

Rabeprazole Sodium Cas No. : 117976-89-3

Rabeprazole works by blocking acid production in the stomach. This medication is known as a proton pump inhibitor (PPI). It is used to treat acid-related stomach/intestinal and throat (esophagus) problems (e.g., acid reflux or GERD, ulcers, erosive esophagitis, Zollinger-Ellison syndrome). Decreasing excess stomach acid can help relieve symptoms such as heartburn, difficulty swallowing, persistent cough, and trouble sleeping.

Active Pharmaceuticals Ingredients Manufacturers



Taj Pharma PDF

Taj Pharmaceuticals Ltd.**Rabeprazole Sodium****CAS No. : 117976-89-3****Systematic (IUPAC) name**

2-([4-(3-methoxypropoxy)-3-methylpyridin-2-yl]methylsulfinyl)-1H-benzo[d]imidazole

Identifiers

CAS number 117976-89-3

ATC code A02BC04

PubChem 5029

DrugBank APRD01212

ChemSpider 4853

Chemical dataFormula C₁₈H₂₁N₃O₃S

Mol. mass 359.444 g/mol

SMILES eMolecules & PubChem

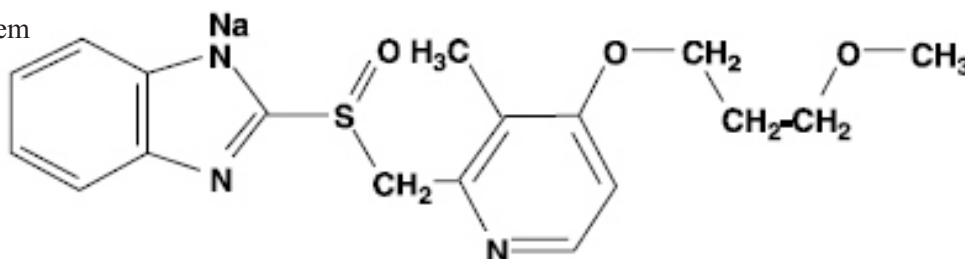
Pharmacokinetic data

Bioavailability 52%

Metabolism Hepatic

Half life 1 - 1.5 hours

Excretion Renal



Inactive ingredients of the 20 mg tablet are carnauba wax, crospovidone, diacetylated monoglycerides, ethylcellulose, hydroxypropyl cellulose, hypromellose phthalate, magnesium stearate, mannitol, propylene glycol, sodium hydroxide, sodium stearyl fumarate, talc, and titanium dioxide. Iron oxide yellow is the coloring agent for the tablet coating. Iron oxide red is the ink pigment.

USES

Rabeprazole works by blocking acid production in the stomach. This medication is known as a proton pump inhibitor (PPI). It is used to treat acid-related stomach/intestinal and throat (esophagus) problems (e.g., acid reflux or GERD, ulcers, erosive esophagitis, Zollinger-Ellison syndrome). Decreasing excess stomach acid can help relieve symptoms such as heartburn, difficulty swallowing, persistent cough, and trouble sleeping. It can also prevent serious acid damage to your digestive system (e.g., ulcers, cancer of the esophagus).

This medication may also be used in combination with antibiotics to treat certain types of ulcers caused by bacterial infection.

HOW TO USE

Take this medication by mouth usually once daily, with or without food, or as directed by your doctor.

Do not crush, chew, or split this medication. Swallow the medication whole.

If needed, antacids may be taken along with this medication.

The dosage and length of treatment is based on your medical condition and response to therapy.



Taj Pharmaceuticals Ltd.
Rabeprazole Sodium

CAS No 117976-89-3

Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. Continue to take this medication for the prescribed length of treatment even if you are feeling better.

SIDE EFFECTS

This medication is generally well tolerated. Although uncommon, headache may occur. If this effect persists or worsens, 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 highly unlikely but very serious side effects occur: signs of vitamin B-12 deficiency with long-term (over 3 years) treatment (e.g., unusual weakness, sore tongue, numbness or tingling of the hands/feet).

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.

PRECAUTIONS

Before taking rabeprazole, tell your doctor or pharmacist if you are allergic to it; or to similar drugs (e.g., lansoprazole, omeprazole); or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: severe liver disease, other stomach problems (e.g., tumors).

