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## PACKAGE LEAFLET

# NovoMix® 30 Penfill®

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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### This leaflet includes:

1. What NovoMix® 30 is and what it is used for
2. Before you use NovoMix® 30
3. How to use NovoMix® 30
4. What to do in an emergency
5. Possible side effects
6. Storing NovoMix® 30

#### NovoMix® 30 Penfill® 100 U/ml Suspension for injection in a cartridge

Insulin aspart, rDNA

**The active substance** is insulin aspart made by recombinant DNA technology in *Saccharomyces cerevisiae* (30% insulin aspart in a soluble fraction and 70% insulin aspart crystallised with protamine). 1 ml contains 100 U (3.5 mg) of insulin aspart. 1 cartridge contains 3 ml equivalent to 300 U.

**The other ingredients** are glycerol, phenol, metacresol, zinc (as chloride), sodium chloride, disodium phosphate dihydrate, protamine sulphate, sodium hydroxide, hydrochloric acid and water for injections. The suspension for injection comes as a white suspension in packs of 5 or 10 cartridges of 3 ml (not all packs may be marketed).

**The marketing authorisation holder is**  
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## 1. What Novomix® 30 is and what it is used for

**NovoMix® 30 is an insulin analogue to treat diabetes.** It comes in a 3 ml cartridge, called Penfill, which fits into a delivery system. NovoMix 30 is a mixture of rapid-acting insulin analogue (30%) and long-acting insulin analogue (70%). This means that it will start to lower your blood sugar 10-20 minutes after you take it, have a maximum effect between 1 and 4 hours and the effect will last for up to 24 hours.

## 2. Before you use Novomix® 30

### Do not use NovoMix 30

- ▶ **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
- ▶ **If you are allergic (hypersensitive)** to this insulin product or any of the other ingredients (see box, below left). Look out for the signs of allergy in 5 *Possible side effects*.

### Take special care with NovoMix 30

- ▶ **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, 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 need less insulin than usual
- ▶ **If you are going abroad:** travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travelling
- ▶ **If you are planning a pregnancy or if you are pregnant or breast-feeding:** please contact your doctor for advice. There is limited clinical experience with insulin aspart in pregnancy
- ▶ **If you drive or use tools or machines:** watch out for signs of a hypo. Your ability to concentrate or to react may be

reduced during 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. 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 recognise hypos.

There is no clinical experience in children and adolescents under the age of 18 years.

### Using other medicines

Many medicines affect the way your 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 Novomix® 30

Talk about your insulin needs with your doctor and diabetes nurse. Follow their advice carefully. This leaflet is a general guide. When NovoMix 30 is used in combination with metformin the dosage should be adjusted.

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. NovoMix 30 may also be given soon after the meal.

It is recommended that you measure your blood glucose regularly. NovoMix 30 is for use by one person only.

### Before using NovoMix 30

- ▶ **Check the label** to make sure it is the right type of insulin
- ▶ **Always check** the cartridge, including the rubber plunger (stopper). Don't use it if any damage is seen or if there is a gap between the rubber plunger and the white label band. Take it back to your supplier. See your delivery system manual for further instructions
- ▶ **Disinfect** the rubber membrane with a medicinal swab.



### NovoMix 30 should not be used

- ▶ **In insulin infusion pumps**
- ▶ **If the cartridge or the device containing the cartridge 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 *Storing NovoMix 30*)
- ▶ **If the insulin is not uniformly white and cloudy** when it's mixed
- ▶ **If clumps of material are present** or if solid white particles stick to the bottom or the wall of the cartridge giving a frosted appearance.

### How to use this insulin

**NovoMix 30 is for injection under the skin** (subcutaneously). Never inject your insulin directly into a vein or muscle.

**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.

NovoMix 30 Penfill is designed to be used with Novo Nordisk insulin delivery systems and NovoFine needles. If you are treated with NovoMix 30 Penfill and another insulin Penfill cartridge, you must use one insulin delivery system for each type of insulin. Do not refill NovoMix 30 Penfill cartridges.

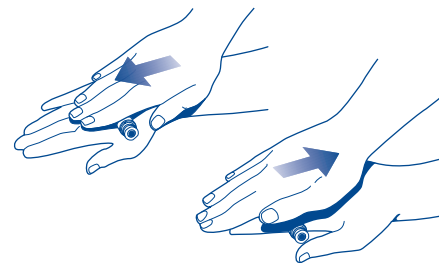
As a precautionary measure, always carry a spare Penfill cartridge in case your Penfill cartridge is lost or damaged.

### Mixing the insulin

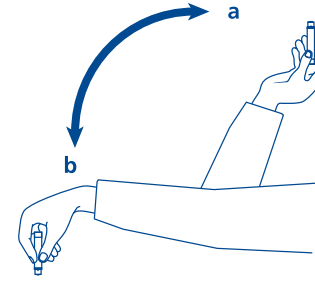
Before you put the cartridge into the insulin delivery system:

- ▶ **The first time you use NovoMix 30 Penfill** roll the cartridge between your palms 10 times - it is important that the cartridge is kept horizontal (see picture **A**). Move the cartridge up and down between positions a and b (see picture **B**) 10 times so that the glass ball moves from one end of the cartridge to the other. Repeat the rolling and moving procedure until the liquid appears uniformly white and cloudy. Mixing is easier when the insulin has reached room temperature. Complete the other stages of injection without delay
- ▶ **For every following injection** move the delivery system with the cartridge inside it up and down between a and b (see picture **B**) at least 10 times until the liquid appears uniformly white and cloudy.

Picture A



Picture B



**Check there are at least 12 units** of insulin left in the cartridge to allow even mixing. If there are less than 12 units left, use a new one.

### How to inject this insulin

- ▶ **Inject the insulin** under the skin. Use the injection technique advised by your doctor or diabetes nurse and described in your delivery system 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 and the strength of the insulin may change.

## 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 it is needed.

**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 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, NovoMix 30 can have side effects. 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 condition usually disappears.

**Changes of the injection site.** If you inject yourself too often in the same site, lumps may develop underneath. Prevent this by choosing different injection sites each time within the same region.

**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 NovoMix 30 or one of its ingredients (called a systemic allergic reaction). See also the warning in 2 *Before you use NovoMix 30*.

**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.

### Side effects reported rarely

(less than 1 in 1,000)

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

**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 you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## 6. Storing Novomix® 30

Keep out of the reach and sight of children.

**NovoMix 30 Penfill that is not being used** is to be stored in the refrigerator (2°C - 8°C), away from the freezer compartment. Do not freeze.

**NovoMix 30 Penfill that is being used** or about to be used is not to be kept in the refrigerator. After removing NovoMix 30 Penfill from the refrigerator it is recommended to mix the insulin as instructed for the first time use. See 3 *How to use NovoMix 30*.

You can carry it with you and keep it at room temperature (not above 30°C) for up to 4 weeks, but any remainder must then be discarded.

Always keep the cartridge in the outer carton when you're not using it in order to protect it from light. NovoMix 30 Penfill must be protected from excessive heat and sunlight.

Do not use NovoMix 30 after the expiry date stated on the label and carton.

This leaflet was last approved on 04/2007

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