

Questions you may have about AVANDIA

I've been hearing about Avandia in the news. What is the news about?

An FDA Advisory Committee Meeting took place on July 13-14, 2010 to review the data on AVANDIA related to cardiovascular safety.

What is an FDA Advisory Committee Meeting?

The FDA brings together outside experts to an advisory committee meeting to provide advice for FDA consideration on topics, such as approvals of new drugs or safety questions about drugs.

What did the FDA Advisory Committee vote on?

The committee voted on six different questions related to the cardiovascular safety of AVANDIA.

What happens next?

The FDA will think about the Advisory Committee's advice. The FDA will make a final decision that may or may not agree with the committees' advice.

Has AVANDIA been pulled from the market?

AVANDIA is still available for appropriate patients with type 2 diabetes pending a final decision from the FDA.

What is GSK's position about the FDA Advisory Committee Meeting?

GSK remains confident in the efficacy and safety of AVANDIA when used appropriately.

What should I do if I currently take AVANDIA?

Discuss any questions or concerns you have about AVANDIA with your health care professional. Read the Medication Guide that comes with each prescription of AVANDIA to better understand the risks and benefits of your medication. Report any side effects with rosiglitazone to FDA's MedWatch program either online, by regular mail, by fax, or by phone. See bottom of page for details.

Should I stop taking AVANDIA?

You should always talk to your healthcare provider before making changes to your use of AVANDIA or any other diabetes medicine.

Please read – Important Safety Information

AVANDIA can cause or worsen heart failure. 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 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 AVANDIA, 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.

Before taking AVANDIA, 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[®] (troglitazone).
- Are pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed.
- Women taking AVANDIA should know that AVANDIA may increase the risk of pregnancy. More fractures have been observed in women taking AVANDIA. Other possible side effects of AVANDIA include anemia and hypoglycemia. Your doctor should do blood tests to check your liver before you start AVANDIA and during treatment as needed.

Prescription AVANDIA, along with diet and exercise, helps improve blood sugar control in adults with type 2 diabetes. Taking AVANDIA with insulin or nitrates is not recommended.

For more information about AVANDIA, please see Medication Guide. For further information on AVANDIA, please see full Prescribing Information.

Questions you may have about AVANDIA

What is the advice of professional diabetes societies (ADA, AACE, the Endocrine Society) for diabetes patients in light of recent events?

The American Diabetes Association (ADA), American Association of Clinical Endocrinologists (AACE), and the Endocrine Society released a joint statement on July 12, 2010, stating: "Patients should continue taking all currently prescribed medications unless instructed otherwise by their health care provider. Stopping diabetes medications can result in higher levels of blood glucose that may cause serious short term health problems and could increase the risk of diabetes-related complications in the long term."

"Additionally, patients and health care professionals should be aware that multiple classes of drugs, often with more than one agent per class, are available to maintain glucose control in patients with type 2 diabetes. Until further clarification is provided by the FDA, the decision whether or not to use any medication must remain that of the treating provider in direct discussion with the individual patient."

How can I stay up to date on the safety of AVANDIA?

Your doctor and other health care professionals are your best resources for information about the medicines you take. Consult with them because they know your medical history.

To view GSK's response to recent news, you can log onto www.gsk.com

You can also call 1-800-AVANDIA to speak to someone from GlaxoSmithKline about your questions.

What if I take another product containing rosiglitazone?

The information in this leaflet is important and also applies to you.

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AVANDIA 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 AVANDIA, 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.

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- 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[®] (troglitazone).
- Are pregnant or planning to become pregnant.
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- Women taking AVANDIA should know that AVANDIA may increase the risk of pregnancy. More fractures have been observed in women taking AVANDIA. Other possible side effects of AVANDIA include anemia and hypoglycemia. Your doctor should do blood tests to check your liver before you start AVANDIA and during treatment as needed.

Prescription AVANDIA, along with diet and exercise, helps improve blood sugar control in adults with type 2 diabetes. Taking AVANDIA with insulin or nitrates is not recommended.

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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 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.

AVANDIA may cause serious side effects, including:

New or worse heart failure

- 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

Other heart problems

AVANDIA may raise the risk of heart problems related to reduced blood flow to the heart. These include possible increases in the risk of heart-related chest pain (angina) or “heart attack” (myocardial infarction). This risk seemed to be higher in people who took AVANDIA with insulin or with nitrate medicines. Most people who take insulin or nitrate medicines should not also take AVANDIA.

- If you have chest pain or a feeling of chest pressure, get medical help right away, no matter what diabetes medicines you are taking.
- People with diabetes have a greater risk for heart problems. It is important to work with your doctor to manage other conditions, such as high blood pressure or high cholesterol.

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.

- For AVANDIA to work best, it is very important to exercise, lose extra weight, and follow the diet recommended by your doctor.

- AVANDIA has not been studied enough in children under 18 years of age to know if it is safe or effective in children.
- AVANDIA is not for people with type 1 diabetes mellitus or to treat a condition called diabetic ketoacidosis.

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?”.

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 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.** AVANDIA should not be used during pregnancy. 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 breast-feeding or planning to breast-feed.** It is not known if AVANDIA passes into breast milk. You should not use AVANDIA while breastfeeding.

Tell your doctor about all 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.**
- **nitrate medicines** such as nitroglycerin or isosorbide to treat a type of chest pain called angina.
- **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?"
- **Other 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 heart-related chest pain (angina) or "heart attack" (myocardial infarction). See "What is the most important information I should know about AVANDIA?"
- **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 experienced 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, in females. 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° 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 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 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.

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 strength tablets – pink with "SB" on one side and "2" on the other.

4 mg strength tablets – orange with "SB" on one side and "4" on the other.

8 mg strength tablets – red-brown with "SB" on one side and "8" on the other.

AVANDIA is a registered trademark of GlaxoSmithKline.

REZULIN is a registered trademark of Parke-Davis Pharmaceuticals Ltd.

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



GlaxoSmithKline
Research Triangle Park, NC 27709

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