



## USES

Pioglitazone is an anti-diabetic drug (thiazolidinedione-type, also called "glitazones") used along with a proper diet and exercise program to control high blood sugar in patients with type 2 diabetes (non-insulin-dependent diabetes). It 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.Pioglitazone is used either alone or in combination with other anti-diabetic medications (e.g., metformin, sulfonylureas, insulin).

## HOW TO USE

Read the Medication Guide provided by your pharmacist before you start taking this medication and each time you get a refill. If you have any questions, consult your doctor or pharmacist. Take this medication by mouth, with or without food, usually once 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

See also Warning section.Sore throat, muscle pain, or tooth problems 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, new/worsening vision problems (e.g., color or night vision problems), 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. 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 pioglitazone, tell your doctor or pharmacist if you are allergic to it; if you are allergic to other "glitazones" (e.g., rosiglitazone); or if you have any other allergies. 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), newly diagnosed or worsening heart failure (acute congestive heart failure), very high blood glucose (diabetic ketoacidosis), 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), liver problems, fluid in your lungs, swelling (edema), anemia, eye (retina) problems. 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 developing 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 a change in your medication may be required. This medication may increase the risk of bone fracture (e.g.,

upper arm, hand, foot, ankle) 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 not known whether this drug passes into breast milk. Breast-feeding while using this drug is not recommended. 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), herbal/natural products (e.g., fenugreek, ginseng, gymnema), drugs affecting liver enzymes that remove pioglitazone from your body (e.g., gemfibrozil, rifamycins including rifampin), quinolone antibiotics (e.g., ciprofloxacin). This medication may decrease the effectiveness of birth control pills. This can result in pregnancy. You may need to use an additional form of reliable birth control while using this medication. Consult your doctor or pharmacist for details.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.

## **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 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 a certain heart problem (congestive heart failure). Tell your doctor immediately if you notice any symptoms of heart failure, including: swelling of the hands/feet, unusual/sudden weight gain, trouble breathing, or unusual tiredness.

**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.



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