

## Fact Sheet for AVANDAMET® (rosiglitazone maleate and metformin HCl)

### **Indication**

AVANDAMET 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 metformin therapy is appropriate.

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

- AVANDAMET combines two oral antidiabetic 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 metformin HCl, a member of the biguanide class.
- AVANDAMET is one tablet that provides patients with a convenient way to take two diabetes medications, requiring only one prescription.
- Rosiglitazone, a component of AVANDAMET, 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.
- Metformin primarily reduces glucose production by the liver.

### **Dosing and Administration**

The dosage of antidiabetic therapy with AVANDAMET should be individualized on the basis of effectiveness and tolerability while not exceeding the maximum recommended daily dose of 8 mg/2,000 mg.

AVANDAMET is available in four tablet strengths of rosiglitazone/metformin, respectively: 2 mg/500 mg, 4 mg/500 mg, 2mg/1000 mg, and 4mg/1000 mg.

### **Important Safety Information for Avandamet**

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

**A small number of people who have taken metformin, another medicine in AVANDAMET, have developed a rare yet serious condition called lactic acidosis (a buildup of lactic acid in the blood) that can cause death. You have a higher chance of getting lactic acidosis if you have kidney problems; have liver problems; drink alcohol very often or excessively; get dehydrated, as when you are sick with a fever, vomiting or diarrhea; or you are going to have surgery. Tell your doctor if you have any of these problems before or while taking AVANDAMET. You should not take AVANDAMET if you have kidney problems or metabolic acidosis. Tests should be used to check your kidneys and liver before and while taking AVANDAMET. If you are taking medicines for heart failure, you may be at increased risk of lactic acidosis.**

Call your doctor right away if you feel any of the following, which may be signs of lactic acidosis: very weak or tired; you have unusual (not normal) muscle pain; you have stomach pains; you have trouble breathing; you feel dizzy or lightheaded; or you have a slow or irregular heartbeat.

**Before taking AVANDAMET**, 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 kidney problems.
- Are going to have dye injected into a vein for an X-ray, CAT scan, heart study, or other type of scanning.
- Drink a lot of alcohol.
- Develop a serious condition such as a heart attack, severe infection, or a stroke.
- Are 80 years of age or older.
- 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 AVANDAMET should know that AVANDAMET may increase the risk of pregnancy. More fractures have been observed in women taking AVANDAMET. Other possible side effects of AVANDAMET include anemia, hypoglycemia, diarrhea, nausea, and upset stomach. Your doctor should do blood tests to check your liver before you start AVANDAMET and during treatment as needed.

Prescription AVANDAMET, along with diet and exercise, helps improve blood sugar control in patients with type 2 diabetes. It is a combination of two drugs – rosiglitazone maleate and metformin HCl.

**For more information about AVANDAMET, please see [Medication Guide \(http://www.avandia.com/pdf/AVANDAMET\\_Medication\\_Guide\\_KMT059R0.pdf\)](http://www.avandia.com/pdf/AVANDAMET_Medication_Guide_KMT059R0.pdf) and full [Prescribing Information \(http://us.gsk.com/products/assets/us\\_avandamet.pdf\)](http://us.gsk.com/products/assets/us_avandamet.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 AVANDAMET, please visit the AVANDAMET website at [www.avandamet.com](http://www.avandamet.com) or call 1-888-825-5249.

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