

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

NovoRapid® FlexPen®

**100 U/ml
Insulin aspart
Solution for injection in a pre-filled pen**

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, diabetes nurse or pharmacist
- This medicine has been prescribed for you personally. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, diabetes nurse or your pharmacist.

This side of the leaflet:

- 1. What NovoRapid® is and what it is used for**
- 2. Before you use NovoRapid®**
- 3. How to use NovoRapid®**
- 4. What to do in an emergency**
- 5. Possible side effects**
- 6. How to store NovoRapid®**
- 7. Further information**

Overleaf: How to use your FlexPen.

1. What NovoRapid® is and what it is used for

NovoRapid® is an insulin analogue to treat diabetes. It comes in a 3 ml pre-filled pen, called FlexPen® - see overleaf for detailed instructions. NovoRapid is a rapid-acting insulin for use in adults and children from 2 years of age. It 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.

2. Before you use NovoRapid®

- Do not use NovoRapid**
- ▶ **If you are allergic (hypersensitive)** to insulin aspart, metacresol or any of the other ingredients (see *7 Further information*). Look out for the signs of allergy in *5 Possible side effects*
 - ▶ **If you feel a hypo** coming on (a hypo is short for a hypoglycaemic reaction and is symptoms of low blood sugar). See *4 What to do in an emergency* for more about hypos.

Take special care with NovoRapid

- ▶ **If you have trouble** with your kidneys or liver, your doctor may decide to alter your insulin dose
- ▶ **If you are drinking alcohol (also beer and wine):** watch for signs of a hypo and never drink alcohol on an empty stomach
- ▶ **If you are exercising** more than usual or if you want to change your usual diet
- ▶ **If you are ill:** carry on taking your insulin. Your need for insulin may change
- ▶ **If you have an infection, fever or an operation** you may need more insulin than usual
- ▶ **If you suffer from diarrhoea, vomiting or eat less than usual** you may also need less insulin than usual
- ▶ **If you are going abroad:** travelling over time zones may affect your insulin needs and the timing of the injections. Consult your doctor if you are planning such travelling.

Pregnancy and breast-feeding

If you are planning a pregnancy or if you are pregnant or breast-feeding: please contact your doctor for advice. NovoRapid can be used during pregnancy. Your insulin dosage may need to be changed during pregnancy and after delivery. Careful control of your diabetes, and prevention of hypoglycaemia, is important, also for the health of your baby.

Driving and using machines

If you drive or use tools or machines: your ability to concentrate or react may be reduced if you have a hypo. Please keep this possible problem 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. You should contact your doctor about the advisability of driving if you have frequent episodes of hypos or reduced or absent warning signs of hypos.

NovoRapid has a rapid onset of effect therefore if hypoglycaemia occurs, you may experience it earlier after an injection when compared to soluble insulin human. There is no clinical experience with NovoRapid in children under the age of 2 years. NovoRapid can be used in children instead of soluble insulin human when a rapid onset of effect might be better. For example, when it is difficult to dose the child in relation to meals.

Front

Using 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. Please consult your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed. **Your need for insulin may change** if you also take: Oral antidiabetic medicinal products, monoamine oxidase (MAO) inhibitors, beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and glucocorticoids (except topical administration), oral contraceptives, thiazides, thyroid hormones, sympathomimetics, danazol, octreotide and sulphonamides.

3. How to use NovoRapid®

Talk about your insulin needs with your doctor and diabetes nurse. Follow their advice carefully. This leaflet is a general guide. 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. Eat a meal or snack containing carbohydrates within 10 minutes of the injection to avoid hypoglycaemia. When necessary, NovoRapid may be given soon after the meal, instead of before the meal. It is recommended that you measure your blood glucose regularly.

Injecting the insulin

See overleaf for detailed instructions.

Before using NovoRapid

- ▶ **Check the label to make sure** it is the right type of insulin.

