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Victoza (*liraglutide*)

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

What is Victoza and what is it used for?

Victoza is a medicine used in addition to diet and exercise in adults and children from 10 years of age who have type 2 diabetes.

Victoza is used:

- on its own when use of metformin (another medicine for type 2 diabetes) is not recommended;
- as an 'add-on' to other diabetes medicines.

Victoza contains the active substance liraglutide.

How is Victoza used?

Victoza is a solution for injection available in pre-filled pens (6 mg/ml). 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.

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, thiazolidinedione or a sodium-glucose cotransporter 2 inhibitor (SGLT2i), 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).

The medicine can only be obtained with a prescription. For more information about using Victoza, see the package leaflet or contact your doctor or pharmacist.

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

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(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.

What benefits of Victoza have been shown in studies?

Victoza was effective at controlling blood glucose in six main studies involving 4,289 adults and children with type 2 diabetes. In these studies, the main measure of effectiveness was the reduction in the amount of a substance in the blood called glycosylated haemoglobin (HbA1c) after six months or one year of treatment. HbA1c gives an indication of how well the blood glucose is controlled.

In one 'monotherapy' study in adults, Victoza on its own was compared with glimepiride (a sulphonylurea). Victoza used on its own was more effective at controlling blood glucose than glimepiride. Results from this 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 compared with a reduction of 0.5 percentage points with glimepiride.

In two 'dual therapy' adult studies, Victoza plus metformin or Victoza plus glimepiride were compared with metformin or glimepiride taken with a placebo (a dummy treatment). Combinations containing Victoza were more effective at controlling blood glucose than combinations without the medicine. Dual therapies containing Victoza and metformin or glimepiride led to reductions in HbA1c of around 1 percentage point compared with no reduction without Victoza.

In two 'triple therapy' adult studies, Victoza with metformin and either glimepiride or rosiglitazone (a thiazolidinedione) were compared with treatments that included placebo or another anti-diabetes medicine instead of Victoza. The triple therapies containing Victoza 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.

In another triple therapy adult study, Victoza was compared with a single dose of a short-acting insulin, insulin aspart, when added to treatment with basal insulin (a long-acting insulin) plus metformin. Adding Victoza to treatment with basal insulin plus metformin reduced HbA1c by 0.7 percentage points, compared with 0.4 points when adding Victoza to insulin aspart.

In a study in 134 adolescents and children from 10 years of age Victoza was found to be more effective than placebo. In this study, HbA1c fell by 0.64 percentage points in patients treated with Victoza while HbA1c increased by 0.42 points in patients treated with placebo.

In addition to the above studies, Victoza in adults was shown to be effective in reducing adverse cardiovascular (heart and blood vessels) effects. The study involved 9,340 patients with type 2 diabetes who already had cardiovascular disease (such as angina, heart attack or stroke). The main measure of effectiveness was the occurrence of one of three major cardiovascular events: stroke, heart attack or death caused by cardiovascular disease. Victoza was compared with placebo and all patients also received standard care. Patients were followed up on average for 3.8 years. Cardiovascular events occurred in 13% (608 out of 4668) of patients taking Victoza compared with 14.9% (694 out of 4672) of patients taking placebo.

What are the risks associated with Victoza?

The most common side effects with Victoza (seen in more than 1 patient in 10) are nausea and diarrhoea. These side effects usually pass after a few days or weeks of treatment. For the full list of side effects and restrictions with Victoza, see the package leaflet.

Why is Victoza authorised in the EU?

The European Medicines Agency 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 been included in the summary of product characteristics and the package leaflet.

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

Other information about Victoza

Victoza received a marketing authorisation valid throughout the EU on 30 June 2009.

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

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