

PART III: CONSUMER INFORMATION

Important: Please Read

NovoRapid[®]
[Penfill[®]]
Insulin Aspart
Solution for Injection

10 mL / 3 mL

This leaflet is Part III of a three-part 'Product Monograph' published when NovoRapid[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NovoRapid[®]. Contact your doctor or pharmacist if you have any questions about the drug.

Read all of this leaflet carefully before you start using your insulin. Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor, Diabetes Nurse Educator or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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

If you have trouble reading this, ask a family member or a friend for help.

ABOUT THIS MEDICATION

A direction leaflet containing information for the patient is included in each package.

What is NovoRapid[®]
[Penfill[®]]

NovoRapid[®] (insulin aspart) is an insulin analogue used to treat diabetes. It comes in a 10 mL vial that you use with a syringe and 3 mL cartridge called Penfill[®], which fits into a Novo Nordisk Insulin Delivery device.

NovoRapid[®] will start to lower your blood sugar 10 to 20 minutes after you take it, it has a maximum effect between 1 and 3 hours and the effect lasts for 3 to 5 hours. Due to this short action NovoRapid[®] should normally be taken in combination with intermediate-acting or long-acting insulin preparations.

NovoRapid[®] (insulin aspart) is indicated for:

- The treatment of patients with diabetes mellitus who require insulin for the control of hyperglycemia.

When NovoRapid[®] should not be used

Do not use NovoRapid[®]:

- ▶ **If you feel a hypo** coming on (a hypo is short for a hypoglycemic reaction or low blood sugar). See ‘*What to do in an emergency*’, for more about hypos.
- ▶ **If you are allergic (hypersensitive)** to insulin aspart, metacresol or any of the other ingredients in this insulin. Look out for the signs of an allergic reaction (see ‘*Possible side effects*’).

What the medicinal ingredient is

The active ingredient in NovoRapid® is insulin aspart made by recombinant DNA technology.

What the important nonmedicinal ingredients are

Glycerol; phenol; metacresol; zinc chloride; sodium chloride; disodium phosphate dihydrate; sodium hydroxide; hydrochloric acid and water for injection.

What dosage forms NovoRapid® comes in

NovoRapid® is available from Novo Nordisk Canada in the following format:

NovoRapid® 10 mL vial

NovoRapid® Penfill® 3 mL cartridge

(designed for use with Novo Nordisk Insulin Delivery Devices)

NovoRapid® [Penfill®] is designed for use with NovoFine® needles. Novo Nordisk cannot be held responsible for malfunctions occurring as a consequence of using NovoRapid® with products that do not meet the same specifications or quality standards as NovoFine® needles.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- **NovoRapid® should not be used if it is not water-clear and colourless.**

Before you use NovoRapid® [Penfill®]

Before you use NovoRapid® [vial / Penfill®] talk to your doctor or pharmacist:

- ▶ **If you have trouble** with your kidneys or liver, your doctor may decide to alter your insulin dose.
- ▶ **If you drink alcohol (including wine and beer):** watch for signs of a hypo and never drink alcohol on an empty stomach.
- ▶ **If you exercise more than usual** or if you want to change your usual diet.
- ▶ **If you are ill:** continue taking your insulin. Your need for insulin may change.
- ▶ **If you have an infection, fever or have had an operation** you may need more insulin than usual.
- ▶ **If you suffer from diarrhea, vomiting or eat less than usual** you may need less insulin than usual.
- ▶ **If you go abroad:** travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travel.
- ▶ **If you are pregnant, or planning a pregnancy or are breastfeeding** please contact your doctor for advice.
- ▶ **If you drive or use tools or machines:** watch for signs of a hypo. Your ability to concentrate or to react will be less during a hypo. Please keep this in mind in all situations where you might put

yourself and others at risk (e.g. driving a car or operating machinery). Never drive or use machinery if you feel a hypo coming on.

Discuss with your doctor whether you should drive or use machines at all, if you have a lot of hypos or if you find it hard to recognize hypos.

Before you travel, check with your physician or pharmacist on the availability of NovoRapid® in other countries. If possible, bring enough NovoRapid® with you on your trip.

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

INTERACTIONS WITH THIS MEDICATION

When you use other medicines

Many 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. Talk to your doctor or pharmacist if you take, or change any other medicines, even those not prescribed.

Your need for insulin may change if you also take: oral antidiabetic products; monoamine oxidase (MAO) inhibitors; beta-blockers; angiotensin converting enzyme (ACE) inhibitors; salicylates (aspirin); anabolic steroids; glucocorticoids (except topical administration); oral contraceptives; thiazides; thyroid hormones; sympathomimetics; danazol; octreotide and sulphonamides.