NovoRapid must not be used

- ▶ **If the FlexPen is dropped, damaged or crushed,** there is a risk of leakage of insulin
- ▶ **If it hasn't been stored correctly** or if it has been frozen (see *6 How to store NovoRapid*)
- ▶ **If the insulin does not appear clear and colourless.**

NovoRapid is for injection under the skin (subcutaneously) or 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 sites you inject, to avoid lumps (see *5 Possible side effects*). The best places to give yourself an injection are: the front of your waist (abdomen); your buttocks; the front of your thighs or upper arms. Your insulin will work more quickly if you inject around the waist.

For use in an infusion pump system:

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 use of NovoRapid in the pump system you must have received a comprehensive instruction in the 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 clean your hands and the skin 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 of 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 possible malfunction of the insulin pump, it is recommended that you 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.

4. What to do in an emergency

If you get a hypo (hypoglycaemia)

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; difficulty in 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. 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 straight away. They must not give you any food or drink, as it could choke you.

- ▶ **If severe hypoglycaemia** 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 a lot of hypos, talk to your doctor. The amount or timing of your insulin, food or exercise may need to be adjusted.

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. Contact your doctor or an emergency ward after an injection of glucagon: you need to find the reason for your hypo to avoid getting more.

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 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; 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 don't treat it, this could lead to diabetic coma and death.

Causes of hyperglycaemia

- Having forgotten to take your insulin
- Repeatedly taking less insulin than you need
- An infection or a fever
- Eating more than usual
- Less exercise than usual.

5. 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 (hypoglycaemia). See the advice in *4 What to do in an emergency*.

Side effects reported uncommonly

(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 of the injection site. (Lipodystrophy). If you inject yourself too often at the same site, fatty tissue under the skin at this site may shrink (lipotrophy) 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 because 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 your 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.

You may have a very rare serious allergic reaction to NovoRapid or one of its ingredients (called a systemic allergic reaction). See also the warning in *2 Before you use NovoRapid*.

Diabetic retinopathy. 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. Normally this soon disappears.

Side effects reported rarely

(less than 1 in 1,000)

Painful neuropathy. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, diabetes nurse or pharmacist.

6. How to store NovoRapid®

Keep out of the reach and sight of children. Do not use NovoRapid after the expiry date which is stated on the label and carton.

NovoRapid FlexPen that is not being used is to be stored at 2°C - 8°C in the refrigerator, away from the freezer compartment. Do not freeze.

NovoRapid FlexPen that is being used or 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. Always keep the pen cap on your FlexPen when you're not using it in order to protect it from light.

NovoRapid must be protected from excessive heat and sunlight.

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

7. Further information

What NovoRapid contains

- The active substance is insulin aspart made by recombinant DNA technology
- The other ingredients are glycerol, phenol, metacresol, zinc chloride, sodium chloride, disodium phosphate dihydrate, sodium hydroxide, hydrochloric acid and water for injections.

What NovoRapid looks like and contents of the pack


The solution for injection comes as a clear, colourless, aqueous solution in packs of 1, 5 or 10 pre-filled pens of 3 ml (not all packs may be marketed). 1 ml contains 100 U of insulin aspart. 1 pre-filled pen contains 3 ml equivalent to 300 U.

The marketing authorisation holder:

Novo Nordisk A/S,
Novo Allé, DK-2880 Bagsværd, Denmark
and manufacturer:
Novo Nordisk Production SAS
45, Avenue d'Orléans F-28002 Chartres, France

Now turn for information on how to use your FlexPen.

