European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NOVONORM

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is NovoNorm?

NovoNorm is a medicine that contains the active substance repaglinide. It is available as round tablets (white: 0.5 mg; yellow: 1 mg; peach: 2 mg).

What is NovoNorm used for?

NovoNorm is used in patients who have type 2 diabetes (non-insulin-dependent diabetes). It is used together with diet and exercise to lower blood glucose (sugar) levels in patients whose hyperglycaemia (high blood glucose levels) cannot be controlled by diet, weight reduction and exercise. NovoNorm may also be used with metformin (another anti-diabetes medicine) in type 2 diabetes patients whose blood glucose levels are not satisfactorily controlled on metformin alone.

How is NovoNorm used?

NovoNorm is taken before meals, normally up to 15 minutes before each main meal. The dose is adjusted to give the best control. A doctor should regularly test the patient's blood glucose to find the lowest effective dose. NovoNorm can also be used for type 2 diabetes patients whose blood glucose levels are usually controlled well on diet, but are experiencing temporary loss of blood glucose control.
The recommended starting dose is 0.5 mg. This dose may need to be increased after one or two weeks. If patients are transferred from another anti-diabetes medicine, the recommended starting dose is 1 mg.
NovoNorm is not recommended for patients below 18 years of age because of a lack of information on safety and effectiveness in this age group.

How does NovoNorm work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. NovoNorm helps the pancreas to produce more insulin at mealtimes and is used to control type 2 diabetes.

How has NovoNorm been studied?

NovoNorm has been studied in 45 'clinical pharmacology' studies (looking at how the medicine works in the body) and 16 clinical trials (looking at its effects in treating type 2 diabetes patients). A total of 2,156 patients received NovoNorm in all trials combined.

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The main studies compared NovoNorm with other medicines used in type 2 diabetes (glibenclamide, glipizide or gliclazide). Another study looked at the effect of adding NovoNorm to metformin. The studies measured the level of a substance in the blood called glycosylated haemoglobin (HbA1c) which gives an indication of how well the blood glucose is controlled.

What benefit has NovoNorm shown during the studies?
In all studies, NovoNorm led to a decrease in the level of HbA1c, which showed that blood glucose levels had been controlled to a similar level to that seen with the comparator medicines. In the study where NovoNorm was added to metformin, the effects of the two medicines were at least additive (equivalent to the effects of the two medicines added together).
NovoNorm produced a good insulin response to a meal within 30 minutes of being dosed in type 2 diabetes patients, leading to a blood glucose-lowering effect throughout the meal. The raised insulin levels returned to normal after the meal.

What is the risk associated with NovoNorm?
The most common side effects with NovoNorm (seen in between 1 and 10 patients in 100) are hypoglycaemia (low blood glucose levels), abdominal (tummy) pain and diarrhoea. For the full list of all side effects reported with NovoNorm, see the Package Leaflet.
NovoNorm should not be used in people who may be hypersensitive (allergic) to repaglinide or any of the other ingredients. It should also not be used in patients with type 1 (insulin-dependent) diabetes who do not have any 'C-peptide' in their blood (a marker of type 1 diabetes). It should also not be used in patients with diabetic ketoacidosis (high levels of ketones [acids] in the blood), in patients with severe liver problems or in patients also taking gemfibrozil (a medicine used to reduce blood fat levels). NovoNorm doses may also need to be adjusted when given with some medicines used in heart conditions, and to treat pain, asthma and other conditions. The full list of these medicines is available in the Package Leaflet.

Why has NovoNorm been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that NovoNorm's benefits are greater than its risks for the treatment of type 2 diabetes. The Committee recommended that NovoNorm be given marketing authorisation.

Other information about NovoNorm:
The European Commission granted a marketing authorisation valid throughout the European Union for NovoNorm to Novo Nordisk A/S on 17 August 1998. The marketing authorisation was renewed on 17 August 2003 and on 17 August 2008.

The full EPAR for NovoNorm is available here.

This summary was last updated in 07-2008.