PROPER USE OF THIS MEDICATION

How to use NovoRapid® [Penfill®]

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Follow their advice carefully. This leaflet is a general guide only.

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.

Due to the faster onset of action, NovoRapid® should be given close to a meal (start of the meal should be no more than 5 - 10 minutes after the injection). When necessary, NovoRapid® can be given soon after a meal, instead of before the meal.

It is recommended that you measure your blood glucose regularly.

Before using NovoRapid®:

- ▶ **Check the label** to make sure you have the right type of insulin.
- ▶ Remove the protective cap [vial].
- ▶ **Always check** the Penfill® cartridge, including the rubber stopper (plunger). Don't use it if any damage is seen or if there is a gap between the rubber stopper and the white barcode label. Take it

back to your supplier or call Novo Nordisk Canada at 1 800 465-4334 for assistance. See your Novo Nordisk Insulin Delivery Device manual for further instructions.

- ▶ **Disinfect** the rubber membrane with an alcohol swab [vial / Penfill®].
- ▶ Always use a new needle for each injection to prevent contamination [Penfill®].

Do not use NovoRapid®:

- ▶ **If the protective cap is loose or missing.** Each vial has a protective, tamper proof plastic cap. If the cap is not in perfect condition when you get the vial, return the vial to your supplier.
- ▶ **If the Penfill® cartridge or Novo Nordisk Insulin Delivery Device containing the cartridge is dropped, damaged or crushed;** there is a risk of leakage of insulin.
- ▶ **If the insulin has not been stored correctly** or if it has been frozen (see '*How to Store NovoRapid®*').
- ▶ **If the insulin does not appear clear and colourless.**

How to use this insulin

NovoRapid® is for injection under the skin (subcutaneously).

NovoRapid® 10 ml vial is also for continuous infusion in a pump system. NovoRapid® may also be given intravenously by healthcare professionals under close supervision by a doctor.

Always vary the site you inject within the same region, to avoid lumps (see '*Possible side effects*'). The best places to give yourself an injection are: your buttocks; the front of your thighs; the front of your waist (abdomen); or the upper arm. Your insulin will work more quickly if you inject around the waist.

NovoRapid® Penfill® is designed to be used with Novo Nordisk Insulin Delivery Devices and NovoFine® needles as part of **The All-In-One System®**.

If you are treated with NovoRapid® Penfill® and another insulin in Penfill® cartridge, you must use two insulin delivery devices, one for each type of insulin.

Do not refill NovoRapid® Penfill®.

As a precautionary measure, always carry a spare syringe and extra insulin in case your insulin delivery device is lost or damaged.

You should always measure your blood glucose regularly.

How to inject this insulin

If you use only one type of insulin [vial]:

1. Draw into the syringe the same amount of air as the dose of insulin you are going to inject. Inject the air into the vial.
2. Turn the vial and syringe upside down and draw the correct insulin dose into the syringe. Pull the needle out of the vial. Then expel the air from the syringe and check that the dose is correct.

If you have to mix two types of insulin [vial]

1. Just before use, roll the long-acting (cloudy) insulin between your hands until the liquid is uniformly white and cloudy.

2. Draw into the syringe the same amount of air as the dose of long-acting insulin. Inject the air into the vial containing long-acting insulin and pull out the needle.
3. Draw into the syringe the same amount of air as the dose of NovoRapid[®]. Inject the air into the vial containing NovoRapid[®]. Turn the vial and syringe upside down and draw up the prescribed dose of NovoRapid[®]. Expel any air from the syringe and check that the dose is correct.
4. Push the needle into the vial of long-acting insulin, turn the vial and syringe upside down and draw out the dose you have been prescribed. Expel any air from the syringe and check the dose. Inject the mixture immediately.
5. Always mix NovoRapid[®] and long-acting insulin in the same order.

How to inject this insulin [vial]

- **Pinch your skin** between two fingers, push the needle into the skin fold and inject the insulin under the skin.
- **Keep the needle under your skin** for at least 6 seconds to make sure you have injected all the insulin.

For use in an infusion pump system [vial]:

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 using NovoRapid[®] in a pump system you must receive comprehensive instructions in its 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 wash your hands and the skin around the area where the needle is inserted so as 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 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 a possible malfunction of the insulin pump, you should 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 to inject this insulin [Penfill[®]]

- ▶ **Inject the insulin** under the skin. Use the injection technique advised by your doctor or Diabetes Nurse Educator and described in your insulin delivery device manual.
- ▶ **Keep the needle under your skin** for at least 6 seconds to make sure that the full dose has been delivered.
- ▶ **After each injection** be sure to discard the needle. Otherwise, the liquid may leak out when the temperature changes.

