

Pioglitazone Cas No. : 105355-26-8

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.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Pioglitazone

CAS No. : 105355-26-8

**Systematic (IUPAC) name**

2-(pyridinyl)ethoxy]phenyl]methyl]-4(5H)-thiazolone; Pioglitazone 2-imine

Chemical dataMolecular Formula C₁₉H₂₁N₃O₂S

Molecular Weight 355.45

CAS Registry Number 105355-26-8

Pharmacokinetic data

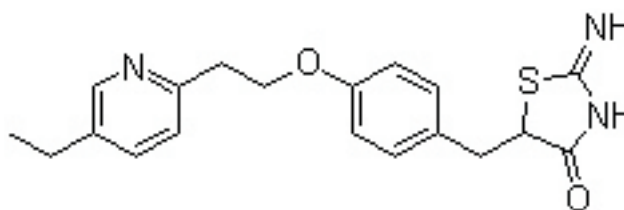
Bioavailability ?

Protein binding >99%

Metabolism liver (CYP2C8)

Half life 3–7 hours

Excretion in bile

**DOSAGE**

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.

Pioglitazone should be taken once daily without regard to meals. The dose of Pioglitazone should not exceed 45 mg once daily in monotherapy or in combination with sulfonylurea, metformin, or insulin.

SIDE EFFECTS

Sore throat, muscle pain, or tooth problems may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: swelling, unexplained rapid weight gain, trouble breathing, unusual fatigue, fast/pounding heartbeat, changes in menstrual cycles. 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, dizziness, trouble breathing.



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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, troglitazone); 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. You may experience blurred vision, dizziness, or drowsiness due to extremely low or high blood sugar levels; use caution engaging in activities requiring alertness such as driving or using machinery. 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 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.

INTERACTION

Sulfonamides, metformin, and insulin reciprocally exponentiate hypoglycemia. Therapy with pioglitazone increased risk for pregnancy in those taking oral contraception.

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 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.





DRUG DESCRIPTION

Pioglitazone is a prescription drug of the class thiazolidinedione (TZD) with hypoglycemic (antihyperglycemic, antidiabetic) action. Pioglitazone is used for the treatment of diabetes mellitus type 2 (previously known as non-insulin-dependent diabetes mellitus, NIDDM) in monotherapy and in combination with sulfonylurea, metformin, or insulin. Pioglitazone has also been used to treat non-alcoholic steatohepatitis (fatty liver), but this use is presently considered experimental

Pioglitazone hydrochloride is an odorless white crystalline powder that has a molecular formula of $C_{19}H_{20}N_2O_3S \cdot HCl$ and a molecular weight of 392.90 daltons. It is soluble in N,N-dimethylformamide, slightly soluble in anhydrous ethanol, very slightly soluble in acetone and acetonitrile, practically insoluble in water, and insoluble in ether.

Pioglitazone is an anti-diabetic drug 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. Effectively controlling high blood sugar helps prevent heart disease, strokes, kidney disease, blindness, and circulation problems, as well as sexual function problems (impotence). Pioglitazone is used either alone or in combination with other anti-diabetic medications.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

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