

NovoRapid® 10mL vial

Insulin aspart (rys)

Consumer Medicine Information

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This leaflet answers some common questions about NovoRapid® 10mL vial. It does not contain all the available information. It does not take the place of talking to your doctor, diabetes education nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using NovoRapid® 10mL vial against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, diabetes education nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NovoRapid® is used for

The insulin aspart, or “NovoRapid®”, in NovoRapid® 10mL vial is a rapid-acting insulin used to treat diabetes mellitus in adults and children. Diabetes mellitus is a condition where your

pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

Type 1 diabetes - also called juvenile onset diabetes

Type 2 diabetes - also called maturity onset diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

NovoRapid® lowers your blood sugar level after injection. When injected under your skin, NovoRapid® has a faster onset of action than soluble human insulin. It takes effect within 10 to 20 minutes. Usually, the maximum effect will occur between 1-3 hours after injection and the effect may last for up to 5 hours.

As with all insulins, the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity. Due to its shorter duration of action, NovoRapid® has a lower risk of causing nocturnal hypoglycaemic episodes.

NovoRapid® is not addictive.

NovoRapid® 10mL vial is available only with a doctor's prescription.

Ask your doctor, diabetes education nurse or pharmacist if you have any questions about why NovoRapid® has been prescribed for you.

Before you use NovoRapid® 10mL vial

When you must not use it

Do not use NovoRapid® if:

1. you have an allergy to:

- any medicine containing insulin
- any of the ingredients listed in the “Ingredients” section of this leaflet.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.

2. you are experiencing a low blood sugar level (a “hypo”) when the dose is due.

If you have a lot of hypos discuss appropriate treatment with your doctor.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not use this medicine after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- liver problems
- adrenal, pituitary or thyroid gland problems.

Tell your doctor if you are pregnant or plan to become pregnant.

NovoRapid® can be used during pregnancy. Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

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).

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.

If you have not told your doctor about any of the above, tell them before you use NovoRapid®.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and NovoRapid® may interfere with each other and this may mean that your insulin dose has to change.

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

- other medicines used for the treatment of diabetes

- monoamine oxidase inhibitors (MAOI) – used for the treatment of depression
- alpha-blocking agents – used for the treatment of high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- non-selective beta-blocking agents – used for the treatment of certain heart conditions and high blood pressure which may also mask the symptoms of hypoglycaemia and delay recovery from hypoglycaemia
- angiotensin converting enzyme (ACE) inhibitors – used for the treatment of certain heart conditions, high blood pressure or elevated protein/albumin in the urine
- salicylates e.g. aspirin – used to relieve pain and lower fever
- anabolic steroids – used to promote growth
- sulfonamides – used to treat bacterial infections
- quinine – used for the prevention of malaria and the relief of muscle cramps
- quinidine – used for the control of heart problems.

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

- glucocorticoids (except when applied locally) – used to treat inflammatory conditions
- oral contraceptives (“the pill”) – used for birth control
- thiazides, frusemide or ethacrynic acid – used for the treatment of high blood pressure or fluid retention (oedema)
- thyroid hormones – used for the treatment of malfunction of the thyroid gland
- sympathomimetics – used for the treatment of asthma
- growth hormone – used to treat growth disorders
- danazol – used to treat endometriosis, menorrhagia,

fibrocystic breast disease and hereditary angioedema

- oxymetholone – used to treat certain blood disorders
- diazoxide – used for the treatment of high blood pressure
- nicotinic acid – used for the treatment of high cholesterol levels in the blood
- asparaginase – used to treat leukaemia and lymph gland tumours.

If you take the following medicines, your blood sugar level may rise or fall:

- octreotide – used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide – used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal hormone levels.

Tell your doctor about any other medicines that you are taking.

This is very important. Your doctor will advise you if it is all right to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use NovoRapid® 10mL vial

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions.

They may differ from the information contained in this leaflet.

Your doctor may also want you to use another insulin such as Protaphane® or Levemir®.

Any change in dose or type of insulin should be made cautiously and only under medical supervision.

If you change the type of insulin that you use, you may have to use more or less than before. This may happen with the first dose or over a period of time.

NovoRapid® may be used for injection under the skin or for continuous infusion in a pump system. NovoRapid® may also be injected into a vein under supervision by a doctor.

Before you use NovoRapid® in a pump system you should receive comprehensive instructions about the use of the system, and what to do in case of illness, too high or too low blood sugar levels, or failure of the pump system.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

How much to use

Your doctor or diabetes education nurse will tell you how much of this medicine you need to use.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

When to use it

NovoRapid® should normally be used immediately (up to 10 minutes) before your meal or carbohydrate snack. When necessary, NovoRapid® may be used immediately after the meal.

How to use it

- Inject NovoRapid® under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse.
- NovoRapid® may be injected into the abdomen, thighs, buttocks or upper arms.
- Remember to change your injection site regularly as shown

to you by your doctor or diabetes education nurse.

- NovoRapid® 10mL vial is suitable for intravenous administration in an emergency under medical supervision only.
Discard the vial after emergency use.

