which is usually transient.

**c) Consequences of diabetes**

**High blood sugar (hyperglycemia)**

**High blood sugar can occur if:**

* you have not injected enough insulin;
* forget to inject your insulin or stop using insulin;
* repeatedly use less insulin than you need;
* develop an infection and/or fever;
* eat more than usual;
* engage in less physical activity than usual.

**Warning signs of high blood sugar:**

The warning signs occur gradually and include: increased urination, thirst, loss of appetite, nausea or vomiting, drowsiness or fatigue, dry red skin, dry mouth, and a fruity (acetone) breath odor.

What to do if you experience high blood sugar:

* If you experience any of the above symptoms, you should check your blood sugar level, if possible, check your urine for the presence of ketones, and then seek immediate medical help.
* These symptoms may indicate a very serious condition called 'diabetic ketoacidosis' (an increase in acid in the blood due to the breakdown of fats instead of sugar by the body). If this condition is left untreated, it can lead to diabetic coma and ultimately death.

**How to store this medicine?**

* Keep out of sight and reach of children.
* Do not use this medicine after the expiry date which is stated on the label of the vial and the carton, after EXP. The expiry date refers to the last day of that month.
* Store the vial in the original carton to protect it from light.
* Before opening: store in a refrigerator at 2°C–8°C. Do not freeze.
* During use or when carried as a spare: the medicine can be stored for a maximum of 4 weeks. Store below 30°C. Do not store in the refrigerator or freezer.
* Dispose of the needle after each injection.
* Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines that are no longer needed. They will be disposed of in a responsible manner and will not harm the environment.