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EPAR summary for the public

Eperzan

albiglutide

This is a summary of the European public assessment report (EPAR) for Eperzan. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Eperzan.

For practical information about using Eperzan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Eperzan and what is it used for?

Eperzan is a diabetes medicine that contains the active substance albiglutide. It is used in adults with type 2 diabetes to control their blood glucose (sugar) level.

Eperzan can be used on its own in patients whose blood glucose levels are not satisfactorily controlled on diet and exercise alone and who cannot take metformin (another diabetes medicine).

Eperzan can also be used as an 'add-on' to other diabetes medicines, including insulin, when these medicines together with exercise and diet are not providing adequate control of blood glucose.

How is Eperzan used?

Eperzan is available as prefilled pens that contain a powder (30 and 50 mg) and solvent for making a solution to be injected under the skin. It can only be obtained with a prescription.

Patients inject the medicine themselves (after suitable training) under the skin in the abdomen, thigh or the upper arm. The recommended dose is 30 mg injected once a week, though this may be increased by their doctor to 50 mg depending on the effects on their blood sugar levels.

When used in combination with a sulphonylurea or insulin, the dose of the sulphonylurea or insulin may need to be lowered to avoid hypoglycaemia (low blood sugar levels).

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How does Eperzan 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. The active substance in Eperzan, albiglutide, is a 'GLP-1 receptor agonist'. It works by attaching to receptors for a substance called glucagon-like peptide 1 (GLP-1), which are found on the surface of the cells in the pancreas and stimulate them to release insulin. When Eperzan is injected, albiglutide reaches the receptors in the pancreas and activates them. This causes the release of insulin and helps to reduce blood glucose levels and control type 2 diabetes.

What benefits of Eperzan have been shown in studies?

The benefits of Eperzan were studied in over 5,000 patients with type 2 diabetes in which Eperzan was compared with placebo (a dummy treatment) or with other diabetes medicines when used as an add-on to various combination treatments or when used alone.

The main measure of effectiveness was the change in the level of glycosylated haemoglobin (HbA1c), which is the percentage of haemoglobin in the blood that has glucose attached. HbA1c gives an indication of how well the blood glucose is controlled.

Eperzan was more effective than placebo at reducing HbA1c levels when used alone, and was more effective than the diabetes medicines sitagliptin and glimepiride and comparable to insulin glargine and insulin lispro when used as add-on to other treatments. Two other medicines, pioglitazone and liraglutide, were found to be more effective as an add-on than Eperzan.

Overall, the effect of Eperzan in reducing HbA1c varied between 0.6 and 0.9%. This was considered to be clinically meaningful and there were three-year data showing that this effect was maintained during long-term treatment.

What are the risks associated with Eperzan?

The most common side effects with Eperzan, affecting more than 1 in 20 people, are diarrhoea, nausea (feeling sick) and reactions at the injection site including rash, redness, or itching. For the full list of all side effects and restrictions, see the package leaflet.

Why is Eperzan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Eperzan's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP noted that the effects of Eperzan in controlling blood glucose were shown to be clinically meaningful when the medicine was used alone and when compared with other medicines in combination treatments. The risks seen with the medicine were similar to those of other medicines in its class and Eperzan has the advantage of being given only once a week.

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

A risk management plan has been developed to ensure that Eperzan is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Eperzan, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Eperzan

The European Commission granted a marketing authorisation valid throughout the European Union for Eperzan on 28 March 2014.

The full EPAR and risk management plan summary for Eperzan can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Eperzan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2014.