

PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

PATIENT INFORMATION

**AVANDIA[®] (ah-VAN-dee-a)
Rosiglitazone Maleate Tablets**

Read this Patient Information leaflet carefully before you start using AVANDIA and each time you get a refill. 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 AVANDIA, ask your doctor or pharmacist.

What is the most important information I should know about AVANDIA?

AVANDIA is a prescription medicine to treat adults with diabetes. It helps to control high blood sugar. (See “What is AVANDIA?”). It is important that you take AVANDIA exactly how it is prescribed by your doctor to best treat your diabetes.

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 can cause your body to keep extra fluid (fluid retention), which leads to swelling (edema) and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure.

Call your doctor right away if you have symptoms such as:

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

AVANDIA may increase the risk of heart problems related to reduced blood flow to the heart. These include possible increases in the risk of angina (heart-related chest pain) or myocardial infarction (“heart attack”). This risk appeared higher in patients who took AVANDIA with insulin or with nitrate medication. The use of AVANDIA with insulin or nitrate medication is not recommended.

If you have chest pain or a feeling of chest pressure, you should seek immediate medical attention, regardless of what diabetes medications you are taking.

AVANDIA can have other serious side effects. Be sure to read the section below entitled “What

are the possible side effects of AVANDIA?”.

What is AVANDIA?

AVANDIA is a prescription medicine used with diet and exercise to treat type 2 (“adult-onset” or “non-insulin dependent”) diabetes mellitus (“high blood sugar”). AVANDIA may be used alone or with other diabetes medicines. AVANDIA can help your body respond better to insulin made in your body. AVANDIA does not cause your body to make more insulin.

You should first try to control your diabetes by diet, weight loss, and exercise. In order for AVANDIA to work best, it is very important to exercise, lose excess weight, and follow the diet recommended for your diabetes.

Patients with diabetes are at a greater risk of heart problems than are people without diabetes. It is important to work with your doctor to manage other conditions, such as high blood pressure or high cholesterol. You should discuss these conditions with your doctor so they can help you manage them.

AVANDIA has not been studied enough in children under 18 years of age to know if it is safe or effective in children.

What is type 2 diabetes?

Type 2 diabetes happens when a person does not make enough insulin or does not respond normally to the insulin their body makes. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems including kidney damage, heart disease, loss of limbs, and blindness. The main goal of treating diabetes is to lower your blood sugar to a normal level. Lowering and 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 certain medicines taken by mouth, and by insulin shots.

Who should not take AVANDIA?

Many patients with heart failure should not start taking AVANDIA. See “What should I tell my doctor before taking AVANDIA?”.

What should I tell my doctor before taking AVANDIA?

Before starting AVANDIA, ask your doctor about what the choices are for diabetes medications, and what the expected benefits and possible risks are for you in particular.

Before taking AVANDIA, tell your doctor about all your medical conditions, including if you:

- have heart problems or heart failure. AVANDIA can cause your body to keep extra fluid (fluid retention), which leads to swelling and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure.

- are taking insulin for your diabetes.
- are taking any medicines called nitrates. Nitrates, also called nitroglycerin or isosorbide, are commonly used to treat chest pain known as angina. Ask your doctor or pharmacist if you are not sure if any of your medicines are nitrates.
- have type 1 (“juvenile”) diabetes or had diabetic ketoacidosis. These conditions should be treated with insulin.
- have a type of diabetic eye disease called macular edema (swelling of the back of the eye).
- have liver problems. Your doctor should do blood tests to check your liver before you start taking AVANDIA and during treatment as needed.
- had liver problems while taking REZULIN[®] (troglitazone), another medicine for diabetes.
- are taking any medications for high blood pressure, high cholesterol or heart failure, or for prevention of heart disease or stroke.
- are taking other prescription or non-prescription medicines, vitamins or herbal supplements. AVANDIA and certain other medicines can affect each other and lead to serious side effects including high blood sugar or low blood sugar. Keep a list of all the medicines you take. Show this list to your doctor and pharmacist before you start a new medicine. They will tell you if it is okay to take AVANDIA with other medicines.

How should I take AVANDIA?

