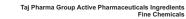
Acamprosate calcium Cas No. : 77337-73-6

This medication is used to help alcohol dependent patients keep from drinking alcohol. It should be used as part of a complete treatment program that includes both counseling and psychological support. Acamprosate is believed to work by restoring the natural balance of chemicals in the brain (neurotransmitters). Before beginning this medication, you should no longer be drinking alcohol. Acamprosate has not been shown to be effective if you are still drinking when you start taking it.





Active Pharmaceuticals Ingredients Manufacturers

Taj Pharmaceuticals Ltd. Acamprosate calcium CAS No. : 77337-73-6

Catalog No.: PI-21684

Synonym: Molecular Formula: 2C5H10NO4S.Ca Molecular Weight: 400.48 CAS Number: 77337-Molecular Formula: 2C5H10NO4S.Ca73-6 MDL Number:

Properties & Safety

Appearance: Purity: 98.0% Freezing/Melting Point: Boiling Point: Flash Point: Density: nD20: EINECS: RTECS: UN: Beilatein: HTS: TSCA Inventory: Storage:

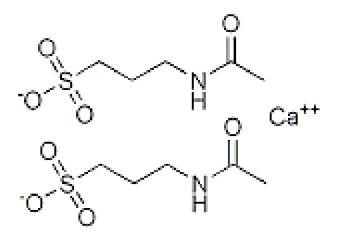
3-Acetamidopropane-1-sulfonic acid Identifiers CAS number 77337-76-9 ATC code N07BB03 PubChem 71158 DrugBank APRD00661

Chemical data

Formula C10H20N2O8S2 Mol. mass 181.211 g/mol

Pharmacokinetic data

Bioavailability 11% Protein binding Negligible Metabolism Nil Half life 20 to 33 hours Excretion Renal





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Taj Pharmaceuticals Ltd. ACAMPROSATE

CALCIUM CAS NO- 77337-76-9

Percentage attending program Abstinence rates Average number of days abstinence1 Days until first breach of abstinence1

Acamprosate group 66.1% 50.8% 45.07 days 26.79 days Naltrexone group 79.7% 66.1% 49.95 days 26.7 days Drug combination group 83.1% 67.8% 53.58 days 37.32 days

USES

This medication is used to help alcohol dependent patients keep from drinking alcohol. It should be used as part of a complete treatment program that includes both counseling and psychological support. Acamprosate is believed to work by restoring the natural balance of chemicals in the brain (neurotransmitters). Before beginning this medication, you should no longer be drinking alcohol. Acamprosate has not been shown to be effective if you are still drinking when you start taking it.

HOW TO USE

Take this medication by mouth generally three times a day or as directed by your doctor. Acamprosate may be taken with or without food. Take this medication with a full glass of water (8 ounces or 240 milliliters) unless your doctor directs you otherwise. Do not lie down for 30 minutes after taking this medication. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same times each day. Dosage is based on your medical condition and response to therapy. Continue taking this medication, but inform your doctor if you begin drinking alcohol again.

SIDE EFFECTS

Diarrhea, nausea, vomiting, gas, stomach pain, loss of appetite, headache, drowsiness, dizziness, constipation, fatigue, weight gain/loss, muscle/joint pain, change in sexual desire or decreased sexual ability 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 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 unlikely but serious side effects occur: mental/mood changes (including severe depression, thoughts of suicide), chest pain, fainting, fast or pounding heartbeat, vision or hearing changes, increased thirst. Tell your doctor immediately if any of these rare but very serious side effects occur: change in the amount of urine, seizures, persistent stomach pain, black/tarry stools, vomit that looks like coffee grounds. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

DRUG DESCRIPTION

(acamprosate calcium) is supplied in an enteric-coated tablet for oral administration. Acamprosate calcium is a synthetic

compound with a chemical structure similar to that of the endogenous amino acid homotaurine, which is a structural analogue of the amino acid neurotransmitter γ -aminobutyric acid and the amino acid neuromodulator taurine. Its chemical name is calcium acetylaminopropane sulfonate. Its chemical formula is C10H20N2O8S2Ca and molecular weight is 400.48. Its structural formula is:

(acamprosate calcium) Structural Formula Illustration

Acamprosate calcium is a white, odorless or nearly odorless powder. It is freely soluble in water, and practically insoluble in absolute ethanol and dichloromethane.

H₃C Ca2+

H_aC



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Each Acamprosate calcium tablet contai ns acamprosate calcium 333 mg, equivalent to 300 mg of acamprosate. Inactive ingredients in Acamprosate calcium tablets include: crospovidone, microcrystalline cellulose, magnesium silicate, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, talc, propylene glycol and Eudragit® L 30 D or equivalent. Sulfites were used in the synthesis of the drug substance and traces of residual sulfites may be present in the drug product.

Mechanism Of Action

Both COX-1 and COX-2 catalyze the conversion of arachidonic acid to prostaglandin (PG) H2, the precursor of PGs and thromboxane. Valdecoxib selectively inhibits the cyclooxygenase-2 (COX-2) enzyme, important for the mediation of inflammation and pain. Unlike non-selective NSAIDs, Valdecoxib does not inhibit platelet aggregation.



PHARMACEUTICALS^{™™}

ACTIVE PHARMACEUTICAL I N G R E D I E N T S

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

