MEDICATION GUIDE

AVANDIA® (ah-VAN-dee-a)
(rosiglitazone maleate) tablets

Read this Medication Guide carefully before you start taking 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 may cause serious side effects, including:

New or worse heart failure
- The risk of heart failure may be higher in people who take AVANDIA with insulin.
  Most people who take insulin should not also take AVANDIA.
- 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. Heart failure means your heart does not
pump blood well enough.
- If you have severe heart failure, you cannot start AVANDIA.
- If you have heart failure with symptoms (such as shortness of breath or
  swelling), even if these symptoms are not severe, AVANDIA may not be right for
  you.

Call your doctor right away if you have any of the following:
- 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 can have other serious side effects. Be sure to read the section below
“What are possible side effects of AVANDIA?”

What is AVANDIA?

AVANDIA is a prescription medicine used with diet and exercise to treat adults with
type 2 (“adult-onset” or “non-insulin dependent”) diabetes mellitus (“high blood
sugar”).

AVANDIA helps to control 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.

AVANDIA is not for people with type 1 diabetes mellitus or to treat a condition
called diabetic ketoacidosis.

It is not known if AVANDIA is safe and effective in children younger than 18 years old.

**Who should not take AVANDIA?**

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

**Do not** take AVANDIA if you are allergic to rosiglitazone or any of the ingredients in AVANDIA. See the end of this leaflet for a complete list of ingredients in AVANDIA.

Symptoms of a severe allergic reaction with AVANDIA may include:

- swelling of your face, lips, tongue, or throat
- problems with breathing or swallowing
- skin rash or itching
- raised red areas on your skin (hives)
- blisters on your skin or in your mouth, nose, or eyes
- peeling of your skin
- fainting or feeling dizzy
- very rapid heartbeat

**What should I tell my doctor before taking AVANDIA?**

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

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

- **have heart problems or heart failure.**
- **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 pregnant or plan to become 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 diabetes 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. Tell your doctor right away if
you become pregnant while taking AVANDIA.

- **are breastfeeding or planning to breastfeed.** It is not known if AVANDIA
passes into breast milk. You and your doctor should decide if you will take
AVANDIA or breastfeed. You should not do both.

Tell your doctor about all of the medicines you take including prescription and non-
 prescription medicines, vitamins or herbal supplements. AVANDIA and certain other
medicines can affect each other and may lead to serious side effects including high
or low blood sugar, or heart problems. Especially tell your doctor if you take:

- **insulin.**
- **any medicines for high blood pressure, high cholesterol or heart failure,**
  or for prevention of heart disease or stroke.

Know the medicines you take. Keep a list of your medicines and show it to your
doctor and pharmacist before you start a new medicine. They will tell you if it is
alright 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 one
time each day or 2 mg taken two times each 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 it 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
double doses 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 extra 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.
What are possible side effects of AVANDIA?

AVANDIA may cause serious side effects including:

- **New or worse heart failure.** See “What is the most important information I should know about AVANDIA?”
- **Heart attack.** AVANDIA may increase the risk of a heart attack. Talk to your doctor about what this means to you.

**Symptoms of a heart attack can include the following:**

- chest discomfort in the center of your chest that lasts for more than a few minutes, or that goes away or comes back
- chest discomfort that feels like uncomfortable pressure, squeezing, fullness, or pain
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

**Call your doctor or go to the nearest hospital emergency room right away if you think you are having a heart attack.**

- **Swelling (edema).** AVANDIA can cause swelling due to fluid retention. See “What is the most important information I should know about AVANDIA?”
- **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. See “What is the most important information I should know about AVANDIA?”
- **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.
- **Macular edema** (a diabetic eye disease with swelling in the back of the eye). Tell your doctor right away if you have any changes in your vision. Your doctor should check your eyes regularly. Very rarely, some people have had vision changes due to swelling in the back of the eye while taking AVANDIA.
- **Fractures (broken bones),** usually in the hand, upper arm, or foot. Talk to your doctor for advice on how to keep your bones healthy.
• **Low red blood cell count (anemia).**

• **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.

• **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. See “What should I tell my doctor before taking AVANDIA?”

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store AVANDIA?**

• Store AVANDIA at room temperature, 59°F to 86°F (15°C 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 Medication Guide. 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 Medication Guide 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.

**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.

Always check to make sure that the medicine you are taking is the correct one.
AVANDIA tablets are triangles with rounded corners and look like this:
- 2 mg – pink with “GSK” on one side and “2” on the other.
- 4 mg – orange with “GSK” on one side and “4” on the other.
- 8 mg – red-brown with “GSK” on one side and “8” on the other.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.