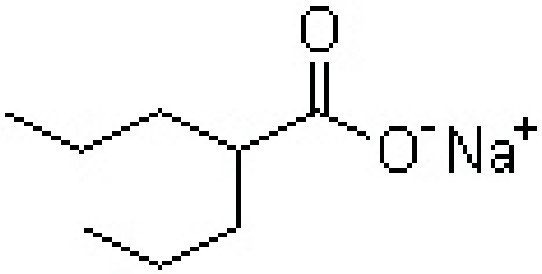
Taj Pharmaceuticals Ltd.

Sodium Valproate
CAS No. : 1069-66-5

Chemical data

CAS number 1069-66-5
Formula C8H15NaO2
Molecular Weight 166.19
ATC code N03AG01
PubChem 14047
ChemSpider 13428
Mol. mass 166.20 g/mol



Pharmacokinetic data

Bioavailability ?
Protein binding 90–95%
Metabolism 75% by CYP enzymes
Half life 9–18 hours
Excretion 20% excreted as glucuronide

DOSAGE

A standard dose of Sertraline is 50 to 200 mg per day. It is taken once a day, either in the morning or evening, and may be taken with or without food.Take this medication by mouth, usually once daily or as directed by your doctor. This medication may make you sleepy or wakeful. Therefore, depending on how this medication affects you, your doctor may direct you to take the entire dose once daily either in the morning or evening.

The tablet form of this medication may be taken with or without food. The capsule form is usually taken with food after breakfast or after your evening meal as directed by your doctor.The dosage is based on your medical condition and response to therapy. To reduce your risk of side effects, your doctor may start you at a low dose and gradually increase your dose. Usually, the daily dose will not be more than 200 milligrams. Follow your doctor's instructions carefully.Do not take more or less medication or take it more frequently than prescribed. Your condition will not improve any faster and your risk of side effects will increase. Use this medication regularly in order to get the most benefit from it.
To help you remember, use it at the same time each day. It is important to continue taking this medication as prescribed even if you feel well. Do not stop taking this medication without consulting your doctor.

SIDE EFFECTS

Diarrhea, dizziness, drowsiness, hair loss, blurred/double vision, change in menstrual periods, ringing in the ears, shakiness (tremor), unsteadiness, weight changes may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these serious side effects occur: mental/mood changes, signs of infection (e.g., fever, persistent sore throat). Tell your doctor immediately if any of these unlikely but serious side effects occur: chest pain, easy bruising/unexplained bleeding, fast/irregular heartbeat, swelling of hands/feet, uncontrolled eye movement (nystagmus). Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: dark urine, persistent nausea/vomiting, severe stomach/abdominal pain, yellowing eyes or skin. Severe (sometimes fatal) brain disorder (encephalopathy) has rarely occurred, particularly in patients with certain metabolic disorders (urea cycle disorders). Tell your doctor immediately if you develop unexplained weakness and vomiting or sudden mental changes. 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, severe dizziness, trouble breathing

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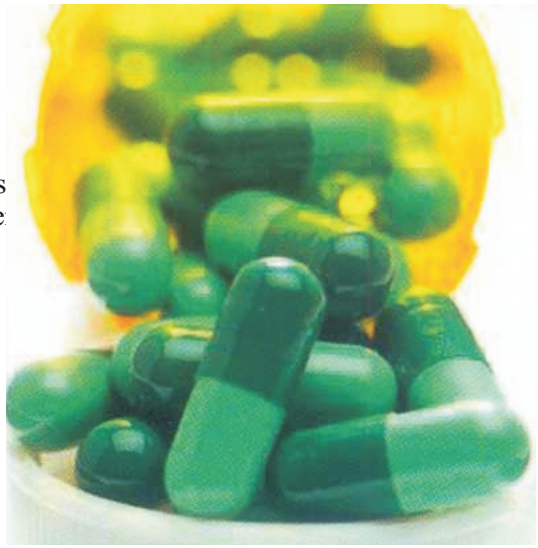
PRECAUTIONS



Before taking valproate sodium, tell your doctor or pharmacist if you are allergic or if you have any other allergies.

