EMA/441132/2013
EMEA/H/C/001039

EPAR summary for the public

Onglyza

saxagliptin

This is a summary of the European public assessment report (EPAR) for Onglyza. 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 Onglyza.

What is Onglyza?

Onglyza is a medicine that contains the active substance saxagliptin. It is available as tablets (2.5 mg and 5 mg).

What is Onglyza used for?

Onglyza is used in adults who have type 2 diabetes to control their blood glucose (sugar) level. It is used on its own, in addition to diet and exercise, in patients who cannot take metformin and whose glucose levels are not satisfactorily controlled by diet and exercise alone. It is also used in addition to diet and exercise and together with other antidiabetes medicines in the following ways:

- with metformin in patients whose glucose levels are not satisfactorily controlled on metformin;
- with a sulphonylurea in patients whose glucose levels are not satisfactorily controlled on sulphonylurea and in whom treatment with metformin is not considered appropriate;
- with a thiazolidinedione in patients whose glucose levels are not satisfactorily controlled on thiazolidinedione;
- with insulin (with or without metformin) in patients whose glucose levels are not satisfactorily controlled on insulin (with or without metformin);
- with metformin and a sulphonylurea in patients whose blood glucose is not adequately controlled by combined metformin and sulphonylurea treatment.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The medicine can only be obtained with a prescription.

How is Onglyza used?

The recommended dose of Onglyza is 5 mg taken once a day, at any time of the day. The dose of Onglyza should be reduced to 2.5 mg once a day in patients with moderate or severe renal problems. If used in combination with insulin or a sulphonylurea the dose of these medicines may need to be lowered, to reduce risk of hypoglycaemia (low blood sugar levels).

How does Onglyza 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 Onglyza, saxagliptin, is a dipeptidyl peptidase 4 (DPP-4) inhibitor. It works by blocking the breakdown of 'incretin' hormones in the body. These hormones are released after a meal and stimulate the pancreas to produce insulin. By increasing levels of incretin hormones in the blood, saxagliptin stimulates the pancreas to produce more insulin when blood glucose levels are high. Saxagliptin does not work when the blood glucose is low. Saxagliptin also reduces the amount of glucose made by the liver, by increasing insulin levels and decreasing the levels of the hormone glucagon. Together, these processes reduce blood glucose levels and help to control type 2 diabetes.

How has Onglyza been studied?

Onglyza was investigated in ten main studies involving over 5,000 adults with type 2 diabetes.

Four studies involving a total of 2,531 patients looked at Onglyza when added to metformin, a thiazolidinedione, a sulphonylurea, or insulin with or without metformin, comparing its effect to that of placebo (a dummy treatment). A fifth study in 257 patients compared Onglyza with placebo when added to metformin and a sulphonylurea.

Five additional studies looked at Onglya given on its own, with four studies comparing Onglyza with placebo and another comparing Onglyza with metformin in patients who had not previously received substantial treatment with antidiabetes medicines.

The main measure of effectiveness was the change in the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled. HbA1c levels were measured after 24 weeks.

What benefit has Onglyza shown during the studies?

Onglyza was more effective than placebo at controlling blood glucose, when used as an 'add-on' in patients in whom previous treatment had failed.

In patients who took Onglyza in addition to metformin, HbA1c levels had fallen by around 0.7% after 24 weeks (from around 8.1% to around 7.4%) compared with an increase of around 0.1% in patients taking placebo. For patients who took Onglyza with a sulphonylurea and a thiazolidinedione, HbA1c levels fell by around 0.6% and 0.9%, respectively, compared with an increase of around 0.1% and a decrease of around 0.3%, respectively, in patients who took placebo. For patients who took Onglyza in addition to insulin (with or without metformin), HbA1c levels fell by around 0.7%, compared with a decrease of around 0.3% in patients who took placebo. For patients who took Onglyza with metformin and a sulphonylurea, a reduction in HbA1c levels of 0.7% was seen, compared with a reduction of 0.1% in patients who were given placebo in place of Onglyza.

The studies with Onglyza on its own showed that, on average, in patients given Onglyza HbA1c levels fell by around 0.5% more than in patients given placebo.

The results of study with Onglyza plus metformin in patients who had not previously received substantial treatment with antidiabetes medicines were not considered to be clinically relevant and the company withdrew its application for the use of Onglyza as an initial combination medicine in previously untreated patients.

What is the risk associated with Onglyza?

The most common side effects with Onglyza (seen in between 1 and 10 patients in 100) are upper respiratory tract infection (colds), urinary tract infection (infection of the structures that carry urine), gastroenteritis (inflammation of the stomach and gut), sinusitis (inflammation of the sinuses), headache, vomiting and mild to moderate peripheral oedema (swelling, especially of the ankles and feet) in patients taking Onglyza with a thiazolidinedione. For the full list of all side effects reported with Onglyza, see the package leaflet.

Onglyza must not be used in people who are hypersensitive (allergic) to saxagliptin, any of the other ingredients or who have ever had a serious allergic reaction to any DPP-4 inhibitor.

Why has Onglyza been approved?

The CHMP decided that Onglyza's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Onglyza

The European Commission granted a marketing authorisation valid throughout the European Union for Onglyza on 1 October 2009.

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

This summary was last updated in 08-2013.