- Take AVANDIA exactly as prescribed. Your doctor will tell you how many tablets to take and how often. The usual daily starting dose is 4 mg a day taken once a day or 2 mg taken twice a day. Your doctor may need to adjust your dose until your blood sugar is better controlled.
- AVANDIA may be prescribed alone or with other diabetes medicines. This will depend on how well your blood sugar is controlled.
- Take AVANDIA with or without food.
- It can take 2 weeks for AVANDIA to start lowering blood sugar. It may take 2 to 3 months to see the full effect on your blood sugar level.
- If you miss a dose of AVANDIA, take your pill as soon as you remember, unless it is time to take your next dose. Take your next dose at the usual time. Do not take a double dose to make up for a missed dose.
- If you take too much AVANDIA, call your doctor or poison control center right away.
- Test your blood sugar regularly as your doctor tells you.
- Diet and exercise can help your body use its blood sugar better. It is important to stay on your recommended diet, lose excess weight, and get regular exercise while taking AVANDIA.
- Your doctor should do blood tests to check your liver before you start AVANDIA and during treatment as needed. Your doctor should also do regular blood sugar tests (for example, “A1C”) to monitor your response to AVANDIA.
- 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 AVANDIA.

What should I avoid while taking AVANDIA?

- **You should avoid becoming pregnant.** It is not known if AVANDIA can harm your unborn baby. You and your doctor should talk about the best way to control your high blood sugar during pregnancy. If you are a premenopausal woman (before the “change of life”) who does not have regular monthly periods. AVANDIA may increase your chances of becoming pregnant. Talk to your doctor about birth control choices while taking AVANDIA.
- **Do not breastfeed.** It is not known if AVANDIA passes into breast milk. You should not use AVANDIA while breastfeeding.

What are possible side effects of AVANDIA?

- heart failure. AVANDIA can cause your body to keep extra fluid (fluid retention), which leads to swelling and weight gain. Extra body fluid can make some heart problems worse or lead to heart failure.
- swelling (edema) from fluid retention. Call your doctor right away if you have symptoms such as:
 - swelling or fluid retention, especially in the ankles or legs
 - shortness of breath or trouble breathing, especially when you lie down
 - an unusually fast increase in weight
 - unusual tiredness
- **heart problems. AVANDIA may increase the risk of heart problems related to reduced blood flow to the heart. These include possible increases in the risk of angina (heart-related chest pain) or myocardial infarction (“heart attack”). This risk appeared higher in patients who took AVANDIA with insulin or with nitrate medication. The use of AVANDIA with insulin or nitrate medication is not recommended.**
- **if you have chest pain, or a feeling of chest pressure, seek immediate medical attention.**
- low blood sugar (hypoglycemia). Lightheadedness, dizziness, shakiness or hunger may mean 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. Call your doctor if low blood sugar levels are a problem for you.
- fractures, usually in the hand, upper arm or foot, in females. Talk to your doctor for advice on how to keep your bones healthy.
- weight gain. AVANDIA can cause weight gain that may be due to fluid retention or extra body fat. Weight gain can be a serious problem for people with certain conditions including heart problems. Call your doctor if you have an unusually fast increase in weight.
- low red blood cell count (anemia).
- ovulation (release of egg from an ovary in a woman) leading to pregnancy. Ovulation may happen in premenopausal women who do not have regular monthly periods. This can increase the chance of pregnancy.

- liver problems. It is important for your liver to be working normally when you take AVANDIA. Your doctor should do blood tests to check your liver before you start taking AVANDIA and during treatment as needed. 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.

The most common side effects of AVANDIA reported **in clinical trials** included cold-like symptoms, injury, and headache.

How should I store AVANDIA?

- Store AVANDIA at room temperature, 59° to 86°F (15° to 30°C). Keep AVANDIA in the container it comes in.
- Safely, throw away AVANDIA that is out of date or no longer needed.
- Keep AVANDIA and all medicines out of the reach of children.

General information about AVANDIA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use AVANDIA for a condition for which it was not prescribed. Do not give AVANDIA to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes important information about AVANDIA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about AVANDIA that is written for healthcare professionals. You can also find out more about AVANDIA by calling 1-888-825-5249 or visiting the website www.avandia.com.

What are the ingredients in AVANDIA?

Active Ingredient: Rosiglitazone maleate.

Inactive Ingredients: Hypromellose 2910, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 3000, sodium starch glycolate, titanium dioxide, triacetin, and 1 or more of the following: Synthetic red and yellow iron oxides and talc.

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