Overdose

Causes of a hypo:

- You get a hypo if your blood sugar gets too low. This might happen:
- If you take too much insulin.
- If you eat too little or miss a meal.

- If you exercise more than usual.

If your blood sugar gets too high:

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

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; a dry mouth and a fruity (acetone) smelling breath.

If you get any of these signs: test your blood sugar level; test your urine for ketones if you can; then seek medical advice right away.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

Causes of hyperglycemia:

- Forgetting to take your insulin.
- Repeatedly taking less insulin than you need.
- An infection or fever.
- Eating more than usual.
- Exercising less than usual.

**SIDE EFFECTS AND
WHAT TO DO ABOUT THEM**

*What to do
in an emergency*

If you get a hypo (hypoglycemia)

A hypo means your blood sugar level is too low.

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; and difficulty concentrating.

If you get any of these signs: eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest.

Don't take any insulin if you feel a hypo coming on.

If you feel a hypo coming on: take a high sugar snack and then measure your blood sugar.

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

Tell your relatives, friends and close colleagues that if you pass out (become unconscious); they must turn you on your side and get medical help right away. They must not give you anything to eat or drink as it could choke you.

- ▶ **If severe hypoglycemia is not treated,** it can cause brain damage (temporary or permanent) and even death.

- ▶ **If you have a hypo that makes you pass out**, or if you get a lot of hypos, talk to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon you will need to eat 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 hospital emergency after an injection of glucagon: you need to find the reason for your hypo in order to avoid getting more.

Possible side effects

Like all medicines, NovoRapid® can cause side effects, although not everybody gets them. The most common side effect is low blood sugar (hypoglycemia). See the advice in *'What to do in an emergency'*.

Less commonly reported side effects

(less than 1 in 100)

Vision problems When you first start your insulin treatment it may disturb your vision, but the reaction usually disappears.

Changes at the injection site (Lipodystrophy) If you inject yourself too often at the same site, fatty tissue under the skin at this injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Changing the site with each injection may help to prevent such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or Diabetes Nurse Educator because these reactions can become more severe, or they may change the absorption of your insulin at this 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 the above signs of allergy spread to other parts of your body, or

If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty breathing; have a rapid heart beat; feel dizzy.

You may have a very rare serious allergic reaction to NovoRapid® or one of its ingredients (called a generalized allergic reaction). See also the warning in *'Before you use NovoRapid®'*.

Diabetic retinopathy (eye background changes) If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

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

Rarely reported side effects

(less than 1 in 1,000)

Painful neuropathy (nerve related pain) If your blood glucose levels improve very fast you may get nerve related pain. This is called acute painful neuropathy and is usually transient.

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

HOW TO STORE IT

How to store NovoRapid[®] [Penfill[®]]

Keep out of the reach and sight of children.

NovoRapid[®] [vial] that is not being used is to be stored in the refrigerator between 2°C - 10°C, in the original package, away from the freezer section. Do not freeze.

Always keep the vial in the outer carton when you're not using it in order to protect it from light.

NovoRapid[®] [Penfill[®]] that is not being used is to be stored in the refrigerator between 2°C - 10°C, not in or too near the freezer section or cooling element. Do not freeze.

NovoRapid[®] [vial / Penfill[®]] that is being used or is about to be used is not to be kept in the refrigerator. You can carry it with you and keep it at room temperature (not above 30°C) for up to 4 weeks.

NovoRapid[®] should be protected from excessive heat and sunlight.

Do not use NovoRapid[®] after the expiry date printed on the label and carton. The date refers to the last day of the month.

NovoRapid[®] should not be disposed of in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 1-866-234-2345

By toll-free fax: 1-866-678-6789

Online: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office Marketed Health Products Safety and Effectiveness
Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

Note: Should you require information related to the management of the side effect, please contact your healthcare provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

What NovoRapid[®] [vial / Penfill[®]] looks like and package content

NovoRapid[®] comes as a clear, colourless, aqueous solution in packages of one 10 mL vial per carton.

NovoRapid[®] Penfill[®] comes as a clear, colourless, aqueous solution in packages of 5 cartridges of 3 mL per carton.

1 mL contains 100 U (units) of insulin aspart.

1 vial contains 10 mL of insulin aspart equivalent to 1000 U.

1 Penfill[®] cartridge contains 3 mL of insulin aspart equivalent to 300 U.

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NovoRapid[®] - Product Monograph

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containing Novo Nordisk Canada in. at 1-800-465-4334.**

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