

NovoMix®30 FlexPen®100 units/ml suspension for injection in a pre-filled pen

(30% soluble insulin aspart and 70% insulin aspart crystallised with protamine)

Ref: 2118/260424/1/F

Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine because it contains important information for you

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is NovoMix®30 FlexPen®100 units/ml suspension for injection in a pre-filled pen but will be referred to as NovoMix®30 throughout this leaflet.

What is in this leaflet

1. **What NovoMix®30 is and what it is used for**
2. **What you need to know before you use NovoMix®30**
3. **How to use NovoMix®30**
4. **Possible side effects**
5. **How to store NovoMix®30**
6. **Contents of the pack and other information**

1 What NovoMix®30 is and what it is used for

NovoMix®30 is a modern insulin (insulin analogue) with both a rapid-acting and an intermediate-acting effect, in the ratio 30/70. Modern insulin products are improved versions of human insulin.

NovoMix®30 is used **to reduce the high blood sugar level** in adults, adolescents and children aged 10 years and above with diabetes mellitus (diabetes). Diabetes is a disease where your body does not produce enough insulin to control the level of your blood sugar.
NovoMix®30 will start to lower your blood sugar 10–20 minutes after you inject it, the maximum effect occurs between 1 and 4 hours after the injection, and the effect lasts for up to 24 hours.

In treatment of type 2 diabetes mellitus, NovoMix®30 may be used in combination with tablets for diabetes and/or with injectable antidiabetic products.

2 What you need to know before you use NovoMix®30

Do not use NovoMix®30

- ► If you are allergic to insulin aspart or any of the other ingredients in this medicine (see section 6, *Contents of the pack and other information)*.
- ► If you suspect hypoglycaemia (low blood sugar) is starting, see a) *Summary of serious and very common side effects* in section 4.
- ► In insulin infusion pumps.
- ► If FlexPen®is dropped, damaged or crushed.
- ► If it has not been stored correctly or if it has been frozen, see section 5, *How to store NovoMix®30*.
- ► If the resuspended insulin does not appear uniformly white, cloudy and aqueous.
- ► If after resuspension, clumps of material are present or if solid white particles stick to the bottom or the wall of the cartridge.

If any of these apply, **do not use NovoMix®30.** Talk to your doctor, nurse or pharmacist for advice.

Before using NovoMix®30

- ► Check the label to make sure it is the right type of insulin.
- ► Always use a new needle for each injection to prevent contamination.
- ► Needles and NovoMix®30 FlexPen®must not be shared.
- ► NovoMix®30 FlexPen®is only suitable for injecting under the skin. Speak to your doctor if you need to inject your insulin by another method.

Warnings and precautions
Some conditions and activities can affect your need for insulin. Consult your doctor:

- ► If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- ► If you exercise more than usual or if you want to change your usual diet, as this may affect your blood sugar level.
- ► If you are ill, carry on taking your insulin and consult your doctor.
- ► If you are going abroad, travelling over time zones may affect your insulin needs and the timing hereof.

Skin changes at the injection site
The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area (see section 3, How to use NovoMix®30). Tell your doctor if you notice any skin changes at the injection site. 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.

Children and adolescents

- NovoMix®30 can be used in adolescents and children aged 10 years and above.
- There is limited experience with NovoMix®30 in children aged 6–9 years.
- No data are available for NovoMix®30 in children below 6 years of age.

Other medicines and NovoMix®30
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines affect your blood sugar level and this may mean that your insulin dose has to change. Listed below are the most common medicines which may affect your insulin treatment.

Your blood sugar level may fall (hypoglycaemia) if you take:

- Other medicines for the treatment of diabetes
- Monoamine oxidase inhibitors (MAOI) (used to treat depression)
- Beta-blockers (used to treat high blood pressure)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure)
- Salicylates (used to relieve pain and lower fever)
- Anabolic steroids (such as testosterone)
- Sulfonamides (used to treat infections).

Your blood sugar level may rise (hyperglycaemia) if you take:

- Oral contraceptives (birth control pills)
- Thiazides (used to treat high blood pressure or excessive fluid retention)
- Glucocorticoids (such as 'cortisone' used to treat inflammation)
- Thyroid hormones (used to treat thyroid gland disorders)
- Sympathomimetics (such as epinephrine [adrenaline], salbutamol or terbutaline used to treat asthma)
- Growth hormone (medicine for stimulation of skeletal and somatic growth and pronounced influence on the body's metabolic processes)
- Danazol (medicine acting on ovulation).

