

## **NovoMix® 30 Patient Insert**

### **Why have you been given NovoMix® 30?**

**NovoMix® 30** is an antidiabetic agent used for the treatment of diabetes mellitus as it reduces the level of sugar in the blood and urine. To control your diabetes, your doctor has prescribed injections of **NovoMix® 30**.

When injected under your skin (subcutaneously), the onset of action will occur within 10 to 20 minutes of injection, the maximum effect is between 1 and 4 hours and the effect lasts for up to 24 hours.

### **Availability of NovoMix® 30**

**NovoMix® 30** is available in the following format:

3 mL **Penfill®** cartridge, (designed for use with Novo Nordisk Insulin Delivery Devices),

**NovoMix® 30 Penfill®** cartridges are especially designed for use with Novo Nordisk Insulin Delivery Devices and NovoFine® needles. Novo Nordisk cannot be held responsible for malfunctions occurring as a consequence of using **NovoMix® 30 Penfill®** cartridges in combination with products that do not meet the same specifications or quality standards.

### **Before you take NovoMix® 30**

**You should not take NovoMix® 30:**

- If your blood sugar is too low (hypoglycemia). Follow the guidelines for hypoglycemia.
- If you are allergic to insulin aspart or any of the ingredients contained in **NovoMix® 30** (check with your doctor or pharmacist if you are not sure).
- **NovoMix® 30** should be given immediately before a meal. When necessary, **NovoMix® 30** may be given soon after a meal.

### **Dosage**

Follow carefully the instructions given by your doctor concerning type of insulin, dose, and time of injection. Any change in insulin should be made cautiously and only under medical supervision. Your insulin requirements may change due to a number of factors (illness, stress, medications, changes in diet or exercise routines, etc.). Follow your doctor's instructions to allow for these changes. The following can be considered as general guidelines only and you should consult your doctor for information, which is specific to your diabetes.

### **Can NovoMix® 30 be taken with other medicines?**

A number of drugs are known to influence insulin requirement. Therefore, if you are taking any other medication, (including over the counter medication), please consult your doctor.

### **What do you have to consider during pregnancy or while breastfeeding?**

If you are pregnant or planning to become pregnant you should see your doctor immediately to discuss your need for and type of insulin in order to control your diabetes and avoid hyperglycemia (too high blood sugar) and hypoglycemia (too low blood sugar) as these conditions could harm your baby.

There is limited clinical experience with insulin aspart in pregnancy.

Breastfeeding while you are taking insulin does not put your baby at risk. Your insulin dosage and diet may, however, need to be adjusted.

### **Alcohol use**

Alcohol (including beer and wine) may lead to hypoglycemia (too low blood sugar). Therefore, be careful when you drink alcohol and never drink alcohol on an empty stomach. Follow your physician's advice regarding diet and alcohol consumption.

**What should be done during an illness?**

Never stop taking insulin if you are ill. Your need for insulin may, however, be changed.

If you have an infection, fever or an operation you may need to have more insulin than usual.

If you suffer from diarrhea, vomiting or eat less than usual you may also need less insulin than usual.

**What about travelling?**

The time difference between countries may mean that you have to take your insulin and meals at different times than usual. You should therefore consult your doctor if you are planning to go abroad or travel across time zones.

**Is NovoMix® 30 available in other countries?**

Before you travel, check with your physician or pharmacist on availability of **NovoMix® 30** in other countries. If possible, bring enough **NovoMix® 30** with you on your trip.

**How to use NovoMix® 30 Penfill®**

*Before using your NovoMix® 30 Penfill®:*

- Do not use **NovoMix® 30 Penfill®** if it does not appear uniformly white and cloudy when rolled between your palms and turned upside down. The cartridge should not be used if clumps of material are present or if solid white particles stick to the bottom or wall of the cartridge, giving a frosted appearance.
- Before use, check that the **Penfill®** cartridge is intact (no cracks). Do not use the **Penfill®** cartridge if any damage is seen or if more of the rubber piston is visible than equal to the width of the white bar code band.
- To avoid possible transmission of disease, a **NovoMix® 30 Penfill®** cartridge must not be used by more than one person.
- Remove and dispose of the needle after each use. If the needle is not removed, temperature changes may cause liquid to leak out of the needle and the insulin concentration may change.
- Do not refill **NovoMix® 30 Penfill®**.
- Do not use **NovoMix® 30 Penfill®** in insulin pumps.
- If you switch from another insulin to **NovoMix® 30**, please consult your doctor, as your dosage may need to be adjusted.

**General information on use of NovoMix® 30**

- *Before injection, make sure that you have got the type and strength of insulin prescribed.*
- **NovoMix® 30** is for injection under the skin (subcutaneously). **NovoMix® 30** should not be injected intravenously.
- You will feel the effect more quickly if the insulin is injected into your abdomen. However, injections may also be given in your thigh, upper arm or buttock.
- It is recommended that you eat a meal or snack containing carbohydrate within 10 minutes of the injection.
- When necessary **NovoMix® 30** may be given soon after the meal.
- If you are treated with **NovoMix® 30 Penfill®** and another insulin in **Penfill®** cartridge, you should use two Novo Nordisk Insulin Delivery Devices, one for each type of insulin.

