

Fact Sheet for AVANDIA® (rosiglitazone maleate)

Indication

AVANDIA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Mechanism of Action

AVANDIA is a thiazolidinedione – a class of oral anti-diabetic agents (more commonly known as glitazones or TZDs) – that improves blood sugar control by directly targeting insulin resistance, an underlying cause of type 2 diabetes, and helps the body respond better to its own natural insulin.

Key Features

- AVANDIA can help the body to respond better to its own natural insulin to reduce the amount of sugar in the blood.
- *As an adjunct to diet and exercise*, AVANDIA helps improve blood sugar control in adults with type 2 diabetes (individual results may vary).
- AVANDIA has been shown to significantly reduce A1c levels. The A1c test provides an average measure of blood sugar control over the previous two to three months.
- AVANDIA is available in a convenient pill form and can be taken either once or twice a day.

Dosing and Administration

- AVANDIA may be taken with or without food.
- The usual starting dose of AVANDIA is 4 mg/day, given as a single dose or in two divided doses.
- The maximum dose of AVANDIA as monotherapy or in combination (except with insulin) is 8 mg/day. Coadministration of AVANDIA and insulin is not recommended.

Important Safety Information

AVANDIA can cause or worsen heart failure. If you have severe heart failure (very poor pumping ability of the heart) you cannot be started on AVANDIA. AVANDIA is also not recommended if you have heart failure with symptoms (such as shortness of breath or swelling) even if these symptoms are not severe.

AVANDIA may increase your risk of other heart problems that occur when there is reduced blood flow to the heart, such as chest pain (angina) or heart attack (myocardial infarction). This risk appeared higher in patients taking medicines called nitrates or insulin.

If you have chest pain or a feeling of chest pressure, you should seek immediate medical attention, regardless of what diabetes medicines you are taking. If you take AVANDIA, tell your doctor right away if you: have swollen legs or ankles, a rapid increase in weight or difficulty breathing, or unusual tiredness; experience changes in vision; become pregnant.

Before taking AVANDIA, review your medical history and tell your doctor if you:

- Have heart failure or other heart problems, or are on any medicines for high blood pressure, high cholesterol or heart failure, or for prevention of heart disease or stroke.
- Take insulin or nitrate medicines.
- Have a type of diabetic eye disease called macular edema.
- Have liver problems or had liver problems while taking REZULIN® (troglitazone).
- Are pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed.

Women taking AVANDIA should know that AVANDIA may increase the risk of pregnancy. More fractures have been observed in women taking AVANDIA. Other possible side effects of AVANDIA include anemia and hypoglycemia. Your doctor should do blood tests to check your liver before you start AVANDIA and during treatment as needed.

Prescription AVANDIA, along with diet and exercise, helps improve blood sugar control in adults with type 2 diabetes.

For more information about AVANDIA, please see [Medication Guide \(http://www.avandia.com/type-2-diabetes-medication-guide.html\)](http://www.avandia.com/type-2-diabetes-medication-guide.html) and full [Prescribing Information, including Boxed WARNING \(http://us.gsk.com/products/assets/us_avandia.pdf\)](http://us.gsk.com/products/assets/us_avandia.pdf).

Manufacturer

GlaxoSmithKline, one of the world's leading research-based pharmaceutical and healthcare companies, is committed to improving the quality of human life by enabling people to do more, feel better and live longer. Additional information about GlaxoSmithKline can be found online at <http://www.gsk.com>.

For more information about AVANDIA, please visit the AVANDIA website at www.avandia.com or call 1-888-825-5249.

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