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EPAR summary for the public

Onglyza

saxagliptin

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

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

What is Onglyza and what is it used for?

Onglyza is a diabetes medicine used with diet and exercise to treat adults with type 2 diabetes to control their blood glucose (sugar) level. It is used either on its own in patients who cannot take metformin (another diabetes medicine) or as 'add-on' to other diabetes medicines, including insulin.

Onglyza contains the active substance saxagliptin.

How is Onglyza used?

Onglyza is available as tablets (2.5 and 5 mg) and can only be obtained with a prescription. The recommended dose is 5 mg once a day. The dose of Onglyza should be reduced to 2.5 mg once a day in patients with moderate or severe kidney problems. If used in combination with a sulphonylurea (medicines that make the body produce insulin) or insulin, the dose of these medicines may need to be reduced to avoid hypoglycaemia (low blood sugar levels).

How does Onglyza work?

In type 2 diabetes, the pancreas does not make enough insulin to control the level of glucose in the blood or the body is unable to use insulin effectively. This leads to high levels of glucose in the blood.

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

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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.

What benefits of Onglyza have been shown in studies?

Saxagliptin, the active substance in Onglyza, has been shown to be more effective than placebo (a dummy treatment) at controlling blood glucose in 8 main studies in over 3,900 patients. In these studies saxagliptin was used as an 'add-on' to other diabetes medicines in patients in whom previous treatment had failed. The main measure of effectiveness was the reduction in blood levels of a substance called glycosylated haemoglobin (HbA1c) after 24 weeks of treatment. This gives an indication of how well the blood glucose is controlled. Results showed that:

- In 743 patients not satisfactorily controlled on metformin alone, HbA1c levels fell by around 0.7 percentage points (from around 8.1% to around 7.4%) in patients adding saxagliptin compared with a rise of around 0.1 percentage points in patients adding placebo.
- In 768 patients not satisfactorily controlled on a sulphonylurea, HbA1c levels fell by around 0.6 percentage points in patients adding saxagliptin compared with a rise of around 0.1 percentage points in patients who added placebo.
- In 565 patients not satisfactorily controlled on a thiazolidinedione (diabetes medicines such as pioglitazone and rosiglitazone), HbA1c levels fell by around 0.9 percentage points in patients adding saxagliptin compared with a fall of around 0.3 percentage points in patients who added placebo.
- In 457 patients not satisfactorily controlled on insulin (with or without metformin), HbA1c levels fell by around 0.7 percentage points in patients adding saxagliptin compared with a fall of around 0.3 percentage points in patients adding placebo.
- In 257 patients who took saxagliptin with metformin and a sulphonylurea, HbA1c levels fell by around 0.7 percentage points, compared with a fall of 0.1 percentage points in patients who were given placebo in place of saxagliptin.
- In 534 patients not satisfactorily controlled with metformin alone, adding saxagliptin reduced HbA1c levels by around 0.9 percentage points and adding saxagliptin and dapagliflozin reduced HbA1c levels by 1.5 percentage points. Adding dapagliflozin to metformin reduced HbA1c levels by 1.2 percentage points. HbA1c levels were on average around 9% at the start of the study.
- In 315 patients not satisfactorily controlled with metformin and dapagliflozin, adding saxagliptin to treatment with dapagliflozin and metformin reduced HbA1c levels by 0.5 percentage points, compared with a reduction of 0.2 percentage points when placebo was added to dapagliflozin and metformin. HbA1c levels were around 8% at the start of the study.
- In 320 patients not controlled with metformin and saxagliptin, adding dapagliflozin to saxagliptin and metformin reduced HbA1c levels by 0.8 percentage points, compared with a reduction of 0.1 percentage points when placebo was added to saxagliptin and metformin.

Saxagliptin given on its own has also been shown to be more effective than placebo at controlling blood glucose in four studies: in patients given saxagliptin HbA1c levels fell by around 0.5 percentage points more than in patients given placebo.

A further study compared saxagliptin with metformin in patients who had not previously received substantial treatment with diabetes medicines. However, the results were not considered to be clinically relevant and the company withdrew its application for the use of saxagliptin as an initial combination medicine in previously untreated patients.

What are the risks associated with Onglyza?

The most common side effects with Onglyza (seen in more than 5 patients in 100) are upper respiratory tract infection (nose and throat infection), urinary tract infection and headache. 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 is Onglyza approved?

Onglyza has been shown to be effective at controlling blood glucose levels both on its own and as add-on to other diabetes medicines. Regarding safety, Onglyza is generally well tolerated. The European Medicine Agency therefore decided that Onglyza'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 Onglyza?

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

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 06-2017.