Checking your NovoRapid® 10mL vial:

On first use of a new vial, check that the protective colour-coded, tamper-proof plastic cap is in place, and is not loose or missing.

Check your NovoRapid® 10mL vial before each preparation and injection. Make sure you are using the correct type of insulin.

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

How to use NovoRapid® 10mL vial in a syringe

- You need to use U100 insulin syringes
- When you are using NovoRapid® vials you should use a new syringe for each injection.

If you only use NovoRapid®:

1. Wash your hands.
2. Draw a volume of air into the syringe that is equal to the dose of insulin to be injected.
3. Put the needle through the rubber top of the vial and inject the air into the vial.
4. Turn the vial and syringe upside down.
5. Make sure that the tip of the needle is in the insulin and withdraw the correct dose into the syringe.
6. Pull the needle out of the vial. Expel any air from the syringe and check that the dose is correct.
7. If you need to put the syringe down, make sure that the needle does not touch anything.

If you have to mix two types of insulin:

Only mix NovoRapid® with NPH (Neutral Protamine Hagedorn)

insulin and only if your doctor has instructed you to. Mixed insulin should be injected straight away.

1. Wash your hands.
2. Just before use, roll the vial of NPH (cloudy) insulin between your hands until the liquid is white and uniformly cloudy. Do not shake the vial.
3. Draw air into the syringe that is equal to the dose of the NPH insulin. Insert the needle into the NPH insulin vial and inject the air. Withdraw the needle without drawing up any insulin.
4. Draw air into the syringe equal to the dose of NovoRapid®. Insert the needle into the vial of NovoRapid® (clear insulin) and inject the air. Do not withdraw the needle.
5. Turn the vial and syringe upside down.
6. Make sure the tip of the needle is in the insulin, and withdraw the correct dose into the syringe.
7. Pull the needle out of the NovoRapid® insulin vial. Expel any air from the syringe and check that the dose is correct.
8. Insert the needle into the vial of NPH insulin.
9. Turn the vial and syringe upside down.
10. Make sure the tip of the needle is in the insulin and withdraw your dose of NPH insulin.
11. Remove the needle from the vial.
12. If you need to put the syringe down, make sure the needle does not touch anything.

Injecting a dose with a syringe:

Choose a site for injection. Inject the medicine into the abdomen, thighs, upper arms or buttocks.

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

Keep the needle under the skin for at least 6 seconds to ensure that the full dose has been injected.

Apply gentle pressure over the injection site for several seconds.

Do not rub the area.

After injecting:

Dispose of your insulin syringes safely into a yellow plastic sharps container.

Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of needlestick injury.

Do not share needles or syringes.

It is recommended that you eat a meal or snack containing carbohydrate within 10 minutes of the injection.

How to use NovoRapid® 10mL vial in a subcutaneous infusion pump system:

- NovoRapid® may also be given under the skin by means of an insulin infusion pump. Use the type of pump system recommended by your doctor, and read and follow the instructions that accompany your pump.
- NovoRapid® should never be mixed with any other insulin when used in a pump.
- Before inserting the needle, use soap and water to clean your hands and the skin where the needle is inserted so as to prevent infection at the infusion site.
- When you are filling a new syringe, be certain not to leave large air bubbles in either the syringe or the catheter.
- Change the syringe and catheter after a maximum of 2 days usage.
- Follow your doctor's or diabetes education nurse's advice about the basal infusion rate and the mealtime insulin boluses to be taken.
- To get the benefit of insulin infusion, and to detect possible malfunction of the insulin pump, you should measure your blood sugar levels regularly.

What to do in case of infusion pump system failure

In case of infusion pump system failure, you should always carry a spare vial of NovoRapid® and a U100 syringe, or an alternative insulin delivery system, for injection under the skin.

After you use it

- Do not refill NovoRapid® vials
- Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of needlestick injury.

How long to use it

Do not stop using NovoRapid® 10mL vial unless your doctor tells you to.

If you use too much (overdose) - Hypoglycaemia

Your blood sugar level may become too low (you may experience hypoglycaemia or a "hypo") if you:

- accidentally use too much of this medicine
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill.

The first symptoms of mild to moderate hypos can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea.

Always carry some sugary food or fruit juice with you.

If you experience any of these symptoms of a hypo, immediately eat some sugary food or have a

sugary drink, e.g. lollies, biscuits or fruit juice, and measure your blood sugar level.

Tell your relatives, friends, close workmates or carers that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.

Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.

If you lose consciousness, make sure they know:

- **to turn you on your side and get medical help immediately**
- **not to give you anything to eat or drink.**

This is because you could choke.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, eat some sugary food or have a sugary drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes education nurse, or the closest hospital.

If you do not respond to glucagon treatment, you will require medical attention.

See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin.

Your insulin dose may need to be changed.

If a severe hypo is not treated, it can cause brain damage and even death.

If you miss a dose - Hyperglycaemia

If you forget your insulin dose, test your blood sugar level as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

Do not use a double dose of your insulin.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember - *don't forget to eat some carbohydrate within 10 minutes of your injection* - and then go back to using it as you would normally.

Your blood sugar levels may become high (hyperglycaemia) if you:

- miss doses of insulin or use less insulin than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed.

