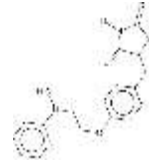


Rx ROSIGLITAZONE

(Rosiglitazone maleate - Rosiglitazone is an oral drug that reduces the amount of sugar (glucose) in the blood.)



GENERIC NAME: rosiglitazone maleate

DRUG CLASS AND MECHANISM

Rosiglitazone is an oral drug that reduces the amount of sugar (glucose) in the blood. It is used for treating patients with type 2 diabetes and is in a class of anti-diabetic drugs called thiazolidinediones. The other member of this class is pioglitazone (Actos). Insulin is a hormone produced by the pancreas that is important for controlling the levels of glucose in the blood. Insulin stimulates the cells of the body to remove glucose from the blood and thereby lowers the level of glucose in the blood. Patients with type II diabetes cannot make enough insulin. As a result, the cells in their bodies do not remove enough glucose from the blood, and the level of glucose rises. Rosiglitazone often is referred to as an "insulin sensitizer" because it attaches to the insulin receptors on cells throughout the body and causes the cells to become more sensitive (more responsive) to insulin and remove more glucose from the blood. At least some insulin must be produced by the pancreas in order for rosiglitazone to work). Rosiglitazone was approved by the FDA on May 28, 1999.

PRESCRIPTION: Yes

PREPARATIONS: Tablets: 2, 4, and 8 mg.

PRESCRIBED FOR

Rosiglitazone, combined with diet, exercise, weight control, and cessation of smoking is used for treating type II diabetes. Rosiglitazone may be used alone or in combination with other types of anti-diabetic drugs such as metformin (Glucophage) or sulfonylureas as well as insulin. Since it requires naturally-secreted insulin to be effective, rosiglitazone is not recommended for use in type I diabetes where the amount of insulin is very low or absent.

DOSING

Rosiglitazone may be taken once or twice daily, with or without meals. Daily doses range from 4 to 8 mg either with or without other antidiabetic medications. Studies do not demonstrate additional effects when more than 8mg per day are taken.

DRUG INTERACTIONS

Rifampin decreases the blood concentration of rosiglitazone by increasing its breakdown in the liver. Therefore, use of rifampin may decrease the effect of rosiglitazone.

Gemfibrozil (Lopid) increases the concentration of rosiglitazone in the blood by reducing its breakdown. Therefore, rosiglitazone may increase the side effects of rosiglitazone.

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). 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.

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. 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.

SIDE EFFECTS AND PRECAUTIONS

The most common side effects seen with rosiglitazone alone or in combination with metformin are upper respiratory tract infection, headache, back pain, hyperglycemia, fatigue, sinusitis, diarrhea, and hypoglycemia. Rosiglitazone has been shown to cause mild to moderate accumulation of fluid (edema) and can lead to heart failure. Patients who already have heart failure may develop worsening symptoms with rosiglitazone. In addition,

anemia may occur with rosiglitazone alone or combined with metformin. Rosiglitazone also causes increasing amounts of weight gain with increasing doses.

A review of the studies of rosiglitazone led the FDA to conclude that the medication might increase the risk of heart attacks and angina, but left the association as inconclusive. Additionally, there isn't enough evidence that the risk of heart attack and angina is any greater with rosiglitazone than with other oral medicines used in the treatment of diabetes.

Since troglitazone, a related drug, was associated with liver injury, it is recommended that liver tests be obtained before starting therapy and periodically thereafter. Side effects which may suggest liver injury include unexplained nausea, vomiting, abdominal pain, fatigue, anorexia (loss of appetite), or dark urine.

Rosiglitazone may cause ovulation in premenopausal women who have stopped ovulating because they are resistant to insulin. Rosiglitazone may improve insulin sensitivity sufficiently to cause ovulation. Therefore, there is the potential for rosiglitazone to lead to pregnancy.

Studies testing rosiglitazone excluded New York Heart Association Class III and IV patients who have more serious heart disease. Therefore, it is not known how these classes of patients will respond to treatment. The concern is that fluid accumulation may lead to heart failure in these patients.

Rosiglitazone alone or combined with metformin has demonstrated various effects on blood lipids. Studies have shown elevated total and low-density cholesterol (LDL) levels within the first two months of rosiglitazone therapy with or without metformin, while high-density cholesterol (HDL) levels increase and free fatty acids decrease with continued therapy.

Two large studies have shown increased upper and lower extremity fractures in women taking rosiglitazone.

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. 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 drug passes into breast milk. Breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

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.

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. **MEDICAL ALERT:** Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).

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.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



Taj Group of Companies ^{INDIA}

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,
(0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

Revised November 2010