Octreotide and lanreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level.

Beta-blockers (used to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognise low blood sugar.

Pioglitazone (tablets used for the treatment of type 2 diabetes)
Some patients with long-standing type 2 diabetes and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. 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).

If you have taken any of the medicines listed here, tell your doctor, nurse or pharmacist.

Drinking alcohol and taking NovoMix®30

- ►If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Pregnancy and breast-feeding

- ►If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. There is limited clinical experience with insulin aspart in pregnancy. Your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of hypoglycaemia, is important for the health of your baby.
- ►There are no restrictions on treatment with NovoMix®30 during breast-feeding.

Ask your doctor, nurse or pharmacist for advice before taking any medicine while pregnant or breast-feeding.

Driving and using machines

► Please ask your doctor whether you can drive a car or operate a machine:
- If you have frequent hypoglycaemia.
- If you find it hard to recognise hypoglycaemia.

If your blood sugar is low or high, it might affect your concentration and ability to react and therefore also your ability to drive or operate a machine. Bear in mind that you could endanger yourself or others.

Important information about some of the ingredients in NovoMix®30
NovoMix®30 contains less than 1 mmol sodium (23 mg) per dose, i.e. NovoMix®30 is essentially 'sodium-free'.

3 How to use NovoMix®30

Dose and when to take your insulin
Always use your insulin and adjust your dose exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure. NovoMix®30 is generally taken immediately before a meal. Eat a meal or snack within 10 minutes of the injection to avoid low blood sugar. When necessary, NovoMix®30 can be given soon after a meal. See *How and where to inject*, below for information.

Do not change your insulin unless your doctor tells you to. 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.

When NovoMix®30 is used in combination with tablets for diabetes and/or with injectable antidiabetic products your dose may have to be adjusted by your doctor.

Use in children and adolescents
NovoMix®30 can be used in adolescents and children aged 10 years and above when premixed insulin is preferred. Limited clinical data exists for children aged 6–9 years. No data are available for NovoMix®30 in children below 6 years of age.

Use in special patient groups
If you have reduced kidney or liver function, or if you are above 65 years of age, you need to check your blood sugar more regularly and discuss changes in your insulin dose with your doctor.

How and where to inject
NovoMix®30 is for **injection under the skin** (subcutaneously). Never inject your insulin directly into a vein (intravenously) or muscle (intramuscularly). NovoMix®30 FlexPen®is only suitable for injecting under the skin. Speak to your doctor if you need to inject your insulin by another method.

With each injection, change the injection site within the particular area of skin that you use. This may reduce the risk of developing lumps or skin pitting (see section 4, *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. The insulin will work more quickly if you inject around the waist. You should always measure your blood sugar regularly.

How to handle NovoMix®30 FlexPen®
NovoMix®30 FlexPen®is a pre-filled, colour-coded, disposable pen containing a mixture of rapid-acting and intermediate-acting insulin aspart in the ratio 30/70.

Read carefully the instructions for use included in this package leaflet. You must use the pen as described in the Instructions for use.

Always ensure you use the correct pen before you inject your insulin.

If you take more insulin than you should
If you take too much insulin, your blood sugar gets too low (hypoglycaemia). See a) *Summary of serious and very common side effects* in section 4.

If you forget to take your insulin
If you forget to take your insulin, your blood sugar may get too high (hyperglycaemia). See c) *Effects from diabetes* in section 4.

If you stop taking your insulin
Do not stop taking your insulin without speaking with a doctor, who will tell you what needs to be done. This could lead to very high blood sugar (severe hyperglycaemia) and ketoacidosis. See c) *Effects from diabetes* in section 4.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

a) Summary of serious and very common side effects
Low blood sugar (hypoglycaemia) is a very common side effect. It may affect more than 1 in 10 people.

Low blood sugar may occur if you:
- Inject too much insulin.
- Eat too little or miss a meal.
- Exercise more than usual.
- Drink alcohol (see *Drinking alcohol and taking NovoMix®30* in section 2).

Signs of low blood sugar: Cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

Severe low blood sugar can lead to unconsciousness. If prolonged severe low blood sugar is not treated, it can cause brain damage (temporary or permanent) and even death. 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 glucose or a sugar snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital.