High blood sugar levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is high or you recognise any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine.

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness.

Severe hyperglycaemia can lead to unconsciousness and in extreme cases death if untreated.

Discuss any worries you may have about this with your doctor,

diabetes education nurse or pharmacist.

While you are using NovoRapid® 10mL vial

Things you must do

Measure your blood sugar level regularly.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

If your child has diabetes it is important to tell their carers.

Keep using your insulin even if you feel well.

It helps to control your condition, but does not cure it.

Tell your doctor if you often have hypos (low blood sugar levels).

Your doctor may need to adjust your insulin dose.

Always carry some sugary food or fruit juice with you.

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor if you have trouble recognising the symptoms of hypos.

Under certain conditions, the early warning signs of hypos can be different or less obvious. Your doctor may need to adjust your insulin dose.

Make sure that you tell every doctor, dentist, pharmacist or other health care professional who is treating you that you have diabetes and are using insulin.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your insulin and eat your meals at different

times because of time differences in and between countries.

You may not be able to get the same type of insulin in the country you are visiting.

Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

Things you must not do

Do not stop using your medicine unless your doctor tells you to.

Do not use the medicine if you think it has been frozen or exposed to excessive heat.

It will not work as well.

Do not refill your NovoRapid® 10mL vial.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how the insulin affects you.

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 hypos
- if you find it hard to recognise hypoglycaemia.

Tell your doctor if you drink alcohol.

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

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an

insulin plan for those times when you are sick.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for this medicine. Exercise may also speed up the effect of a dose of it, especially if the exercise involves the area of the injection site (e.g. the leg should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

Side effects

Ask your doctor or pharmacist to answer any questions you have.

Tell your doctor, diabetes education nurse or pharmacist as soon as possible if you do not feel well while you are using NovoRapid® 10mL vial.

This medicine helps most people for whom it is prescribed, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you may have.

The most common side effect when using insulin is low blood sugar levels (a hypo).

Tell your doctor if you notice any of the following and they worry you:

- hypos (mild to moderate).
- pain, redness, hives, bruising, swelling or itching at the injection site. Usually these symptoms disappear within a few weeks during continued use. If you have serious or continuing reactions, you may

need to stop using NovoRapid® and use another insulin.

- a depression or thickening of the skin around the injection site (lipodystrophy).
- when you first start your insulin treatment you may get visual problems or swollen hands and feet.

This list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

More severe symptoms of low blood sugar levels, including:

- disorientation
- seizures, fits or convulsions
- loss of consciousness.

If a severe hypo is not treated, it can cause brain damage and death.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- skin rashes over a large part of the body
- shortness of breath, wheezing
- swelling of the face, lips or tongue
- fast pulse
- sweating.

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you have.

After using NovoRapid® 10mL vial

Storage

Store NovoRapid® 10mL vials that are not being used between 2°C and 8°C in a refrigerator (not in or too near the freezer section or cooling element).

Do not keep the NovoRapid® 10mL vial that you are using, or that you are carrying as a spare, in a refrigerator.

You can use it up to 4 weeks below 30°C after taking it out of the refrigerator. **Discard NovoRapid® 10mL vial after 4 weeks even if there is still some NovoRapid® left in it.**

The NovoRapid® in your NovoRapid® 10mL vial must not be frozen, or exposed to excessive heat or light. Protect the NovoRapid® in NovoRapid® 10mL vial from light by keeping the vial in its carton when not in use.

Never use NovoRapid® 10mL vial after the expiry date printed on the label and carton.

Never use NovoRapid® 10mL vial if the solution is not clear and colourless.

Keep out of the reach of children.

Disposal

Dispose of used needles and syringes safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

NovoRapid® is a clear, colourless solution for subcutaneous injection/infusion. NovoRapid® 10mL vial is a 10mL glass vial designed to be used either with

U100 insulin syringes or in insulin infusion pump systems.

Ingredients

NovoRapid® contains insulin aspart (rys) 100 units per mL (100 U/mL) as the active ingredient. The abbreviation “rys” indicates the method of genetic engineering used to manufacture this insulin.

NovoRapid® also contains the following inactive ingredients: glycerol, phenol, metacresol, zinc chloride, sodium chloride, dibasic sodium phosphate dihydrate, sodium hydroxide, hydrochloric acid and water for injections.

Sponsor

NovoRapid® 10mL vial is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 3

21 Solent Circuit

Baulkham Hills NSW 2153

NovoRapid® 10mL vial is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

58 Richard Pearse Drive

Airport Oaks

Mangere

New Zealand

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This leaflet was prepared on 14 July 2017.

Australian Registration Number:

AUST R 133443

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Novo Nordisk A/S

- www.novonordisk.co.nz

You can also get more information about diabetes and insulin from Diabetes Australia:

- freecall helpline 1300 136 588
- www.diabetesaustralia.com.au

Diabetes New Zealand:

- www.diabetes.org.nz

Further Information

For further information call the NovoCare® Customer Care Centre on 1800 668 626 (Australia) or 0800 733 737 (New Zealand).

- www.novonordisk.com.au