NovoRapid® FlexPen®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor, diabetes education nurse, or pharmacist.

1. Why am I using NovoRapid® FlexPen®?

NovoRapid® contains the active ingredient insulin aspart. Insulin aspart is a rapid-acting insulin used to treat diabetes mellitus in adults and children.
For more information, see Section 1. Why am I using NovoRapid® ?in the full CMI.

2. What should I know before I use NovoRapid® FlexPen®?

Do not use if you have ever had an allergic reaction to insulin aspart or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions (especially kidney, liver or gland problems), take any other medicines, or are pregnant or plan to become pregnant or are breast-feeding.

For more information, see Section 2. What should I know before I use NovoRapid® FlexPen® ?in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NovoRapid® and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use NovoRapid® FlexPen®?

- Use immediately (up to 10 minutes) before your meal or carbohydrate snack. Inject into the abdomen, thighs, buttocks or upper arms.
- Change your injection site regularly. Carefully follow the advice on how to inject under the skin.

Detailed instructions can be found in Section 4. How do I use NovoRapid® ?and in the full CMI.

5. What should I know while using NovoRapid® FlexPen®?

Things you should do	• Remind any doctor, dentist, pharmacist or diabetes education nurse you visit that you have diabetes and are using insulin. • Measure your blood sugar levels regularly. • Tell your doctor if you often have hypos (low blood sugar levels). • **Always carry some sugary food or fruit juice with you.**
Things you should 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.
Driving or 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.
Drinking alcohol	• Alcohol may mask the symptoms of hypos. If you drink alcohol, your need for insulin may change.
Looking after your medicine	• Store NovoRapid® FlexPen® 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). • You can keep the NovoRapid® FlexPen® *that you are using*, or that you are carrying as a spare, **either** below 30°C or in a refrigerator. Discard NovoRapid® FlexPen® after 4 weeks even if there is still some NovoRapid® left in it.

For more information, see Section 5. What should I know while using NovoRapid® ?in the full CMI.

6. Are there any side effects?

The most common side effect when using insulin is low blood sugar levels (a hypo). **Tell your relatives, friends, close workmates, teachers or carers that you have diabetes. It is important that they can recognise the signs and symptoms of a hypo.** For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

NovoRapid® FlexPen®

Active ingredient(s): *Insulin aspart*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NovoRapid®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NovoRapid®.**

Where to find information in this leaflet:

1. Why am I using NovoRapid® ?
2. What should I know before I use NovoRapid® ?
3. What if I am taking other medicines?
4. How do I use NovoRapid® FlexPen® ?
5. What should I know while using NovoRapid® ?
6. Are there any side effects?
7. Product details

1. Why am I using NovoRapid®?

The insulin aspart, or "NovoRapid®" , in NovoRapid® FlexPen® is a rapid-acting insulin.

NovoRapid® is 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
- Type 2 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.

FlexPen® is a pre-filled dial-a-dose insulin pen able to deliver from 1 to 60 units of NovoRapid® in increments of 1 unit.

NovoRapid® is not addictive.

NovoRapid® FlexPen® is available only with a doctor's prescription.

2. What should I know before I use NovoRapid®?

Warnings

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use NovoRapid® FlexPen®.

Do not use NovoRapid® if:

- you are allergic to a medicine containing insulin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
  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.
- 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.
- the expiry date printed on the pack has passed, 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. The expiry date refers to the last day of that month.

Check with your doctor or pharmacist if you:

- have any other medical conditions such as kidney or liver problems, adrenal, pituitary or thyroid gland problems
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breast-feeding

Check with your doctor or pharmacist if you are pregnant or intend 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.

Talk to your doctor or pharmacist if you are breast-feeding or intend to breast-feed.

There are no restrictions on treatment with NovoRapid® during breast-feeding.

Heart disease or stroke history

- 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with NovoRapid® and affect how it works.

This may mean that your insulin dose has to change.

Medicines that may <u>cause your blood sugar to fall</u> (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.

Medicines that may <u>cause your blood sugar to rise</u> (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.

Medicines that may <u>cause your blood sugar to rise or fall</u>:

- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NovoRapid®.

4. How do I use NovoRapid® FlexPen®?

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.

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 NovoRapid®

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 NovoRapid®

Follow the detailed instructions on how to inject NovoRapid® FlexPen® in the instructions for use supplied with the product. These instructions are also available via the following hyperlinks:
NovoRapid® FlexPen®
https://medsinfo.com.au/media/noinrafp

- 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. This may reduce the risk of developing a depression or thickening of the skin around the injection site (lipodystrophy) (see Section 6. Are there any side effects?).
- In an emergency, the insulin contained within NovoRapid® FlexPen® is suitable for intravenous administration, under medical supervision only. For emergency use, the insulin must first be withdrawn from FlexPen® into a syringe. **Discard your FlexPen® after emergency use.**
- If you use NovoRapid® and another type of insulin, you must use a separate insulin delivery system for each type of insulin.

