

Esomeprazole Magnesium Cas No. : 161796-78-7

Esomeprazole 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 and throat (esophagus) problems (e.g., acid reflux or GERD, erosive esophagitis). 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).

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.**Esomeprazole Magnesium****CAS No. : 161796-78-7**

Systematic (IUPAC) name

(S)-5-methoxy-2-[(4-methoxy-3,5-dimethylpyridin-2-yl)methylsulfinyl]-3H-benzimidazole

Identifiers

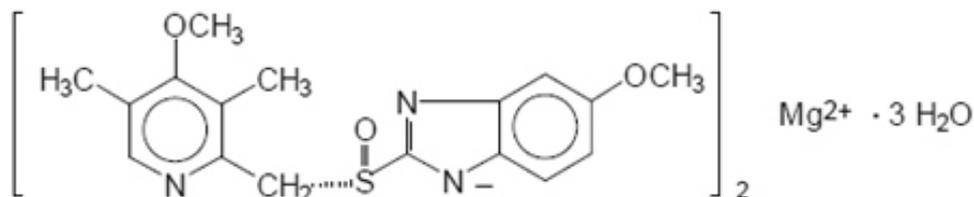
CAS number 161796-78-7

ATC code A02BC05

PubChem 4594

DrugBank APRD00363

ChemSpider 7843322

**Chemical data**Formula C₁₇H₁₉N₃O₃S, Mol. mass 345.417 g/mol, SMILES eMolecules & PubChem**Pharmacokinetic data**

Bioavailability 50 to 90%, Metabolism Hepatic (CYP2C19, CYP3A4), Half life 1–1.5 hours, Excretion 80% Renal 20% faecal

USES

Esomeprazole 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 and throat (esophagus) problems (e.g., acid reflux or GERD, erosive esophagitis). 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 intestinal ulcers caused by bacterial infection.

HOW TO USE

Read the Patient Information Leaflet provided by your pharmacist before you start using esomeprazole and each time you get a refill. If you have any questions, consult your doctor or pharmacist.

Take this medication by mouth usually once daily at least 1 hour before a meal, or as directed by your doctor. Do not crush or chew the capsule(s). Swallow the capsule(s) whole. If you have difficulty swallowing this medication whole, the capsule may be opened and the contents sprinkled onto soft food (cold applesauce or yogurt), or emptied into a small amount of water, orange juice, or apple juice and taken as directed. Rinse the container with an additional small amount of liquid and drink the contents to make sure the entire dose is taken. Do not chew the food/medication mixture or prepare a supply in advance; this may destroy the drug and/or increase side effects. If needed, antacids may be taken along with this medication.

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

Headache, diarrhea, nausea, gas, stomach pain, constipation, or dry mouth 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: signs of a lung infection called pneumonia (e.g., fever, cough, trouble breathing).

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Tell your doctor immediately if any of these rare but very serious side effects occur: severe stomach/abdominal pain, persistent nausea, vomiting, unusual tiredness, dark urine, yellowing eyes/skin, 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 esomeprazole, 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.

Based on information for similar drugs, this medication may pass into breast milk. Breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

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 room temperature (77 degrees F or 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

DOSAGE

Esomeprazole Magnesium is supplied as delayed-release capsules for oral administration or in packets for preparation of delayed-release oral suspensions. The recommended dosages are outlined in the table below. Esomeprazole Magnesium should be taken at least one hour before meals.

The duration of proton pump inhibitor administration should be based on available safety and efficacy data specific to the defined indication and dosing frequency, as described in the Prescribing Information, and individual patient medical needs. Proton pump inhibitor treatment should only be initiated and continued if the benefits outweigh the risks of treatment.

Take Esomeprazole Magnesium at least one hour before meals. Be careful to swallow it whole. If you have trouble swallowing capsules, you can open the capsule and carefully pour the pellets onto one tablespoon of applesauce. The applesauce should not be hot. Mix in the pellets, then swallow the applesauce immediately, without chewing.

* If you miss a dose...

Take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to your regular schedule. Never take 2 doses at the same time.

DRUG DESCRIPTION

The active ingredient in esomeprazole magnesium Delayed-Release Capsules and For Delayed-Release Oral Suspension is bis(5-methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole-1-yl) magnesium trihydrate, a compound that inhibits gastric acid secretion.

Esomeprazole is the S-isomer of omeprazole, which is a mixture of the S- and R- isomers. Its molecular formula is $(C_{17}H_{18}N_3O_3S)_2Mg \cdot 3H_2O$ with molecular weight of 767.2 as a trihydrate and 713.1 on an anhydrous basis. The magnesium salt is a white to slightly colored crystalline powder.

It contains 3 moles of water of solvation and is slightly soluble in water. The stability of esomeprazole magnesium is a function of pH; it rapidly degrades in acidic media, but it has acceptable stability under alkaline conditions. At pH 6.8 (buffer), the half-life of the magnesium salt is about 19 hours at 25°C and about 8 hours at 37°C.

Esomeprazole Magnesium relieves heartburn and other symptoms caused by the backflow of stomach acid into the canal to the stomach (the esophagus)—a condition known as gastroesophageal reflux disease. It is also prescribed to heal the damage (erosive esophagitis) that reflux disease can cause.

Prescribed in combination with the antibiotics amoxicillin and clarithromycin, Esomeprazole Magnesium is also used to treat the infection that causes most duodenal ulcers (ulcers occurring just beyond the exit from the stomach).

Like its sister drug omeprazole, Esomeprazole Magnesium works by reducing the production of stomach acid.

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.

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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.

This leaflet was prepared by
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