

PART III: CONSUMER INFORMATION

**PrAVANDIA
rosiglitazone (as rosiglitazone maleate) tablets**

This leaflet is part III of a three-part “Product Monograph” for AVANDIA and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AVANDIA. Contact your doctor or pharmacist if you have any questions about the drug.

Keep this leaflet until you have finished all your tablets as you may need to read it again.

ABOUT THIS MEDICATION

What the medication is used for:

AVANDIA is used with diet and exercise to lower blood sugar:

- In adults with type 2 diabetes.
- When all other diabetes medicines have not lowered blood sugar enough or cannot be used.

AVANDIA may be used alone or with either metformin OR a sulfonylurea to treat your diabetes. However, AVANDIA is not recommended for use with both metformin AND a sulfonylurea together.

Talk about the benefits and side effects with your doctor. Together decide if it is right for you. The doctor will ask you to read and sign a form showing you understand the risks of AVANDIA.

What it does:

AVANDIA helps to control high blood sugar. It can help your body respond better to insulin made in your body. AVANDIA does not cause your body to make more insulin.

When it should not be used:

- If you have or have had heart problems or heart failure. AVANDIA may increase the risk of serious heart problems.
- If you are allergic to AVANDIA or any of the nonmedicinal ingredients.
- If you have serious liver problems.
- If you are pregnant.

What the medicinal ingredient is:

rosiglitazone maleate

What the nonmedicinal ingredients are:

hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 3000, sodium starch glycolate, titanium dioxide, and triacetin and one or more of the following: synthetic red and yellow iron oxides, and talc.

What dosage forms it comes in:

Tablets: 2 mg, 4 mg and 8 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

AVANDIA may increase the risk of serious heart problems, including:

- heart failure
- angina (chest pain)
- heart attack (myocardial infarction)
- fluid retention (with or without rapid weight gain)

AVANDIA should not be used if you have or have had heart problems.

Before you use AVANDIA, talk to your doctor about other options to treat your diabetes.

Before you use AVANDIA talk to your doctor or pharmacist about all your medical conditions, including if:

- you have or have had swelling in the wrists, hands, feet or ankles (edema).
- you have been diagnosed with angina (chest pain) or have had a heart attack.
- you have heart-related risks, including cigarette smoking, high blood pressure, high cholesterol, or a family history of heart attack.
- you have a type of diabetic eye disease called macular edema (swelling in the back of the eye).
- you have liver problems.
- you are breastfeeding.
- you are pregnant or planning to become pregnant.
- you are not near menopause but not ovulating (polycystic ovary syndrome). AVANDIA could make you ovulate again. This means you could get pregnant. Talk to your doctor about your birth control choices.

AVANDIA can cause a decrease in the amount of calcium and other minerals in your bones. The strength of your bones may be decreased especially in the hips and spine.

AVANDIA is not recommended for use in children under 18 years of age.

AVANDIA is not recommended for type 1 diabetes or diabetic ketoacidosis (dangerously high levels of ketones, which signals the body doesn't have enough insulin).

AVANDIA is not recommended for use with insulin.

AVANDIA is not recommended for use with both metformin **and** a sulfonylurea together.

INTERACTIONS WITH THIS MEDICATION

AVANDIA may affect how other medicines work and some medicines may affect how AVANDIA works.

Tell your doctor about all medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

In particular, tell your doctor if you are using any of the following medicines:

- drugs used to lower cholesterol and triglyceride levels in your blood (gemfibrozil)
- drugs used to treat tuberculosis (rifampin)
- drugs used to treat psoriasis or rheumatoid arthritis (methotrexate).
- drugs for heart pain (nitrate medicines). Examples are nitroglycerine or isosorbide dinitrate.

PROPER USE OF THIS MEDICATION

Remember: This medicine has been prescribed only for you. Do not give it to anybody else.

Take AVANDIA:

- by mouth.
- with or without food.
- each day. Either once a day (in the morning) or twice a day (in the morning and in the evening).

Diet and exercise can help your body control its blood sugar better. It is important to stay on the diet and exercise program recommended by your doctor.

Usual Starting dose: 4 mg per day.

Your doctor will decide on the dose of AVANDIA that is best for you.

Overdose:

Taking too much of any medicine can be dangerous.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you take AVANDIA **once a day** and miss one dose, take the dose as soon as you remember.

If you take AVANDIA **twice a day**, take the missed dose as soon as you remember. Then take the next dose at the usual time.

Never take three doses in one day to make up for a missed dose the day before.

If you **miss a whole day** of AVANDIA, just take your dose as usual the next day. Don't try to make it up by taking extra tablets.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If any of the side effects listed becomes severe or troublesome, tell your doctor or pharmacist.

Side effects may include:

Common side effects:

- Broken bones, usually in the hand, upper arm or foot. Talk to your doctor about the risk of fracture.
- A small increase in total cholesterol levels.
- Weight gain in a short period of time.

Uncommon side effects:

- Constipation.
- Increased hunger.

Very rare side effects:

- Abnormal vaginal bleeding or spotting.
- Swelling of the parotid gland (salivary glands located over the jaw, in front of the ears).

AVANDIA can cause abnormal liver and blood sugar test results. Your doctor will decide when to perform blood tests and will interpret the results.

Your doctor should check your eyes regularly. Some patients may experience vision changes. This can be due to swelling in the back of the eye while taking AVANDIA.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor		Stop taking AVANDIA and call your doctor immediately
		Only if severe	In all cases	
Common	Anemia (Low red blood cell count): Feeling very weak or tired.		✓	
	Edema (Fluid retention): swelling in arms and legs, hands and feet. Rapid or unexpected increase in weight.		✓	
	Hypoglycemia (Low blood sugar levels): Dizziness, lack of energy, drowsiness, headache, trembling sweating, or hunger.	✓		
	Heart failure or fluid in the lungs (pulmonary edema): Trouble breathing or shortness of breath, getting tired easily after light physical activity such as walking, unusual tiredness, severe breathlessness which worsens on lying down, waking up short of breath at night, an unusually rapid increase in weight, swollen ankles or feet.			✓
	Angina: Chest pain		✓	
Rare	Liver problems: Nausea, vomiting, stomach pain, lack of appetite, tiredness, dark urine, or yellowing of the skin or eyes.			✓
	Blurred vision or decreased vision			✓
Very rare	Allergic reactions: Hives or rash (which may be itchy), or more serious symptoms which may occur suddenly, such as swelling of the face, lips, mouth, tongue or throat (may cause difficulty in swallowing or breathing).			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor		Stop taking AVANDIA and call your doctor immediately
		Only if severe	In all cases	
Muscle Disorders: Muscle tenderness or weakness, muscle pain that you cannot explain.			✓	
Fatigue: Generalized weakness, especially if you do not feel well.			✓	
Hematuria: Brownish or discoloured urine.				✓

This is not a complete list of side effects. If you experience any unexpected effects while taking AVANDIA, contact your doctor or pharmacist.

HOW TO STORE IT

Store AVANDIA at room temperature (15°C to 30°C). Keep out of reach and sight of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.gsk.ca>

or by contacting the sponsor,

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