

Topiramate Cas No. : 97240-79-4

Topiramate is used alone or with other medications to prevent and control seizures (epilepsy). This medication is also used to prevent migraine headaches and reduce how often you may get them. Topiramate will not work to treat a migraine headache once it occurs. If you get a migraine headache, treat it as directed by your doctor (e.g., take pain medications, decrease sound and light).

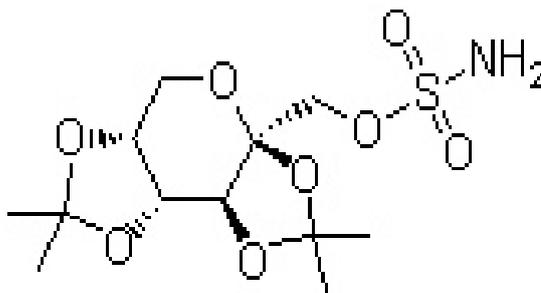
Active Pharmaceuticals Ingredients Manufacturers



Taj Pharma PDF

Taj Pharmaceuticals Ltd.**Topiramate****CAS No. : 97240-79-4**

Molecular Formula C₁₂H₂₁NO₈S
Molecular Weight 339.36
CAS Registry Number 97240-79-4
ATC code N03AX11
PubChem 5284627
DrugBank APRD00237
ChemSpider 4447672

**Chemical data**

Formula C₁₂H₂₁NO₈S
Mol. mass 339.363 g/mol
SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability 80%
Metabolism 30% hepatic, 70% is excreted unchanged
Half life 19 to 23 hours
Excretion 70% renal (in urine) in unchanged form

USES

Topiramate is used alone or with other medications to prevent and control seizures (epilepsy). This medication is also used to prevent migraine headaches and reduce how often you may get them. Topiramate will not work to treat a migraine headache once it occurs. If you get a migraine headache, treat it as directed by your doctor (e.g., take pain medications, decrease sound and light).

HOW TO USE

Take this medication by mouth with or without food, usually twice daily or as directed by your doctor. Swallow the tablets whole. Do not crush, chew or break the tablets because they have a bitter taste. To prevent kidney stones from forming, drink plenty of liquids while taking this medication unless your doctor instructs you otherwise.

The dosage is based on your medical condition and response to therapy. In children, dosage may also be based on body weight. Your doctor may gradually increase your dose to lower your risk of side effects such as drowsiness and memory problems. It may take several weeks to reach the best dose for you. Take this medication exactly as directed. Take this medication regularly in order to get the most benefit from it. To help you remember, take it at the same times each day. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when this drug is suddenly stopped. Your dose may need to be gradually decreased.

DOSAGE

Most commonly, topiramate is started in low doses, 25 or 50 mg per day, and then increased slowly, under a doctor's orders, by 25 to 50 mg per week until an effective daily dose is reached. This slow approach to treatment reduces side effects.



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In children, the starting dose is up to 25 mg (1 to 3 mg/kg/day), taken nightly for the first week. The dose is then increased at 1 or 2 week intervals by 1 to 3 mg/kg/day.

Although the usual adult dose is 200 mg twice daily, some adult patients may begin to see a clinical response at 200 mg per day. Some patients need doses higher than 200 mg daily. In children, the usual dose is 2.5 to 4.5 mg/kg twice daily.

Patients should maintain an adequate fluid intake in order to minimize the risk of kidney stones.

SIDE EFFECTS

Weakness, tiredness, drowsiness, dizziness, confusion, difficulty concentrating, tingling of the hands/feet, loss of appetite, diarrhea, impotence, and weight loss may occur. If any of these symptoms persist or worsen, notify your doctor promptly.

