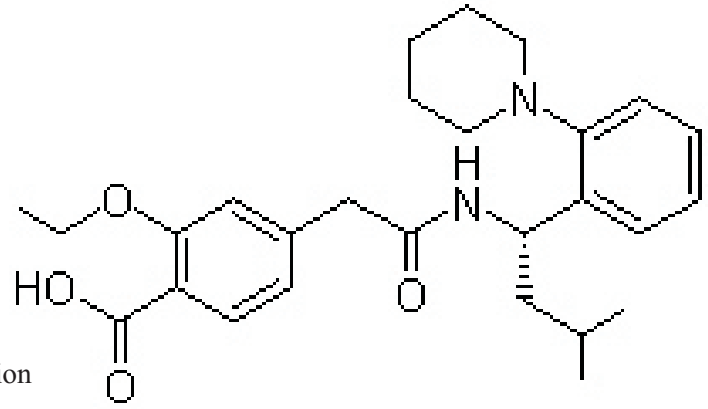
Taj Pharmaceuticals Ltd.

Repaglinide

CAS No. : 135062-02-1

Chemical data

CAS number 135062-02-1
Formula C27H36N2O4
Mol. mass 452.586 g/mol
ATC code A10BX02
PubChem 65981
DrugBank APRD00439



Pharmacokinetic data

Bioavailability 56% (oral)
Protein binding >98%
Metabolism Hepatic oxidation and glucuronidation (CYP3A4-mediated)
Half life 1 hour
Excretion Fecal (90%) and renal (8%)

DOSAGE

Repaglinide is taken immediately before a meal or 15 to 30 minutes before a meal. It should be taken with every meal up to 4 times a day. Doses are adjusted by the physician to achieve the best effect.

Repaglinide comes as a tablet to take by mouth. The tablets are taken before meals, any time from 30 minutes before a meal to just before the meal. If you skip a meal, you need to skip the dose of repaglinide. If you add an extra meal, you need to take an extra dose of repaglinide. Your doctor may gradually increase your dose, depending on your response to repaglinide. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take repaglinide exactly as directed. Do not take more or less of it or take it more often than directed by the package label or prescribed by your doctor.

Continue to take repaglinide even if you feel well. Do not stop taking repaglinide without talking to your doctor.

SIDE EFFECTS

Headache, nausea, vomiting, diarrhea, upset stomach, and joint pain may occur. If any of these effects persist or worsenToo much of this medication can cause low blood sugar (hypoglycemia). This effect may also occur if you do not consume enough calories. The symptoms include chills, cold sweats, blurred vision, dizziness, drowsiness, shaking, fast heartbeat, weakness, headache, fainting, tingling of the hands/feet, or hunger. It is a good habit to carry glucose (sugar) tablets or gel to treat low blood sugar. If you don't have these reliable forms of glucose, raise your blood sugar quickly by eating a quick source of sugar such as table sugar, honey, candy, or drinking a glass of fruit juice or non-diet soda. Tell your doctor immediately about the reaction. To help prevent low blood sugar, eat meals on a regular schedule, and do not skip meals. Too little of this medication can cause high blood sugar (hyperglycemia). Symptoms of high blood sugar 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.

Taj Pharmaceuticals Ltd.
Repaglinide
CAS NO- 135062-02-1

PRECAUTIONS

Tell your doctor your medical history, including: kidney disease, liver disease, adrenal or pituitary gland problems, any allergies. Unusual stresses such as fever, serious infection, trauma or surgery may result in loss of blood sugar control. Consult your doctor or pharmacist. Limit alcohol intake, as it may aggravate drug side effects. This medication should be used only when clearly needed during pregnancy. Insulin therapy may be necessary during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug is excreted into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding. Caution is advised when this drug is used in the elderly since side effects may be aggravated and more difficult to recognize.