What to do if you experience low blood sugar:
► If you experience low blood sugar, eat glucose tablets or another high sugar snack (e.g. sweets, biscuits, fruit juice). Measure your blood sugar if possible and rest. Always carry glucose tablets or high sugar snacks with you, just in case.
► When the symptoms of low blood sugar have disappeared or when your blood sugar level is stabilised, continue insulin treatment as usual.
► If you have such low blood sugar that it makes you pass out, if you have had the need for an injection of glucagon, or if you have experienced many incidents of low blood sugar, talk to a doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

Tell relevant people that you have diabetes and what the consequences may be, including the risk of passing out (becoming unconscious) due to low blood sugar. Let them know that if you pass out, they must turn you on your side and get medical help straight away. They must not give you any food or drink because you may choke.

Serious allergic reactions to NovoMix®30 or one of its ingredients (called a systemic allergic reaction) is a very rare side effect, but it can potentially be life-threatening. It may affect less than 1 in 10,000 people.

Seek medical advice immediately:
- If signs of allergy spread to other parts of your body.
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy.

►If you notice any of these signs, seek medical advice immediately.

Skin changes at the injection site: If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (may affect less than 1 in 100 people). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). 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.

b) List of other side effects

Uncommon side effects
May affect less than 1 in 100 people.

Signs of allergy: Local allergic reactions (pain, redness, hives, inflammation, bruising, swelling and itching) at the injection site may occur. These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor.

Vision problems: When you first start your insulin treatment, it may disturb your vision, but the disturbance is usually temporary.

Swollen joints: When you start taking insulin, water retention may cause swelling around your ankles and other joints. Normally, this soon disappears. If not, contact your doctor.

Diabetic retinopathy (an eye disease related to diabetes which can lead to loss of vision): If you have diabetic retinopathy and your blood sugar level improves very fast, the retinopathy may get worse. Ask your doctor about this.

Rare side effects
May affect less than 1 in 1,000 people.

Painful neuropathy (pain due to nerve damage): If your blood sugar level improves very fast, you may get nerve related pain. This is called acute painful neuropathy and is usually transient.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

c) Effects from diabetes

High blood sugar (hyperglycaemia)
High blood sugar may occur if you:
- Have not injected enough insulin.
- Forget to take your insulin or stop taking insulin.
- Repeatedly take less insulin than you need.
- Get an infection and/or a fever.
- Eat more than usual.
- Exercise less than usual.

Warning signs of high blood sugar:
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.

What to do if you experience high blood sugar:
► If you get any of the above signs: test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.
► These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). If you do not treat it, this could lead to diabetic coma and eventually death.

5 How to store NovoMix®30

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the FlexPen®label and carton after 'EXP'. The expiry date refers to the last day of that month.

Always keep the pen cap on your FlexPen®when you are not using it, in order to protect it from light. NovoMix®30 must be protected from excessive heat and light.

Before opening: NovoMix®30 FlexPen®that is not being used must be stored in the refrigerator at 2°C to 8°C, away from the cooling element. Do not freeze.

Before you use NovoMix®30 FlexPen®, remove it from the refrigerator. It is recommended to resuspend the insulin as instructed every time you use a new pen. See Instructions for use.

During use or when carried as a spare: NovoMix®30 FlexPen®that is being used or carried as a spare should not be kept in the refrigerator. You can carry it with you and keep it at room temperature (below 30°C) for up to 4 weeks.

If your medicine becomes discoloured or shows any sign of deterioration, ask your pharmacist who will advise you on what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What NovoMix®30 contains
- The active substance is insulin aspart. NovoMix®30 is a mixture consisting of 30% soluble insulin aspart and 70% insulin aspart crystallised with protamine. 1 ml contains 100 units of insulin aspart. Each pre-filled pen contains 300 units of insulin aspart in 3 ml suspension for injection.
- The other ingredients are glycerol, phenol, metacresol, zinc chloride, disodium phosphate dihydrate, sodium chloride, protamine sulfate, hydrochloric acid, sodium hydroxide and water for injections.

What NovoMix®30 looks like and contents of the pack
NovoMix®30 is presented as a suspension for injection in a pre-filled pen. The cartridge contains a glass ball to facilitate resuspension. After resuspension, the liquid should appear uniformly white, cloudy and aqueous. Do not use the insulin, if it does not look uniformly white, cloudy and aqueous after resuspension.
Pack size of 5x3ml. The suspension is cloudy, white and aqueous.

Manufacturer and Licence Holder
The manufacturer can be identified by the batch number printed on the slip of the carton and on the label:
- If the second and third characters are S6, P5, K7, R7, VG, FG or ZF, the manufacturer is Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.
- If the second and third characters are H7 or T6, the manufacturer is Novo Nordisk Production SAS, 45 Avenue d'Orléans, F-28000 Chartres, France.

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