PRECAUTIONS

Before taking topiramate,

- * tell your doctor and pharmacist if you are allergic to topiramate or any other medications.
- * tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: acetazolamide (Diamox); amitriptyline; antidepressants; antihistamines; dichlorphenamide; digoxin; ipratropium; iron; isoniazid hydrochlorothiazide; lithium; medications for anxiety, irritable bowel disease, mental illness, motion sickness, Parkinson's disease, ulcers, or urinary problems; metformin; methazolamide; oral contraceptives (birth control pills); other medications for seizures such as carbamazepine and phenytoin; pioglitazone; risperidone; salicylate pain relievers such as aspirin, choline magnesium trisalicylate, choline salicylate, diflunisal, magnesium salicylate, and salsalate; sedatives; sleeping pills; tranquilizers; valproic acid; and zonisamide. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- * tell your doctor if you or any family members have or have ever had kidney stones, if you drink or have ever drunk large amounts of alcohol, and if you have ever thought about killing yourself or tried to do so. Also tell your doctor if you have or have ever had metabolic acidosis (a disturbance in the body's acid-base balance that results in excessive acidity of the blood); osteopenia, osteomalacia, or osteoporosis (conditions in which the bones are soft or brittle and may break easily); diabetes; glaucoma (a type of eye disease); any disease that affects your breathing such as asthma or chronic obstructive pulmonary disease (COPD); depression or abnormal moods; a growth problem; or liver or kidney disease. Also tell your doctor if you have diarrhea or if you develop diarrhea during your treatment.
- * tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking topiramate, call your doctor.
- * if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking topiramate.
- * you should know that topiramate may make you drowsy, dizzy, confused, or unable to concentrate. Do not drive a car or operate machinery until you know how this medication affects you.
- * if you are taking topiramate to control seizures, you should know that you may continue to have seizures during your treatment. You may need to avoid activities such as swimming, driving, and climbing so that you will not harm yourself or others if you lose consciousness during a seizure.
- * ask your doctor about the safe use of alcoholic beverages while you are taking topiramate.
- * if you are taking oral contraceptives (birth control pills), tell your doctor if unexpected bleeding or spotting occurs. Topiramate can decrease the effectiveness of oral contraceptives.
- * you should know that topiramate can prevent you from sweating and make it harder for your body to cool down when it gets very hot. This happens most often in warm weather and to children who take topiramate. Avoid exposure to heat, drink plenty of fluids and tell your doctor if you have a fever, headache, muscle cramps, or an upset stomach, or if you are not sweating as usual.



* you should know that you may be more likely to develop a kidney stone while you are taking topiramate. Drink 6 to 8 glasses of water every day to prevent kidney stones from forming.

DRUG DESCRIPTION

Topiramate is used alone or with other medications to treat certain types of seizures in people who have epilepsy. Topiramate is also used with other medications to control seizures in people who have Lennox-Gastaut syndrome (a severe form of epilepsy that begins during childhood and causes several types of seizures, behavioral disturbances, and developmental delays). Topiramate is used to treat patients who continue to have seizures even when they take other anti-seizure medications. Topiramate is also used to prevent migraine headaches, but not to relieve the pain of migraine headaches when they occur. Topiramate is in a class of medications called anticonvulsants. It works by decreasing abnormal excitement in the brain.



Topiramate is an oral drug that is used to prevent the seizures of epilepsy. (It is an anti-epileptic or anti-seizure drug). It is used primarily among patients who are not controlled by other anti-epileptic drugs. About 1 in 4 Americans diagnosed with epilepsy has seizures that resist treatment with other anti-epileptic drugs. Topiramate also prevents migraine headaches.

Seizures are due to the abnormal activity of nerves in the brain, and the abnormal activity spreads to smaller or larger portions of the brain. Although topiramate's exact mechanism of action is unknown, scientific studies suggest that it may alter neurotransmitters within the brain. Neurotransmitters are chemicals that nerves manufacture and use to communicate with other nearby nerves. By altering the production or action of the neurotransmitters, topiramate may suppress the abnormal activity of the nerves in the brain that cause the seizures or may prevent the abnormal activity from spreading to other nerves. Other studies suggest that topiramate may suppress the nerves directly and make them less likely to fire

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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.

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