

Oxethazaine Cas No. : 126-27-2

The rate and/or extent of absorption of many drugs may be increased or decreased when they are used concurrently with aluminum-magnesium hydroxide- containing antacids. Therefore, as a general rule, medication should not be taken within 1 to 2 hours of an antacid, if possible.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Oxethazaine

CAS No. : 126-27-2



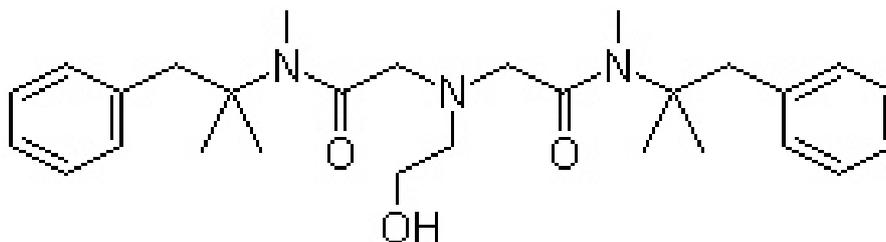
Molecular Formula C₂₈H₄₁N₃O₃
Molecular Weight 467.65
CAS Registry Number 126-27-2
PubChem 4621

Chemical data

Formula C₂₈H₄₁N₃O₃
Mol. mass 467.643 g/mol

Pharmacokinetic data

Bioavailability ?
Metabolism ?
Half life 1 hour

**DOSAGE**

The recommended adult oral dose is one to two 5 mL measures, four times daily, 15 minutes before meals and at bedtime. Do not exceed the recommended dosage. MUCAINE suspension should preferably be taken undiluted; however, if desired, it may be followed by a sip of water. The maximum dose recommended may be decreased following adequate control of the symptoms.

Adult Dosage (>12 years.)

5.000 to 10.000 mg 7.5 (7.5) 8 hourly

Pediatric Dosage (20 Kg.) No data regarding the Pediatrics dosage details of Oxethazaine is available. The maximum dose recommended may be decreased following adequate control of the symptoms. The suspension should preferably be taken undiluted; however, if desired, it may be followed by a sip of water.

SIDE EFFECTS

Hypersensitivity reactions including skin eruptions (dermatitis, urticaria), pruritus, glossitis, angioedema, and collapse have been reported in occasional cases.

If the dose of this product exceeds 60 mL/day, some patients may experience dizziness, faintness, or drowsiness.

Magnesium-containing antacids may cause diarrhea. Aluminum-containing antacids may cause constipation.

The symptomatic adverse reactions produced by Oxethazaine are more or less tolerable and if they become severe, they can be treated symptomatically, these include Hypersensitivity reactions, Idosyncratic rashes.

If the dose of Oxethazaine exceeds 60 mL per day, some patients may experience dizziness, faintness or drowsiness. Sensitivity reactions including skin eruptions (dermatitis, urticaria), pruritus, glossitis, angioedema and collapse have been reported.

Magnesium-containing antacids may cause diarrhoea. Aluminium-containing antacids may cause constipation.



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PRECAUTIONS

The use of magnesium-containing antacids in patients with mild to moderate renal impairment should be carefully monitored due to a possible increased danger of hypermagnesaemia.

In patients with chronic renal failure, hyperalumaemia may occur. Encephalopathy and dementia may occur in patients with poor renal function or patients on dialysis, due to an increase in plasma concentration of aluminium. Hypophosphataemia may occur with prolonged administration or large doses of aluminium-containing antacids (except aluminium phosphate) especially in patients with an inadequate dietary intake of phosphorus.

Laboratory Tests –Serum phosphate levels should be monitored at monthly or bi-monthly intervals in patients on maintenance haemodialysis who are receiving chronic antacid therapy.

Use in children –The safety and effectiveness of Oxethazaine in children has not been established.

Drug Interactions –The rate and/or extent of absorption of many medicines may be increased or decreased. Therefore, medication should not be taken within one to two hours of Oxethazaine .

An incomplete list of substances for which the above statement has been shown to apply includes: tetracycline, iron salts, isoniazid, ethambutol, some anti-muscarinic drugs, benzodiazepines, phenothiazines ranitidine, indomethacin, phenytoin, nitrofurantoin, Vitamin A, fluoride and phosphate. An increase in the plasma level of quinidine and possible toxicity may result if alkalisation of the urine occurs following antacid therapy.

Pregnancy: A reproduction study performed in rabbits revealed no evidence of harm to the fetus. There are, however, no adequate or well-controlled studies in pregnant women. Use during pregnancy if the benefits outweigh the potential risks.

Lactation: It is not known if Oxethazaine is excreted in breast milk. Because many drugs are excreted in breast milk, a decision should be made whether to discontinue nursing or to discontinue Oxethazaine , taking into account the importance of the drug to the mother and the potential risk to the infant.

Children: The safety and effectiveness of Oxethazaine in children have not been established. Therefore this product is recommended for adult use only.

INTERACTION

The rate and/or extent of absorption of many drugs may be increased or decreased when they are used concurrently with aluminum-magnesium hydroxide- containing antacids. Therefore, as a general rule, medication should not be taken within 1 to 2 hours of an antacid, if possible.

An incomplete list of substances for which the above statement has been shown to apply includes; tetracycline, iron salts, chlorpromazine, levodopa, isoniazid, digoxin, H2-antagonists, indomethacin, nitrofurantoin, and dicumarol. An increase in the plasma level of quinidine and possible toxicity may result if alkalization of the urine occurs during antacid therapy.





DRUG DESCRIPTION

Oxcarbazepine is an anticonvulsant and mood stabilizing drug, used primarily in the treatment of epilepsy and bipolar disorder. Oxcarbazepine is a structural derivative of carbamazepine, adding an extra oxygen atom on the dibenzazepine ring. This difference helps reduce the impact on the liver of metabolizing the drug, and also prevents the serious forms of anemia or agranulocytosis occasionally associated with carbamazepine. Aside from this reduction in side effects, it is thought to have the same mechanism as carbamazepine - sodium channel inhibition (presumably, the main mechanism of action) - and is generally used to treat the same conditions. Oxcarbazepine has recently been found associated with a greater enhancement in mood and reduction in anxiety symptoms than other drugs employed to treat epilepsy.



Oxcarbazepine is a white to faintly orange crystalline powder. It is slightly soluble in chloroform, dichloromethane, acetone, and methanol and practically insoluble in ethanol, ether and water. Its molecular weight is 252.27. contains the following inactive ingredients: ascorbic acid; dispersible cellulose; ethanol; macrogol stearate; methyl parahydroxybenzoate; propylene glycol; propyl parahydroxybenzoate; purified water; sodium saccharin; sorbic acid; sorbitol; yellow-plum-lemon aroma.

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>

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91 022 30601000.

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