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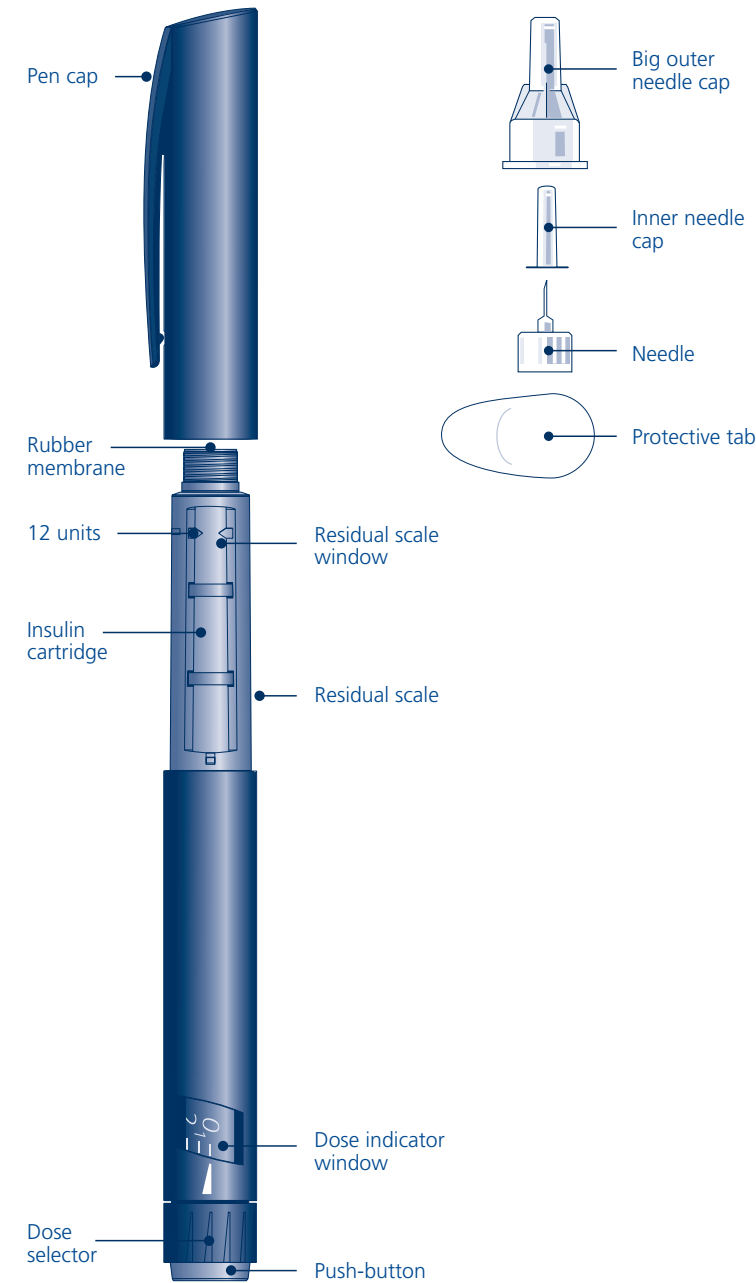
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Please read the following instructions carefully before using your NovoRapid® FlexPen®.

Introduction

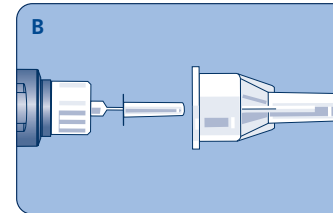
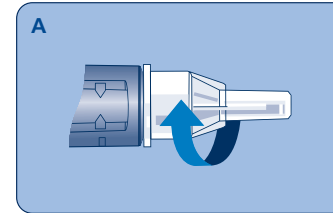
NovoRapid FlexPen is a unique dial-a-dose insulin pen. You can dial doses from 1 to 60 units in increments of 1 unit. NovoRapid FlexPen is designed to be used with NovoFine 5 needles of 8 mm or shorter in length. Look for an 5 on the needle box. The 5 stands for short cap. As a precautionary measure, always carry a spare insulin delivery device in case your FlexPen is lost or damaged.



Getting started

Check the label to be sure that your NovoRapid FlexPen contains the correct type of insulin. Take off the pen cap.

