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.



Active Pharmaceuticals Ingredients Manufacturers

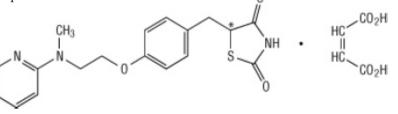


Rosiglitazone Maleate is an oral antidiabetic agent which acts primarily by increasing insulin sensitivity.

Rosiglitazone Maleate improves glycemic control while reducing circulating insulin levels.

Rosiglitazone maleate is not chemically or functionally related to the sulfonylureas, the biguanides, or the alphaglucosidase inhibitors.

Chemically, rosiglitazone maleate is (\pm) -5-[[4-[2-(methyl-2-pyridinylamino)] ethoxy]phenyl]methyl]-2,4-thiazolidinedione, (Z)-2-butenedioate (1:1) with a molecular weight of 473.52 (357.44 free base).



The molecule has a single chiral center and is present as a racemate.

Due to rapid interconversion, the enantiomers are functionally indistinguishable. The molecular formula is C18H19N3O3S•C4H4O4. Rosiglitazone maleate is a white to off-white solid with a melting point range of 122 to 123°C.

The pKa values of rosiglitazone maleate are 6.8 and 6.1. It is readily soluble in ethanol and a buffered aqueous solution with pH of 2.3; solubility decreases with increasing pH in the physiological range.

Rosiglitazone is an anti-diabetic drug in the thiazolidinedione class of drugs.

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.

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. Effectively controlling high blood sugar helps prevent heart disease, strokes, kidney disease, blindness, and circulation problems, as well as sexual function problems (impotence).

HOW TO USE

Read the Medication Guide and the Patient Information Leaflet available from 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 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.



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Taj Pharmaceuticals Ltd. Rosiglitazone Maleate

CAS No 155141-29-0

Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time 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.

SIDE EFFECTS

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.

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. 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.

DOSAGE

Take the recommended dose orally, with your first meal of the day.

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) 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.

PRECAUTIONS

Inform your doctor if you get sick, injured, or have surgery while. This drug may not properly control your blood sugar levels during these times.

Talk to your doctor about all of your medical conditions, especially if you have heart, liver or kidney problems, or are menopausal. Also, keep your doctor informed of all prescription, over-the-counter and herbal medicines you are taking.

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.



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Taj Pharmaceuticals Ltd. Rosiglitazone Maleate CAS No. : 155141-29-0



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). 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.





Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

Information: The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers. ,also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

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. This leaflet was prepared by Taj Pharmaceuticals Limited, Mumbai (India). MPSTJ278 Last revised: 29 August 2009



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