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What NovoRapid® is used for

NovoRapid® is an insulin analogue used to treat diabetes. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of your blood sugar.

How NovoRapid® works

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 taken in combination with intermediate-acting or long-acting insulin preparations.

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®
- ▶ **If you suspect hypoglycaemia (low blood sugar)** is starting
- ▶ **If FlexPen® is dropped, damaged or crushed.**
- ▶ **If it has not been stored correctly** or if it has been frozen
- ▶ **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.**
- ▶ Blood sugar monitoring should be intensified if:
 - you are an elderly
 - if you have kidney or liver impairment
- ▶ Please seek doctor's advice before travelling between different time zones since this may affect the time of meals taken and administration of insulin.

-Taking other medicines

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, nurse 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 mentioned 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 (MAOI) inhibitors, beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulphonamides.

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.

Alcohol may intensify or reduce the hypoglycaemic effect of insulin.

Combination of thiazolidinediones and insulin may increase the risk of heart failure.

How to use NovoRapid®

-How much to use

Talk about your insulin needs with your doctor and nurse. 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.

The individual insulin requirement in adults and children is usually between 0.5 and 1.0 U/kg/day.

-When to use it

Due to the faster onset of action NovoRapid should be given immediately before a meal. When necessary, it can be given soon after a meal.

NovoRapid® is for injection under the skin (subcutaneously) or for continuous infusion in a pump system. NovoRapid® may also be given directly into a vein (intravenously) by healthcare professionals. 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.

-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.
- **Changing of the infusion set (tubing and needle)** must be done according to the instructions in the product information supplied with the infusion set.

-If you forget to use it

Your blood sugar may get too high (this is called hyperglycaemia). **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.

If you get any of these signs, test your blood sugar level and test your urine for ketones if you can. Then seek medical advice straight away. These may be signs of a very serious condition called diabetic ketoacidosis. If you do not treat it, this could lead to diabetic coma and eventually death.

-If you use too much (overdose)

Your blood sugar may get low (this is called hypoglycaemia).

The warning signs of a hypo 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; difficulty in concentrating.

If you get any of these signs, eat glucose tablets or a high sugar snack

(sweets, biscuits, fruit juice), then rest.

Using glucagon

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. Seek medical advice after an injection of glucagon; you need to find the reason for your hypo to avoid getting more.

While you are using it

-Things you must do

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

It is recommended that you measure your blood sugar regularly.

-Things you must not do

Do not take any insulin if you feel a hypo coming on.

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

-Things to be careful of

If you drive or use tools or machines, watch out for signs of a hypo. Your ability to concentrate or to react will be less during a hypo. Never drive or use machinery if you feel a hypo coming on. Discuss with your doctor whether you can drive or use machines at all, if you have a lot of hypos or if you find it hard to recognise hypos.

Side effects

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

Side effects reported very commonly

(in more than 1 patient in 10)

Low blood sugar (hypoglycaemia)

Side effects reported uncommonly
(in less than 1 patient in 100)

Diabetic retinopathy (eye disease related to diabetes which can lead to loss of vision). If you have diabetic retinopathy and your blood sugar levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

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). The fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). 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 nurse. These reactions can become more severe, or they may change the absorption of your insulin if you inject in such a site.

Signs of allergy.

Reactions (redness, swelling, 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 the body, or
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heart beat; feel dizzy.

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

Serious allergic reaction to NovoRapid® or one of its ingredients (called a systemic allergic reaction).

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.

Painful neuropathy (pain due to nerve damage). If your blood sugar level improve very fast, you may get nerve related pain, this is called acute painful neuropathy and is usually transient.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of NovoRapid®

-Storage

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 is not to be kept in the refrigerator. You can carry it with you and keep it at room temperature (below 30°C) for up to 4 weeks.

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.

Keep out of the reach and sight of children.

-Disposal

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

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.

Product Description

-What it looks like

NovoRapid® comes as a clear, colourless, aqueous solution

-Ingredients

-Active ingredient
insulin aspart

-Inactive ingredient(s)

glycerol, phenol, metacresol, zinc chloride, disodium phosphate dihydrate, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

-MAL numbers:

MAL13115137AS

MAL20034597A

Manufacturer

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