

PRONUNCIATION: (row-sih-GLIT-uh-zone)

COMMON BRAND NAME(S): Avandia

HOW TO USE: Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start using rosiglitazone and each time you get a refill. Read and sign the Informed Consent form provided by your doctor. If you have any questions regarding the information, consult your doctor or pharmacist. Take this medication by mouth, with or without food, usually once or twice daily, or as directed by your doctor. Dosage is based on your medical condition, response to therapy, and if you are taking other anti-diabetic drugs. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day. Monitor blood glucose levels on a regular basis. It may take up to 2 to 3 months before the full benefit of this drug takes effect. Take all other medications for diabetes as directed by your doctor.

USES: Rosiglitazone is an anti-diabetic drug (thiazolidinedione-type, also called "glitazones") used with a proper diet and exercise program to control high blood sugar in patients with type 2 diabetes (non-insulin-dependent diabetes). You should only begin taking rosiglitazone when other drugs have not worked well or cannot be taken. If you are currently taking rosiglitazone and have good control of your blood sugars and no new side effects/symptoms, continue to take this drug as directed. Ask your doctor about the risks and benefits of this drug, since a small number of people have had serious side effects. Rosiglitazone works by helping to restore your body's proper response to insulin, thereby lowering your blood sugar. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual function problems. Proper control of diabetes may also lessen your risk of a heart attack or stroke.

SIDE EFFECTS: See also Warning section. Headache or cough may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: fast/pounding heartbeat, changes in menstrual cycles, bone fracture. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: dark urine, yellowing of eyes/skin, persistent nausea/vomiting, stomach/abdominal pain, vision changes (e.g., color or night vision problems). This medication usually does not cause low blood sugar (hypoglycemia), but this effect may occur if you do not consume enough calories (from food, juices, fruit, etc.). The symptoms include chills, cold sweat, dizziness, drowsiness, shaking, rapid heart rate, weakness, headache, fainting, tingling of the hands or feet, or hunger. It is a good habit to carry glucose tablets or gel to treat low blood sugar. If you are in a situation where you don't have these reliable forms of glucose, eat a quick source of sugar such as table sugar, honey, or candy, or drink a glass of orange juice or non-diet soda to quickly raise your blood sugar level. Tell your doctor immediately about the reaction. To help prevent hypoglycemia, eat meals on a regular schedule and do not skip meals. Symptoms of high blood sugar (hyperglycemia) include thirst, increased urination, confusion, drowsiness, flushing, rapid breathing, or fruity breath odor. If these symptoms occur, tell your doctor immediately. Your medication dosage may need to be increased. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching/swelling (especially of the face/tongue/throat), dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS: Before taking rosiglitazone, tell your doctor or pharmacist if you are allergic to it; or to other "glitazones" such as pioglitazone; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Promptly talk with your doctor or pharmacist about the benefits and possible risks of this medication, even if you have been taking it for awhile, especially if you have heart problems. Do not stop taking it unless directed to do so. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: type 1 diabetes (insulin-dependent diabetes), very high blood glucose (diabetic ketoacidosis), newly diagnosed or worsening heart failure (acute congestive heart failure), history of liver disease, active liver disease. Before using this medication, tell your doctor or pharmacist your medical history, especially of: heart disease (e.g., chronic congestive heart failure, heart attack, angina), fluid in your lungs, swelling (edema), anemia, high blood cholesterol, eye (retina) problems, bone problems (e.g., osteoporosis, osteopenia). You may experience blurred vision, dizziness, or drowsiness due to extremely low or high blood sugar levels. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcohol while taking this medication because it can increase the risk of your blood sugar getting too low (hypoglycemia). During times of stress, such as fever, infection, injury or surgery, it may be more difficult to control your blood sugar. Consult your doctor, as additional medication may be required. This medication may increase the risk of bone fracture (upper arm, hand, foot) in female patients. To lower the chance of getting injured, use caution when doing activities such as contact sports. This medication can cause changes in the menstrual cycle (ovulation) in women with certain fertility problems. Consult your doctor or pharmacist about the use of reliable birth control while taking this medication. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. Your doctor may substitute insulin for this drug during your pregnancy. Follow all instructions carefully. It is unknown if this medication passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: other anti-diabetic medications (e.g., insulin, metformin, or sulfonylureas such as glyburide), gemfibrozil, herbal/natural products (e.g., fenugreek, ginseng, gymnema), nitrates (e.g., isosorbide dinitrate), quinolone antibiotics (e.g., ciprofloxacin). Beta-blocker medications (e.g., metoprolol, propranolol, glaucoma eye drops such as timolol) may prevent the fast/pounding heartbeat you would usually feel when your blood sugar level falls too low (hypoglycemia). Other symptoms of low blood sugar such as dizziness, hunger, or sweating are unaffected by these drugs. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE: If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

NOTES: Do not share this medication with others. It is recommended you attend a diabetes education program to understand diabetes and all the important aspects of its treatment including meals/diet, exercise, personal hygiene, medications and getting regular eye, foot and medical exams. Lifestyle changes that help promote healthy bones include increasing weight-bearing exercise, eating well-balanced meals containing adequate calcium and vitamin D, stopping smoking, and limiting alcohol. Consult your doctor to see if you need to take calcium/vitamin D supplements

and discuss lifestyle changes that might benefit you. Keep all medical appointments. Laboratory and/or medical tests (e.g., liver and kidney function tests, fasting blood glucose, hemoglobin A1c, complete blood counts, blood cholesterol levels) will be performed to monitor for side effects and response to therapy. Regularly check your blood or urine for sugar, as directed by your doctor or pharmacist.

MISSED DOSE: If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE: Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

WARNING: This medication may infrequently cause or worsen certain heart problems (congestive heart failure, heart attack). Seek immediate medical attention if you notice any symptoms of heart problems, including: swelling of the hands/feet, unusual/sudden weight gain, trouble breathing, chest pain/discomfort.