

PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

**PATIENT INFORMATION****AVANDAMET<sup>®</sup> (ah-VAN-duh-met)****Rosiglitazone Maleate and Metformin Hydrochloride Tablets**

Read this information carefully before you start taking AVANDAMET and read the information you get each time you get more AVANDAMET. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about AVANDAMET, ask your doctor. Only your doctor can determine if AVANDAMET is right for you.

**What is AVANDAMET?**

AVANDAMET is a medicine used, along with diet and exercise, to treat type 2 (“adult-onset”) diabetes (“high sugar”). This is also called non-insulin-dependent diabetes mellitus. People who have type 2 diabetes do not make enough insulin or do not respond normally to the insulin their bodies make. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems including kidney damage, amputation and blindness. Diabetes is also closely linked to heart disease. The main goal of treating diabetes is to lower your blood sugar to a normal level. Studies have shown that controlling blood sugar may help prevent or delay complications of diabetes such as heart disease, kidney disease or blindness.

High blood sugar can be lowered by diet and exercise, by a number of medicines taken by mouth, and by insulin shots. AVANDAMET combines two sugar- (glucose) lowering medicines, rosiglitazone and metformin, in one tablet. Metformin works mainly by decreasing the production of sugar by your liver. Rosiglitazone helps your body respond better to its natural insulin and does not cause your body to make more insulin. These medicines work together to help control your blood sugar.

Before you take AVANDAMET, you should first try to control your diabetes by diet and exercise. In order for AVANDAMET to be most effective, you should continue to exercise and follow the diet recommended for your diabetes even while taking AVANDAMET.

**WARNING: A small number of people who have taken metformin, one of the two drugs that make up AVANDAMET, have developed a serious condition called lactic acidosis. Lactic acidosis is caused by a build-up of lactic acid in the blood. Lactic acidosis happens most often in people with kidney problems. People with kidney problems should not take AVANDAMET. (See “What are the side effects of AVANDAMET?”)**

**Who should not take AVANDAMET?**

Some conditions increase your chance of getting lactic acidosis, or cause other problems if you take AVANDAMET. Your risk of getting lactic acidosis is very low as long as your kidneys and liver are healthy. Most of the conditions listed below can increase your chance of getting lactic acidosis or cause other problems if you take AVANDAMET.

Do not take AVANDAMET if you:

- Had liver problems while taking REZULIN<sup>®</sup> (troglitazone), another medicine for diabetes.

- Have kidney or liver problems. Before you take AVANDAMET and while you take it, your doctor should test your blood to check for signs of kidney or liver problems.
- Have heart failure, until you talk with your doctor. Certain patients with heart failure should not start taking AVANDAMET. Rosiglitazone, one drug in AVANDAMET, may cause fluid retention (swelling or edema), alone or in combination with other diabetes medicines. Fluid retention can lead to heart failure or make heart failure worse. **Call your doctor if you have shortness of breath or a sudden weight change.**
- Drink a lot of alcohol (all the time or short binge drinking).
- Are seriously dehydrated (as when your body has lost a lot of water from diarrhea or vomiting).
- Are going to have an x-ray procedure with an injection of dyes (contrast agents) in your vein with a needle. Talk to your doctor about when to stop AVANDAMET and when to start it again.
- Are scheduled to have surgery or an operation. Talk to your doctor about when to stop AVANDAMET and when to start it again.
- Develop a serious condition such as a heart attack, severe infection, or a stroke.
- Are 80 years or older and have NOT had your kidney function tested.
- Have had an allergic reaction to AVANDIA<sup>®</sup> (rosiglitazone) or metformin (e.g., GLUCOPHAGE<sup>®</sup>).
- Have type 1 (“juvenile”) diabetes or a history of metabolic ketoacidosis, including diabetic ketoacidosis.
- Have a type of diabetic eye disease called macular edema (swelling of the back of the eye) until you talk to your doctor.

### **Can AVANDAMET be used in nursing or pregnant women or in children?**

Tell your doctor if you are pregnant, plan to become pregnant, or if you are nursing a child. If you are a premenopausal woman (before the “change of life”), who is not having periods regularly or at all, you may need to consider birth control options since AVANDAMET may increase your chances of becoming pregnant. Talk with your doctor about your choices.

AVANDAMET has not been studied in children. AVANDAMET is not recommended for use in children.

### **How should I take AVANDAMET?**

AVANDAMET should be taken by mouth and with meals. AVANDAMET should be taken twice a day to help improve blood sugar levels. Your doctor may need to adjust your dose until your blood sugar is better controlled.

