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EPAR summary for the public

Victoza

liraglutide

This is a summary of the European public assessment report (EPAR) for Victoza. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Victoza.

What is Victoza?

Victoza is a solution for injection that contains the active substance liraglutide. It is available in pre-filled pens (6 mg/ml).

What is Victoza used for?

Victoza is used in adults who have type 2 diabetes to control their blood glucose (sugar) level.

Victoza is used:

- on its own when exercise and diet are not providing adequate control of blood glucose and when use of metformin (another medicine for type 2 diabetes) is not recommended;
- as an 'add-on' to other diabetes medicines and/or basal insulin, when these medicines together with exercise and diet are not providing adequate control of blood glucose. Basal insulin is a long-acting background insulin.

The medicine can only be obtained with a prescription.

How is Victoza used?

Victoza is given by the patient once a day by injection under the skin in the abdomen, thigh or upper arm. It is given independent of meals and preferably at the same time each day.

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The starting dose of Victoza is 0.6 mg. After at least one week, the dose is increased to 1.2 mg. In some patients, the dose can be further increased to 1.8 mg one week later to achieve better control of blood glucose.

When Victoza is added to existing treatment containing metformin or a thiazolidinedione, the doses of these medicines do not have to be changed. When Victoza is added to treatment with a sulphonylurea or insulin, the doctor should consider lowering the dose of the other medicine to reduce the risk of having hypoglycaemia (low blood glucose).

How does Victoza work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose (sugar) in the blood or when the body is unable to use insulin effectively. The active substance in Victoza, liraglutide, is an 'incretin mimetic'. This means that it acts in the same way as incretins (hormones produced in the gut) by increasing the amount of insulin released by the pancreas in response to food. This helps with the control of blood glucose levels.

How has Victoza been studied?

Victoza was investigated in six main studies involving 4,155 adults with type 2 diabetes:

- one 'monotherapy' study, comparing Victoza on its own with glimepiride (a sulphonylurea);
- two 'dual therapy' studies comparing Victoza plus metformin or Victoza plus glimepiride with metformin or glimepiride taken with a placebo (a dummy treatment);
- two 'triple therapy' studies comparing Victoza with metformin and either glimepiride or rosiglitazone (a thiazolidinedione), with treatments that included placebo or another anti-diabetes medicine instead of Victoza;
- another triple therapy study comparing Victoza with a single dose of a short-acting insulin, insulin aspart, when added to treatment with basal insulin plus metformin.

The main measure of effectiveness was the change in the amount of a substance in the blood called glycosylated haemoglobin (HbA1c) after six months or one year. HbA1c gives an indication of how well the blood glucose is controlled.

What benefit has Victoza shown during the studies?

Victoza used on its own was more effective at controlling blood glucose than glimepiride. Results from the monotherapy study show that Victoza at a dose of 1.2 mg reduced HbA1c by 0.8 percentage points, whereas Victoza at a dose of 1.8 mg led to reductions of 1.1 percentage points. This compares with a reduction of 0.5 percentage points with glimepiride.

Combinations containing Victoza were more effective at controlling blood glucose than combinations without the medicine. Dual therapies containing Victoza (0.6 mg, 1.2 mg or 1.8 mg) and metformin or a sulphonylurea led to reductions in HbA1c of around 1 percentage point compared with no reduction without Victoza. Triple therapies containing Victoza (1.2 mg or 1.8 mg) and metformin and either a sulphonylurea or a thiazolidinedione led to a reduction of between 1.3 and 1.5 percentage points compared with a reduction equal or less than 0.5 points without Victoza. Similarly, adding Victoza to treatment with basal insulin plus metformin reduced HbA1c by 0.7 percentage points, compared with 0.4 points when a dose of insulin aspart was added.

What is the risk associated with Victoza?

The most common side effects with Victoza (seen in more than 1 patient in 10) are nausea and diarrhoea. For the full list of all side effects and restrictions with Victoza, see the package leaflet.

Why has Victoza been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Victoza's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Victoza

The European Commission granted a marketing authorisation valid throughout the European Union for Victoza on 30 June 2009.

The full EPAR for Victoza 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 Victoza, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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