

**Valproic Acid Cas No. : 99-66-1**

This medication is used to treat seizure disorders. It works by restoring the balance of certain natural substances (neurotransmitters) in the brain. This drug may also be used for the prevention of migraine headaches and treatment of certain psychiatric conditions (e.g., manic phase of bipolar disorder, schizophrenia).

Active Pharmaceuticals Ingredients Manufacturers

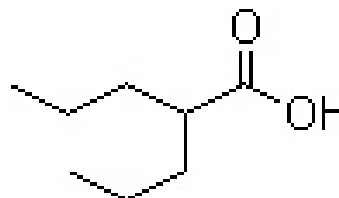


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**Taj Pharmaceuticals Ltd.****Valproic Acid****CAS No. : 99-66-1****Chemical data**Molecular Formula C<sub>8</sub>H<sub>16</sub>O<sub>2</sub>

Molecular Weight 144.21

CAS Registry Number 99-66-1

**Pharmacokinetic data**

Bioavailability Rapid absorption

Protein binding Concentration-dependent, from 90% at 40 µg/mL to 81.5% at 130 µg/mL

Metabolism Hepatic—glucuronide conjugation 30–50%, mitochondrial β-oxidation over 40%

Half life 9–16 hours

Excretion Less than 3% excreted unchanged in urine.

**DOSAGE**

Take this medication exactly as it was prescribed for you. Do not take the medication in larger amounts, or take it for longer than recommended by your doctor.

Take each dose with a full glass of water. Drink plenty of water while you are taking this medication. Your dose may need to be changed if you do not get enough fluids each day.

Measure the liquid form of valproic acid with a special dose-measuring spoon or cup, not a regular table spoon. If you do not have a dose-measuring device, ask your pharmacist where you can get one.

To be sure this medication is not causing harmful effects, your liver function will need to be tested. It is important that you not miss any scheduled visits to your doctor.

Do not stop taking the medication even if you feel better. It is important to take valproic acid regularly to prevent seizures from recurring. Get your prescription refilled before you run out of medicine completely. Call your doctor promptly if this medicine does not seem to be working as well in preventing your seizures. Swallow the capsule whole. Do not crush, chew, or break a capsule because the medicine may irritate your mouth or throat when you swallow it.

Carry an ID card or wear a medical alert bracelet stating that you are taking valproic acid, in case of emergency. Any doctor, dentist, or emergency medical care provider who treats you should know that you are taking valproic acid.

**SIDE EFFECTS**

Seek emergency medical attention if the person taking this medicine has nausea, vomiting, stomach pain, or loss of appetite, low fever, dark urine, clay-colored stools, or jaundice (yellowing of the skin or eyes). These symptoms may be early signs of liver damage. Some of these symptoms may also be early signs of pancreatitis.

Call your doctor at once if you have any new or worsening symptoms such as: mood or behavior changes, depression, anxiety, or if you feel agitated, hostile, restless, hyperactive (mentally or physically), or have thoughts about suicide or hurting yourself.

Get emergency medical help if you have any of these signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Call your doctor at once if you have any of these serious side effects:



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**Valproic Acid**

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- \*unexplained weakness with vomiting and confusion or fainting;
- \*easy bruising or bleeding, unusual weakness;
- \*fever, skin rash, swollen glands;
- \*fever, chills, body aches, flu symptoms;
- \*urinating less than usual;
- \*blood in your urine;
- \*weakness, lack of coordination;
- \*a red, blistering, peeling skin rash;
- \*extreme drowsiness;
- \*unusual bleeding or bruising; or
- \*double vision or back-and-forth movements of the eyes.

Less serious side effects may include:

- \*drowsiness or weakness;
- \*diarrhea, constipation, upset stomach;
- \*changes in your menstrual periods;
- \*enlarged breasts;
- \*tremor (shaking);
- \*hair loss;
- \*weight changes;
- \*a red, blistering, peeling skin rash;
- \*vision changes; or
- \*unusual or unpleasant taste in your mouth.

### PRECAUTIONS

Before taking valproic acid, tell your doctor or pharmacist if you are allergic to it; or to divalproex or valproate sodium; 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: liver 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 valproic acid. 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. Valproic acid can cause birth defects. This medication is not recommended for use during pregnancy. Discuss the risks and benefits with your doctor. If you become pregnant while taking this drug, contact your doctor immediately. If you are pregnant, prenatal care including tests for spinal cord defects is recommended. This medication passes into breast milk. While there have been no reports of harm to nursing infants, consult your doctor before breast-feeding.

Before taking valproic acid, tell your doctor or pharmacist if you are allergic to it; or to divalproex or valproate sodium; 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: liver 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 valproic acid. 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.

## DRUG DESCRIPTION

Valproic acid and its derivative, are oral drugs that are used for the treatment of convulsions, migraines and bipolar disorder. The active ingredient in both products is valproic acid or valproate. Scientists do not know the mechanism of action of valproate. The most popular theory is that valproate exerts its effects by increasing the concentration of gamma-aminobutyric acid in the brain. Gamma-aminobutyric acid is a neurotransmitter, a chemical that nerves use to communicate with one another. (valproic acid) is a carboxylic acid designated as 2-propylpentanoic acid. Valproic acid (pKa 4.8) has a molecular weight of 144 and occurs as a colorless liquid with a characteristic odor. It is slightly soluble in water (1.3 mg/mL) and very soluble in organic solvents.

## Inactive Ingredients

250 mg capsules: corn oil, FD&C Yellow No. 6, gelatin, glycerin, iron oxide, methylparaben, propylparaben, and titanium dioxide. Oral Solution: FD&C Red No. 40, glycerin, methylparaben, propylparaben, sorbitol, sucrose, water, and natural and artificial flavors.

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  
Taj Pharmaceuticals Limited,  
Mumbai (India).

MPSTJ278

Last revised: 29 August 2009