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NovoMix (*insulin aspart*)

An overview of NovoMix and why it is authorised in the EU

What is NovoMix and what is it used for?

NovoMix is a range of insulin medicines used to treat patients who have diabetes and need insulin to keep their blood glucose (sugar) level controlled. NovoMix medicines contain the active substance insulin aspart (100 units/ml) combined with protamine to make it longer acting. It is available as:

- NovoMix 30 (30% insulin aspart and 70% insulin aspart protamine)
- NovoMix 50 (50% insulin aspart and 50% insulin aspart protamine)
- NovoMix 70 (70% insulin aspart and 30% insulin aspart protamine).

NovoMix 30 can be used in patients from 10 years of age. NovoMix 50 and NovoMix 70 can only be used in adults (from 18 years of age).

How is NovoMix used?

NovoMix medicines can only be obtained with a prescription and are available in cartridges and prefilled pens. The medicines are given by injection under the skin of the abdomen (belly), thigh, upper arm or buttock.

The dose of NovoMix depends on the patient's blood glucose levels, which should be tested regularly to find an effective dose. The medicines are normally given shortly before a meal, but can be given just after a meal if necessary.

In type 2 diabetes, NovoMix can be given on its own or together with other diabetes medicines.

Patients can inject themselves with NovoMix once they have been trained appropriately.

For more information about using NovoMix, see the package leaflet or contact your doctor or pharmacist.

How does NovoMix work?

Diabetes is a disease in which the body does not produce enough insulin or is not able to use insulin effectively, resulting in raised levels of glucose in the blood. NovoMix is a replacement insulin.

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The active substance in NovoMix, insulin aspart, is absorbed faster by the body than natural insulin and it starts working soon after it is injected. NovoMix contains both insulin aspart and a longer-acting form called insulin aspart protamine, which is absorbed more slowly and works for longer.

NovoMix acts in the same way as naturally produced insulin and helps glucose from the blood to enter cells. By restoring the effects of insulin, the level of blood glucose is controlled better and the symptoms and complications of diabetes are reduced.

What benefits of NovoMix have been shown in studies?

Several studies have found NovoMix to be effective either at reducing glycosylated haemoglobin (HbA1c, a substance which indicates how well blood glucose is controlled over 12 to 28 weeks) or in reducing blood glucose levels after a meal.

NovoMix 30 gave almost identical results as biphasic human insulin 30 (a combination of 30% rapid-acting and 70% intermediate-acting human insulin) in 294 adults with type 1 diabetes (when the pancreas cannot produce insulin) or type 2 diabetes (when the body is unable to use insulin effectively), and in 167 patients aged between 10 and 17 years with type 1 diabetes. NovoMix 50 and NovoMix 70 gave better overall control of blood glucose than biphasic human insulin 30 in 664 patients with type 1 or type 2 diabetes.

In 5 studies involving a total of around 1,350 patients with type 2 diabetes, adding NovoMix medicines to other diabetes medicines (metformin, sulphonylureas, pioglitazone and liraglutide) also resulted in better control of blood glucose than the other medicines or NovoMix used alone.

What are the risks associated with NovoMix?

The most common side effect with NovoMix (which may affect more than 1 in 10 people) is hypoglycaemia (low blood glucose levels).

For the full list of side effects and restrictions of NovoMix, see the package leaflet.

Why is NovoMix authorised in the EU?

The European Medicines Agency decided that NovoMix's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of NovoMix?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of NovoMix have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of NovoMix are continuously monitored. Side effects reported with NovoMix are carefully evaluated and any necessary action taken to protect patients.

Other information about NovoMix

NovoMix received a marketing authorisation valid throughout the EU on 1 August 2000.

Further information on NovoMix can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/novomix.

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