Checking your NovoRapid® FlexPen®:

- Check your NovoRapid® FlexPen® 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.
- Do not use your FlexPen® if it was dropped, damaged or crushed.
- **Read the instructions printed at the end of this leaflet carefully in order to prepare and handle your NovoRapid® FlexPen® correctly.**

How long to use it

Do not stop using NovoRapid® FlexPen® unless your doctor tells you to.

If you use too much NovoRapid® (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, teachers 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 think that you have used too much NovoRapid®, you may need urgent medical attention.

You should immediately:

- contact your doctor, or
- go to the Accident and Emergency department at your nearest hospital, or
- phone the Poisons Information Centre **(by calling 13 11 26 in Australia or 0800 764 766 in New Zealand).**

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using NovoRapid®?

Things you should 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 teachers and 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 sugary 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.

Remind any doctor, dentist or pharmacist or other health professionals you visit 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 should 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 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.

Do not share needles or pens.

Things to be careful of

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 thigh 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.

Tell your doctor if you notice any skin changes at the injection site.

If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis). 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.

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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor or pharmacist 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.

Looking after your medicine

- Store NovoRapid® FlexPen® **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).
- Keep the NovoRapid® FlexPen® **that you are using**, or that you are carrying as a spare, **either** below 30°C or in a refrigerator (2°C - 8°C).

  You can use it for up to 4 weeks.

  Discard NovoRapid® FlexPen® after 4 weeks even if there is still some NovoRapid® left in it.
- The NovoRapid® in your NovoRapid® FlexPen® must not be frozen, or exposed to excessive heat or light. Protect the NovoRapid® in NovoRapid® FlexPen® from light by keeping the pen cap on when not in use.
- Never use NovoRapid® FlexPen® after the expiry date printed on the label and carton. The expiry date refers to the last day of that month.
- Never use NovoRapid® FlexPen® if the solution is not clear and colourless.
- Keep out of the reach of children.

Disposal of your medicine

- Discard in-use NovoRapid® FlexPen® after 4 weeks even if there is still some NovoRapid® left in it.
- Dispose of used needles and syringes safely into a yellow plastic sharps container.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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® FlexPen®.

Common side effects

Less serious side effects	What to do
The most common side effect when using insulin is low blood sugar levels (a hypo). • Mild to moderate **Other effects:** • 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). • lumps under your skin (cutaneous amyloidosis). • when you first start your insulin treatment you may get visual problems or swollen hands and feet.	**Speak to your doctor, diabetes education nurse or pharmacist if you have any of these less serious side effects and they worry you.** They are usually mild and short-lived

Serious side effects

Serious side effects	What to do
Symptoms of severe low blood sugar levels: • disorientation • seizures, fits or convulsions • loss of consciousness. • If a severe hypo is not treated, it can cause brain damage and death. **Other effects:** • skin rashes over a large part of the body • shortness of breath, wheezing • swelling of the face, lips or tongue	**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these serious side effects.** You may need urgent medical attention or hospitalisation. These side effects are very rare.

Serious side effects	What to do
• fast pulse • sweating.	

Tell your doctor if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What NovoRapid® contains

Active ingredient (main ingredient)	insulin aspart 100 units per mL (100 U/mL)
Other ingredients (inactive ingredients)	glycerol, phenol, metacresol, zinc chloride, sodium chloride, dibasic sodium phosphate dihydrate, sodium hydroxide, hydrochloric acid and water for injections.

Do not take this medicine if you are allergic to any of these ingredients.

What NovoRapid® looks like

NovoRapid® is a clear, colourless solution for subcutaneous injection.

NovoRapid® FlexPen® is a 3mL pre-filled glass cartridge contained in a dial-a-dose insulin pen. (AUST R 133445)

Who distributes NovoRapid®

NovoRapid® FlexPen® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 10

118 Mount Street

North Sydney NSW 2060

Australia

NovoRapid® FlexPen® is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

PO Box 51-268

Pakuranga

Auckland

New Zealand

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For further information:

For further information call Novo Nordisk Medical Information on 1800 668 626 (Australia) or 0800 733 737 (New Zealand).

- www.novonordisk.com.au
- 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

This leaflet was prepared on 21 October 2025.