

## Fact Sheet for AVANDARYL<sup>®</sup> (rosiglitazone maleate and glimepiride)

### **Indication**

AVANDARYL is indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus when treatment with dual rosiglitazone and glimepiride therapy is appropriate.

### **Mechanism of Action and Features**

- AVANDARYL combines two anti-diabetic agents with different, yet complementary, mechanisms of action to improve blood sugar control in patients with type 2 diabetes: rosiglitazone, a member of the thiazolidinedione (TZD) class, and glimepiride, a member of the sulfonylurea class.
- AVANDARYL is a once-daily tablet that provides patients with a convenient way to take their medication.
- Rosiglitazone, a component of AVANDARYL, directly targets insulin resistance, an underlying cause of type 2 diabetes. Rosiglitazone helps the body to respond better to its own natural insulin to reduce the amount of sugar in the blood. Sulfonylureas act primarily by stimulating the release of insulin from the pancreas.

### **Dosing and Administration**

AVANDARYL is a tablet taken by mouth once a day with the first meal of the day. The dosage of AVANDARYL should be determined by the treating physician with respect to a patient's needs and should not exceed the maximum recommended daily dose of 8 mg rosiglitazone and 4 mg glimepiride.

AVANDARYL is available in three tablet strengths of rosiglitazone and glimepiride, respectively: 4 mg/1 mg, 4 mg/2 mg and 4 mg/4 mg.

### **Important Safety Information**

**AVANDARYL can cause or worsen heart failure. If you have severe heart failure (very poor pumping ability of the heart), you cannot be started on AVANDARYL. AVANDARYL 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.**

**Rosiglitazone, one of the medicines in AVANDARYL, 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 AVANDARYL, 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.

AVANDARYL may cause low blood sugar. Lightheadedness, dizziness, shakiness or hunger may mean that your blood sugar is too low. If you have kidney problems, you may need a lower dose of AVANDARYL to reduce problems with low blood sugar. Talk to your doctor if low blood sugar is a problem for you.

**Before taking AVANDARYL, 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<sup>®</sup> (troglitazone).
- Are pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed.

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

Prescription AVANDARYL, along with diet and exercise, helps improve blood sugar control in patients with type 2 diabetes. AVANDARYL is a combination of two drugs - rosiglitazone maleate and glimepiride.

**For more information about AVANDARYL, please see [Medication Guide \(http://www.avandia.com/pdf/AVANDARYL\\_Medication\\_Guide\\_KRL023R0.pdf\)](http://www.avandia.com/pdf/AVANDARYL_Medication_Guide_KRL023R0.pdf) and full [Prescribing Information \(http://us.gsk.com/products/assets/us\\_avandaryl.pdf\)](http://us.gsk.com/products/assets/us_avandaryl.pdf).**

**Manufacturer**

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For more information about AVANDARYL, visit the AVANDARYL website at [www.avandaryl.com](http://www.avandaryl.com) or call 1-888-825-5249.

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