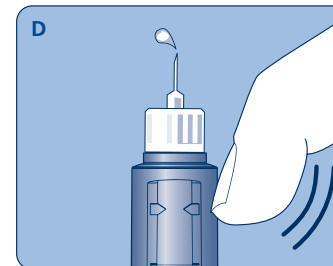
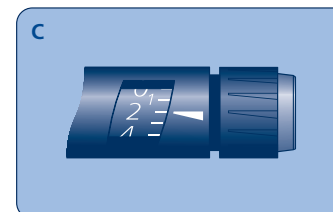
- **Disinfect the rubber membrane** with a medicinal swab
- **Remove the protective tab** from a NovoFine 5 short cap needle
- **Screw the needle straight and tightly** onto NovoRapid FlexPen (picture A)
- **Pull off the big outer needle cap and the inner needle cap** (picture B). Do not discard the big outer needle cap.



Priming to expel air

Prior to each injection small amounts of air may collect in the needle and cartridge during normal use. To avoid injection of air and ensure proper dosing:

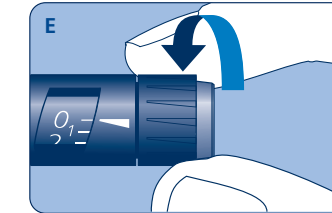
- **Dial 2 units** (picture C)
- **Hold NovoRapid FlexPen with the needle pointing upwards and tap the cartridge gently** with your finger a few times to make any air bubbles collect at the top of the cartridge (picture D)
- **Keeping the needle upwards, press the push-button all the way in.** The dose selector returns to zero
- **A drop of insulin should appear at the needle tip.** If not, change the needle and repeat the procedure no more than 6 times.



Setting the dose

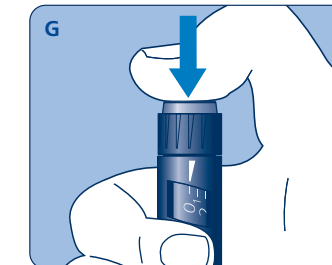
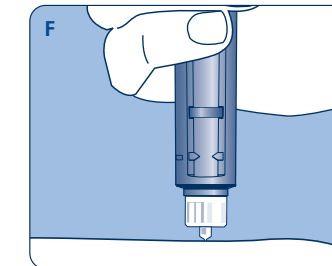
- **Check that the dose selector is set at zero**
- **Dial the number of units you need to inject** (picture E).

The dose can be corrected either up or down by turning the dose selector in either direction. When dialling back, be careful not to push the push-button as insulin will come out. Do not use the residual scale to measure your dose of insulin. You cannot set a dose larger than the number of units left in the cartridge.



Injecting the insulin

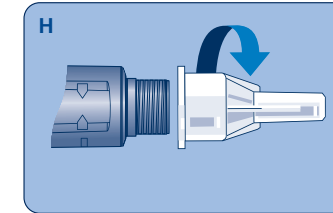
- **Insert the needle into your skin** (picture F). Use the injection technique advised by your doctor
- **Deliver the dose by pressing the push-button all the way in** (picture G). Be careful only to push the push-button when injecting
- **Keep the push-button fully depressed after the injection until the needle has been withdrawn from the skin.** The needle must remain under the skin for at least 6 seconds. This will ensure that the full dose has been delivered.



Removing the needle

- **Replace the big outer needle cap and unscrew the needle** (picture H)
- **Dispose of it carefully.**

Use a new needle for each injection. Remove the needle after each injection. Otherwise, the liquid may leak out when the temperature changes. Health care professionals, relatives and other carers must follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle penetration. Dispose of your used NovoRapid FlexPen carefully without the needle attached.



Maintenance

Your NovoRapid FlexPen is designed to work accurately and safely. It must be handled with care. You can clean the exterior of your NovoRapid FlexPen with a medicinal swab. Do not soak it, wash or lubricate it as this may damage the mechanism. Do not refill NovoRapid FlexPen.

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