**NovoMix® 30 Penfill®**

**Before insertion into a Novo Nordisk Insulin Delivery Device:**

Allow the **NovoMix® 30 Penfill®** cartridge to reach room temperature and then roll it horizontally between your palms 10 times.

Then turn the cartridge upside down 10 times so that the glass ball inside **Penfill®** moves from one end of the insulin cartridge to the other. Then rolling and turning procedure must be repeated until the liquid appears uniformly white and cloudy.

Inject immediately.

**Before each injection:**

If the **Penfill**® cartridge is already inside the Nov Nordisk Insulin Delivery Device turn the device upside down 10 times so that the glass ball inside **Penfill**® moves from one end of the insulin cartridge to the other. The turning procedure must be repeated until the liquid appears uniformly white and cloudy.

Injection immediately.

**Injection procedure**

Follow the instructions of your physician or healthcare professional on how to make injections. Read the instruction manual for the Insulin Delivery Device carefully in order to prepare your **NovoMix® 30 Penfill**® and operate the device correctly.

After injection, the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle has been withdrawn from the skin. This will ensure correct delivery of the dose and limit possible flow of blood or other body fluids into the needle or insulin cartridge.

**Emergencies and overdoses****What factors may result in hypoglycemia (low blood sugar)?**

If you take too much insulin, miss a meal or exercise more than usual your blood sugar may become too low (i.e. hypoglycemia).

The first **symptoms of hypoglycemia** may come on suddenly. They may include: cold sweat, cool pale skin, fatigue, drowsiness, nervousness or tremor, feelings of anxiety, unusual tiredness and weakness, confusion, difficulty concentrating, excessive hunger, changes in vision, headache and nausea and palpitation.

**What to do in case of hypoglycemia?**

If you experience any of the symptoms mentioned above, you should immediately take sugar or a sugar-containing product. Therefore, always carry a few lumps of sugar, candies, biscuits or fruit juice with you.

Your relatives, friends and close work-mates should know that you have diabetes and how they can help you if you get a severe hypoglycemic reaction. They must be aware that an unconscious person should not be given anything to eat or drink (as choking is possible), but should be turned on their side and medical assistance sought immediately.

You may recover from unconsciousness more quickly if you are given an injection of the hormone glucagon by a person who has been instructed in how to use it. If glucagon is injected, you should also be given sugar, a product containing sugar or glucose by mouth as soon as you are conscious again.

If you do not respond to glucagon treatment, you will have to be treated in a hospital. See your doctor if you have had repeated hypoglycemic reactions, or one leading to unconsciousness, as your insulin dose may need to be adjusted.

If severe hypoglycemia is not treated, it can cause temporary or permanent brain damage or death.

**What factors may result in hyperglycemia (high blood sugar)?**

If you are ill with fever or if you eat much more than usual and repeatedly take less insulin than you need, your blood sugar may become unusually high (i.e. result in hyperglycemia).

The **symptoms of unusually high blood sugar levels** will appear gradually. They include: increased urination, thirst, loss of appetite, nausea, vomiting, drowsiness (fatigue), flushed dry skin, dry mouth, and acetone breath.

**What to do in case of hyperglycemia?**

If you recognize any of the symptoms mentioned above, you should test your blood sugar level and your urine for ketones as soon as possible as the symptoms may indicate that you have a condition called ketoacidosis. If hyperglycemia is not treated it can cause diabetic coma or death. You should therefore seek medical advice immediately and possibly take some extra insulin.

**Possible side effects**

**NovoMix® 30** may cause **hypoglycemia** (low blood sugar). See symptoms of hypoglycemia mentioned previously.

Redness, swelling or itching at the injection site (also called **local allergic reactions**) may be experienced by some people. Usually these symptoms disappear within a few weeks during continued use.

If the symptoms do not disappear, spread to other parts of your body or if you suddenly feel sick (i.e. sweat, vomit, have difficulties in breathing, have rapid heart beat, feel dizzy) you should consult your doctor immediately as these reactions may be due to **systemic allergic reactions** which are rare but may be serious.

When you first start your insulin treatment you may suffer from visual disturbances or swelling of the extremities.

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

**Storing NovoMix® 30 Penfill®**

Store **NovoMix® 30 Penfill®** which you are **not using** at 2°C - 10°C preferably in a refrigerator (not too near the freezer compartment). **NovoMix® 30** should never be exposed to heat or direct sunlight and should never be frozen.

**NovoMix® 30 Penfill®** that you **are using** must not be kept in a refrigerator.

**NovoMix® 30 Penfill®** can be used or carried as a spare for up to 4 weeks (not above 30°C).

Keep out of the reach of children.

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

Do not use **NovoMix® 30 Penfill®** if it does not appear uniformly white and cloudy after shaking.

**This summary does not contain all the known information about NovoMix® 30. Talk to your doctor if you have any questions.**