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EPAR summary for the public

Avaglim

rosiglitazone and glimepiride

This document is a summary of the European Public Assessment Report (EPAR) for Avaglim. 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 Avaglim.

What is Avaglim?

Avaglim is a medicine that contains two active substances, rosiglitazone and glimepiride. It is available as triangular tablets (pink: 4 mg rosiglitazone and 4 mg glimepiride; red: 8 mg rosiglitazone and 4 mg glimepiride).

What is Avaglim used for?

Avaglim is used to treat adults who have type 2 diabetes. Avaglim is used in patients who cannot satisfactorily control their blood glucose (sugar) when using an adequate dose of a sulphonylurea (a type of antidiabetes medicine) on its own, and for whom metformin (another antidiabetes medicine) is not suitable.

The medicine can only be obtained with a prescription.

How is Avaglim used?

Avaglim is taken once a day, just before or during a meal, generally breakfast. Doctors must be careful when switching patients who are at risk of developing hypoglycaemia (low blood sugar levels) to Avaglim, such as elderly patients, patients with low weight or those who have been taking certain other medicines.

The patient can start with separate tablets containing only rosiglitazone or a sulphonylurea, before switching to the combination tablet once control is achieved. The dose should start with the

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4-mg/4-mg tablet. The dose can be increased to the 8-mg/4-mg tablets after eight weeks if needed, but this should be done with caution, due to the risk of fluid retention. If the patient develops hypoglycaemia, then a return to separate tablets will be needed so that the dose of glimepiride can be adjusted.

How does Avaglim 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. Avaglim contains two active substances, which have different modes of action:

- rosiglitazone makes cells (fat, muscle and liver) more sensitive to insulin, which means that the body makes better use of the insulin it produces;
- glimepiride is a sulphonylurea: it stimulates the pancreas to produce more insulin.

As a result of the action of both active substances, the blood glucose is reduced and this helps to control type 2 diabetes.

Rosiglitazone has been authorised in the European Union (EU) as Avandia since 2000. It can be used in combination with a sulphonylurea when metformin is not suitable. Glimepiride has been available in the EU since 1995.

How has Avaglim been studied?

Because they have been used in the EU for a number of years, studies of rosiglitazone and glimepiride used on their own were used as the basis for Avaglim. For glimepiride, the information came from scientific publications.

In addition, four studies were carried out, comparing the combination of both active substances to each substance on its own, in patients who had never been treated, as well as in patients whose blood glucose levels were not controlled when treated with only one of the substances. The studies measured the level in the blood of a substance called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

What benefit has Avaglim shown during the studies?

In all four studies, the combination of rosiglitazone and glimepiride was shown to be more effective than either of its components used on its own in lowering the levels of HbA1c.

What is the risk associated with Avaglim?

The most common side effects with Avaglim (seen in more than 1 patient in 10) are hypoglycaemia and oedema (swelling). For the full list of all side effects reported with Avaglim, see the Package Leaflet.

Avaglim should not be used in people who may be hypersensitive (allergic) to rosiglitazone, glimepiride or any of the other ingredients. It must not be used in patients who have heart failure (an inability of the heart to pump enough blood around the body), an ‘acute coronary syndrome’ such as unstable angina (a severe type of chest pain that changes in intensity) or certain types of heart attack, problems with their liver, severe problems with their kidneys, type 1 diabetes, or complications of diabetes (diabetic ketoacidosis or diabetic coma). For the full list of restrictions, see the Package Leaflet.

The doses of Avaglim may need to be adjusted when given with certain other medicines such as gemfibrozil or rifampicin. The full list is available in the Package Leaflet.

Why has Avaglim been approved?

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

Other information about Avaglim:

The European Commission granted a marketing authorisation valid throughout the EU for Avaglim to Smithkline Beecham Ltd. on 27 June 2006. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Avaglim can be found here. For more information about treatment with Avaglim, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2010.