Some symptoms may actually be signs of a more serious condition. Tell your doctor immediately if you have: heartburn combined with lightheadedness/sweating/dizziness, chest pain or shoulder/jaw pain (especially with trouble breathing), pain spreading to arms/neck/shoulders, unexplained weight loss.

This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.

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 the US product at room temperature 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.

Store the Canadian product at 59-77 degrees F (15-25 degrees C) away from moisture.

Keep all medicines away from children and pets.

DOSAGE

Take Rabeprazole sodium once a day, with or without food. Swallow the tablet whole; it should not be crushed, chewed, or split. You can continue taking antacids during Rabeprazole sodium therapy.

If you're using Rabeprazole sodium along with amoxicillin and clarithromycin, take all three drugs at the same time twice a day, once in the morning and again in the evening. This three-drug regimen should be taken with meals.

For healing ulcerative or erosive GERD, the recommended dose for adults is 20 mg daily for 4-8 weeks. If healing does not occur after 8 weeks, another 8 week course may be considered. The recommended maintenance dose is 20 mg daily.



Heartburn due to GERD is treated with 20 mg daily for 4 weeks and an additional 4 weeks if symptoms do not resolve. Ulcers are treated with 20 mg daily for 4 weeks. For the management of Zollinger-Ellison Syndrome, the starting dose for adults is 60 mg daily, and the dose is adjusted based on improvement in symptoms, healing of ulcers, or the effectiveness of acid suppression. Doses of 100 mg per day and 60 mg twice daily have been used in some patients with Zollinger-Ellison Syndrome. The regimen for eradication of Helicobacter pylori is rabeprazole 20 mg given twice daily (morning and evening) for 7 days.

Tablets should be swallowed whole and should not be crushed, split or chewed. Rabeprazole can be taken with or without meals since food has little effect on its absorption.

DRUG DESCRIPTION

The active ingredient in Delayed-Release Tablets is rabeprazole sodium, a substituted benzimidazole that inhibits gastric acid secretion. Rabeprazole sodium is known chemically as 2-[[[4-(3-methoxypropoxy)-3-methyl-2-pyridinyl]-methyl]sulfinyl]-1H-benzimidazole sodium salt. It has an empirical formula of C₁₈H₂₀N₃NaO₃S and a molecular weight of 381.43. Rabeprazole sodium is a white to slightly yellowish-white solid. It is very soluble in water and methanol, freely soluble in ethanol, chloroform and ethyl acetate and insoluble in ether and n-hexane. The stability of rabeprazole sodium is a function of pH; it is rapidly degraded in acid media, and is more stable under alkaline conditions. Tablet is available for oral administration as delayed-release, enteric-coated tablets containing 20 mg of rabeprazole sodium.

Inactive ingredients of the 20 mg tablet are carnauba wax, crospovidone, diacetylated monoglycerides, ethylcellulose, hydroxypropyl cellulose, hypromellose phthalate, magnesium stearate, mannitol, propylene glycol, sodium hydroxide, sodium stearyl fumarate, talc, and titanium dioxide. Iron oxide yellow is the coloring agent for the tablet coating. Iron oxide red is the ink pigment.

Rabeprazole sodium blocks acid production in the stomach. It is prescribed for the short-term (4 to 8 weeks) treatment of sores and inflammation in the upper digestive canal (esophagus). This condition, known as gastroesophageal reflux disease (GERD), is caused by the backflow of stomach acid into the esophagus over a prolonged period of time. Because GERD can be chronic, your doctor may continue to prescribe Rabeprazole sodium to prevent a relapse after your initial course of treatment and to relieve symptoms of GERD such as heartburn.

Rabeprazole sodium can also be prescribed for the short-term (up to 4 weeks) treatment of duodenal ulcers (ulcers that form just outside the stomach at the top of the small intestine), and for Zollinger-Ellison syndrome, a disease which causes the stomach to produce too much acid. The drug is classified as a "proton pump inhibitor." It works by blocking a specific enzyme essential to the production of stomach acid. It begins reducing acid within an hour of administration.

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



CAS 117976-90-6
Rabeprazole Sodium

TAJ GROUP OF COMPANIES
TAJ PHARMACEUTICALS LIMITED.
Working For Healthier World™ INDIA



Taj Group of Companies

TAJ PHARMACEUTICALS LIMITED INDIA

"Working for human race"