This medication should not be used if you have certain medical conditions Before using this drug, consult your doctor or pharmacist if you have: live disease, pancreatitis, certain metabolic disorders (urea cycle disorders).

Before using this medication, tell your doctor or pharmacist your medical history, especially of: alcohol abuse, bleeding problems, brain disease (dementia), kidney disease, low body water (dehydration), poor nutrition.

Before having surgery, tell your doctor or dentist that you are taking this medication.This drug may make you dizzy, drowsy, or cause blurred vision. Use caution engaging in activities requiring alertness or clear vision such as driving or using machinery. Do not engage in such activities until you know how this medication affects you. Limit alcoholic beverages.

Caution is advised when using this drug in the elderly because they may be more sensitive to its side effects, especially drowsiness or tremor.

This medication is not recommended for use during pregnancy due to the possible risk of birth defects and harm to an unborn baby. Do not suddenly stop taking this medication unless directed by your doctor. Suddenly stopping your medication could cause a severe, possibly fatal, seizure.

If you become pregnant or think you may be pregnant, tell your doctor immediately. If you are planning pregnancy, discuss a plan for managing your condition with your doctor before you become pregnant. Your doctor may switch the type of medication you use during pregnancy. Talk to your doctor for more information.

This medication passes into breast milk. While there have been no reports of harm to nursing infants, consult your doctor before breast-feeding.

INTERACTION

If you are taking enteric-coated sodium valproate tablets it is important that you don't take indigestion remedies (antacids) at the same time of day as the tablets. This is because indigestion remedies can make the special 'enteric coating' ineffective.

Sodium valproate may increase the blood levels of the following medicines. As this could increase the risk of their side effects, your doctor may need to reduce the dose of these medicines if you taken them in combination with sodium valproate:

* benzodiazepines such as lorazepam
* bupropion
* lamotrigine (sodium valproate may also increase the risk of skin reactions associated with lamotrigine)
* phenobarbital
* phenytoin (phenytoin blood levels should be monitored if taken with sodium valproate)
* primidone
* tricyclic antidepressants such as amitriptyline and nortriptyline
* zidovudine.

There may be increased drowsiness and sedation if sodium valproate is taken with benzodiazepines, eg diazepam.
There may be an increased risk of side effects on the liver if sodium valproate is taken with phenytoin or carbamazepine.
There may be an increased chance of side effects such as dizziness, tiredness, blurred vision and vomiting if sodium valproate is taken with carbamazepine.

DRUG DESCRIPTION

The drug valproate is an epilepsy drug, which has been studied for the treatment of spinal muscular atrophy (SMA), a motor neuron disease. Sodium volproate is also used for mania (a condition in which a person is very excited, agitated, talking quickly, sleeping little and with expansive ideas). Sodium valproate has been used for prevention of migraine, and pain conditions including trigeminal neuralgia. Usually the medicine is started as a low dose and increased gradually to get the best benefit. Epilim comes in a cherry flavored liquid or syrup, chewable tablets or enteric-coated tablets. The syrup contains regular sugar and artificial sweeteners and the liquid contains artificial sweeteners.

Like all medicines, sodium valporate may have side effects. But mostly all people will not get these problems. Most commonly stomach effects can occur, especially when starting with this medicine. The enteric-coated tablets are intended to stay intact in the stomach and not dissolve until they get to the intestine, so can reduce the stomach effects. The syrup liquid or chewable tablets can be taken with meals.

Sodium valproate belongs to a class of medicines called Anti-Epileptics. It can stop these extra messages in the brain. In this way it makes epileptic seizures less likely.

Sodium valproate 100 mg tablets, 200 mg gastro-resistant tablets, 200 mg modified-release tablets, 200 mg/5 ml oral solution, 200 mg/5 ml oral solution sugar free, 300 mg modified-release tablets, 500 mg gastro-resistant tablets, 500 mg modified-release tablets:

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture 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

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This leaflet was prepared by
Taj Pharmaceuticals Limited,
Mumbai (India).
MPSTJ278
Last revised: 29 August 2009