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EPAR summary for the public

Avandia

rosiglitazone

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

What is Avandia?

Avandia is a medicine that contains the active substance rosiglitazone. It is available as tablets (pink: 2 mg; orange: 4 mg; red-brown: 8 mg).

What is Avandia used for?

Avandia is used in adults who have type 2 diabetes, particularly those who are overweight. It is used in addition to diet and exercise.

Avandia is used on its own in patients for whom metformin (another antidiabetes medicine) is not suitable.

Avandia can also be used in combination with metformin in patients who are not satisfactorily controlled on metformin alone, or with a sulphonylurea (another type of antidiabetes medicine) when metformin is not suitable ('dual therapy').

Avandia can also be used with both metformin and a sulphonylurea in patients who are not satisfactorily controlled despite dual therapy by mouth ('triple therapy').

The medicine can only be obtained with a prescription.

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How is Avandia used?

The recommended starting dose of Avandia is 4 mg per day, given as a single dose or in two 2-mg doses. This dose may need to be increased to 8 mg per day after eight weeks if better blood glucose (sugar) control is needed, but this should be done with caution in patients who are also taking a sulphonylurea, due to the risk of fluid retention. The tablets should be swallowed whole with water.

How does Avandia 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 Avandia, rosiglitazone, makes cells (fat, muscle and liver) more sensitive to insulin, which means that the body makes better use of the insulin it produces. As a consequence, the blood glucose is reduced and this helps to control type 2 diabetes.

How has Avandia been studied?

Avandia, used on its own, has been compared with placebo (a dummy treatment), metformin and glibenclamide (a sulphonylurea). It has also been studied in patients who were already using metformin, a sulphonylurea, or both metformin and a sulphonylurea. The studies measured the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

What benefit has Avandia shown during the studies?

Avandia taken alone was more effective than placebo in reducing HbA1c. Combination with other antidiabetes medicines led to further decreases in the level of HbA1c, indicating that blood glucose levels had been further reduced.

What is the risk associated with Avandia?

The most common side effects with Avandia (seen in between 1 and 10 patients in 100) are anaemia (low red blood cell counts) and oedema (swelling), as well as hypercholesterolaemia (high blood cholesterol levels), hypertriglyceridaemia (high blood levels of triglycerides, a type of fat), hyperlipaemia (high blood fat levels), weight increase, increased appetite, cardiac ischaemia (reduced oxygen supply to the heart muscle), constipation, bone fractures (broken bones) and hypoglycaemia (low blood glucose levels). If Avandia is used in combination with other antidiabetes medicines, other side effects may occur. Doctors should monitor patients for fluid retention as this can lead to heart failure (an inability of the heart to pump enough blood around the body). For the full list of all side effects reported with Avandia, see the Package Leaflet.

Avandia should not be used in people who may be hypersensitive (allergic) to rosiglitazone or any of the other ingredients. It must not be used in patients who have heart failure, problems with their liver, an ‘acute coronary syndrome’ such as unstable angina (a severe type of chest pain that changes in intensity) or certain types of heart attack, or complications of diabetes (diabetic ketoacidosis or diabetic precoma).

The doses of Avandia 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 Avandia been approved?

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

Other information about Avandia:

The European Commission granted a marketing authorisation valid throughout the European Union for Avandia to SmithKline Beecham Ltd. on 11 July 2000. After 10 years, the marketing authorisation was renewed for a further five years.

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

This summary was last updated in 05-2010.