Before taking repaglinide,

* tell your doctor and pharmacist if you are allergic to repaglinide or any other drugs.
* tell your doctor and pharmacist what prescription and nonprescription medications you are taking, especially acetophenazine (Tindal), aspirin, blood pressure medicines, carbamazepine (Tegretol), chloramphenicol (Chloromycetin), chlorpromazine (Thorazine), corticosteroids, diuretics ('water pills'), drugs for arthritis, erythromycin, troglitazone (Rezulin), estrogens, fluphenazine (Prolixin), isoniazid (Rifamate), ketoconazole (Nizoral), mesoridazine (Serentil), oral contraceptives, perphenazine (Trilafon), phenelzine (Nardil), phenobarbital (Luminal), phenytoin (Dilantin), probenecid (Benemid), prochlorperazine (Compazine), promazine (Sparine), promethazine (Phenergan), rifampin (Rifadin, Rimactane), thioridazine (Mellaril), tranylcypromine (Parnate), trifluoperazine (Stelazine), trifluprom azine (Vesprin), trimeprazine (Temaril), vitamins, or warfarin (Coumadin).
* tell your doctor if you have or have ever had liver or kidney disease or if you have been told you have type I diabetes mellitus.
* tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking repaglinide, call your doctor.
* if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking repaglinide.

INTERACTION

Repaglinide should not be used with the following medication because very serious effects (very low blood sugar) may occur: gemfibrozil. If you are currently using this medication, tell your doctor or pharmacist before starting repaglinide. Fenofibrate may be an alternative medication for the gemfibrozil. Also, itraconazole should not be used in combination with repaglinide and gemfibrozil because extremely low blood sugar could occur. Tell your doctor of all nonprescription and prescription medication you may use, especially: beta-blocker type drugs (e.g., propranolol, metoprolol), NSAIDs (e.g., aspirin, ibuprofen), sulfa drugs (e.g., sulfamethoxazole), chloramphenicol, "blood thinners" (e.g., warfarin), probenecid, MAO Inhibitors (e.g., phenelzine, tranylcypromine, selegiline, furazolidone), "water pills" (e.g., thiazides, furosemide), corticosteroids, phenothiazines (e.g., chlorpromazine), thyroid drugs, estrogens and birth control pills, niacin, "adrenaline-like" drugs (e.g., pseudoephedrine), "calcium blockers" (e.g., verapamil), isoniazid (INH), drugs which affect certain liver enzymes (CYP 3A4 inhibitors and inducers such as azole antifungals- e.g., ketoconazole, macrolide antibiotics- e.g., clarithromycin, cimetidine, rifamycins- e.g., rifampin, St John's wort, certain anti-seizure medications- e.g., phenytoin). Check all medicine labels (including nonprescription drugs) since many products contain "adrenaline-like" drugs. Consult your pharmacist. Do not start or stop any medicine without doctor or pharmacist approval.

DRUG DESCRIPTION

Repaglinide lowers blood glucose by stimulating the release of insulin from the pancreas. It achieves this by closing ATP-dependent potassium channels in the membrane of the beta cells. This depolarizes the beta cells, opening the cells' calcium channels, and the resulting calcium influx induces insulin secretion.

Repaglinide

CAS No. : 135062-02-1

Repaglinide is a white to off-white powder with molecular formula C27H36N2O4 and a molecular weight of 452.6. Repaglinide tablets contain 0.5 mg, 1 mg, or 2 mg of repaglinide. In addition each tablet contains the following inactive ingredients: calcium hydrogen phosphate (anhydrous), microcrystalline cellulose, maize starch, polacrilin potassium, povidone, glycerol (85%), magnesium stearate, meglumine, and poloxamer. The 1 mg and 2 mg tablets contain iron oxides (yellow and red, respectively) as coloring agents.

Repaglinide is an oral medication for lowering blood sugar (glucose) in diabetics. It is in a class of drugs for treating diabetes type 2 called meglitinides and is chemically unlike other anti-diabetic medication.

Approximately 90% of patients with diabetes have type 2 or non-insulin dependent diabetes mellitus. (Type 2 diabetes usually occurs in adulthood, and is associated with obesity and a strong family history of diabetes.) Glucose intolerance in diabetes type II is caused by reduced insulin secretion from the pancreas after meals and resistance of the body's cells to insulin's effect which is to stimulate the cells to remove glucose from the blood. This leads to high levels of blood glucose.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture 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