While you are taking AVANDAMET, you should also follow recommendations of your healthcare professional for appropriate diet and exercise. Diet and exercise can help your body use blood sugar better. Test your blood sugar regularly as your doctor tells you.

AVANDAMET can begin to work 1 or 2 weeks after you start taking it. It may take 2-3 months to see the full effect.

Your doctor should check your eyes regularly. Very rarely, some patients have experienced vision changes due to swelling in the back of the eye while taking rosiglitazone, one of the drugs in AVANDAMET.

While taking AVANDAMET tell your doctor if you:

- Have an illness that causes severe vomiting, diarrhea or fever, or if you drink a much lower amount of liquid than normal. These conditions can lead to severe dehydration (loss of water from your body). You may need to stop taking AVANDAMET for a short time.
- Plan to have surgery or an x-ray procedure with injection of dye (contrast agent). You may need to stop taking AVANDAMET for a short time.
- Start to take other medicines (including non-prescription and dietary or herbal supplements) or change how you take a medicine. AVANDAMET may affect how well other drugs work, and some drugs may affect how well AVANDAMET works. Some medicines may cause high blood sugar or low blood sugar.

### **What should I avoid while taking AVANDAMET?**

Avoid drinking a lot of alcoholic drinks while taking AVANDAMET. This means you should not binge drink for short periods, and you should not drink a lot of alcohol on a regular basis. Drinking a lot of alcohol can increase the chance of getting lactic acidosis.

### **What are the possible side effects of AVANDAMET?**

**In rare cases, metformin, one of the drugs in AVANDAMET, can cause a serious side effect called lactic acidosis. This is caused by a build-up of lactic acid in your blood. This build-up can cause serious damage. Lactic acidosis is a medical emergency that must be treated in a hospital.** Lactic acidosis is rare and has occurred mostly in people whose kidneys were not working normally. Lactic acidosis has been reported in about 1 in 33,000 patients taking metformin over the course of a year. Although rare, if lactic acidosis does occur, it can be fatal in up to half the people who develop it. Call your doctor right away if you have signs of lactic acidosis such as:

- feeling very weak, tired, or uncomfortable (malaise)
- unusual muscle pain
- unusual sleepiness
- rapid breathing that you can't explain
- unusual or unexpected stomach problems (such as nausea or vomiting)
- low body temperature
- feeling dizzy or light-headed
- suddenly having a slow or uneven heartbeat

It is important for your liver to be working normally when you take AVANDAMET. Your liver helps remove lactic acid from your blood. Before you take AVANDAMET, your doctor will test your blood to check for signs of liver problems. Sometimes after you start taking it, your doctor may recheck your blood. Very rarely, serious liver problems have been reported with rosiglitazone, one of the drugs in AVANDAMET. Call your doctor right away if you have unexplained symptoms such as:

- nausea or vomiting
- stomach pain
- unusual or unexplained tiredness
- loss of appetite
- dark urine
- yellowing of your skin or the whites of your eyes

AVANDAMET may cause fluid retention or swelling, which could lead to heart failure or make heart failure worse, so tell your doctor if you have a history of heart failure or swelling (edema). Call your doctor right away if you have symptoms such as:

- swelling or fluid retention, especially of the ankles or legs
- shortness of breath or trouble breathing, especially when you lie down
- unusual tiredness
- an unusually rapid increase in weight

There is a small risk of developing low blood sugar (hypoglycemia) while taking AVANDAMET. Lightheadedness, dizziness, shakiness or hunger may indicate that your blood sugar is too low. This can happen if you skip meals, if you use another medicine that lowers blood sugar, or if you have certain medical problems.

Fractures, usually in the hand, upper arm or foot, have occurred in females taking rosiglitazone, one of the components of AVANDAMET. Talk to your doctor for advice on how to keep your bones healthy.

*Other Side Effects.* Common side effects of AVANDAMET are diarrhea, nausea, and upset stomach. These side effects usually occur during the first few weeks of therapy. Taking AVANDAMET with meals can help reduce these side effects. Stomach problems when you first take AVANDAMET are common. However, stomach problems that start up later may be a sign of something more serious and should be discussed with your doctor. Other common side effects are cold-like symptoms, headache, weight gain, and anemia.

#### **How should I store AVANDAMET?**

AVANDAMET should be stored at room temperature in a childproof container out of the reach of children. Store AVANDAMET in its original container.

#### **General Advice about prescription medicines**

This leaflet summarizes important information about AVANDAMET. If you have questions or problems, talk with your doctor or other healthcare provider. You can ask your doctor or pharmacist for information about AVANDAMET that is written for healthcare providers. Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use AVANDAMET for a condition for which it was not prescribed. Do not share your medicine with other people.

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