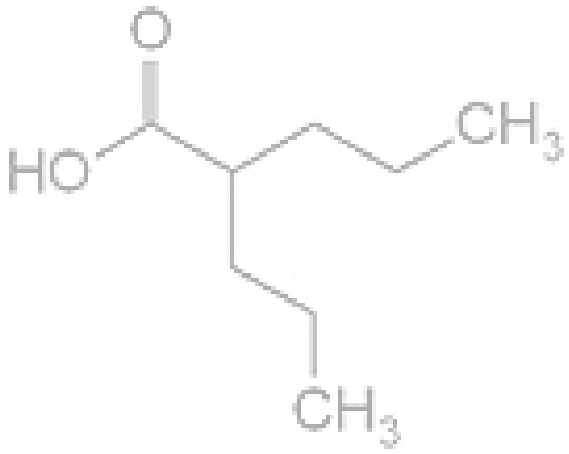
Taj Pharmaceuticals Ltd.

Divalproex Sodium

CAS No. : 76584-70-8

Molecular Structure

Molecular Formula: C8H16O2C8H15O2Na
Molecular Weight: 310.41
CAS NO.: 76584-70-8



Properties

Packing: 20/25kg cardboard drum
Standard: BP2000
Content: ≥99%
Model: 76584-70-8

Product : Divalproex Sodium

Analysis As Per In- House Specification
Specification No. FP â€“ 011
Test Specification
White or almost white crystalline powder.

Solubility

Soluble in ethanol (95 %), methanol, Isopropyl Alcohol; Partially soluble in water, ether.
The infra red absorption spectrum is concordant with the spectrum obtained from reference standard.
Loss on Drying
Not more than 2 %
Valproic Acid
Between 43 % to 47 % on dry basis
Sodium Valproate
Between 53 % to 57 % on dry basis
Sulphated Ash
Not more than 200 ppm

Related Substances

a) Total Impurities not more than 0.3 %
b) Individual impurities not more than 0.1 %
Assay
Between 98.5 % to 101 % on dry basis

DOSAGE

Divalproex sodium is available in tablets of 125 mg, 250 mg, and 500 mg. Divalproex sodium is also available in 125-mg capsules, and in a 500-mg extended release tablet. A syrup is also available, containing 250 mg active drug per 5 mL.
Divalproex sodium therapy is usually started at 10–15 mg per kg of body weight per day. Dosages are then increased until seizures seem to be well controlled. This is usually achieved at averages under 60 mg per kg per day.

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To treat mania, divalproex sodium is usually started at a daily dose of about 750 mg.

For migraine prevention, divalproex sodium is started at 250 mg, twice per day. In some patients, this dose will have to be raised to a total of 1,000 mg per day.

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:

*unexplained weakness with vomiting and confusion or fainting;
*easy bruising or bleeding, blood in your urine;
*fever, sore throat, and headache with a severe blistering, peeling, and red skin rash;
*fever, chills, body aches, flu symptoms;
*urinating less than usual;
*hallucinations (seeing things that aren't there);
*extreme drowsiness, lack of coordination; or
*double vision or back-and-forth movements of the eyes.

Less serious side effects may include:

*mild drowsiness or weakness;
*diarrhea, constipation, upset stomach;
*depression, anxiety, or other emotional changes;
*changes in your menstrual periods;
*enlarged breasts;
*tremor (shaking);
*hair loss;
*weight changes;
*vision changes; or
*unusual or unpleasant taste in your mouth.

PRECAUTIONS

This medication has rarely caused serious (sometimes fatal) liver problems. Children less than 2 years old are more likely to develop severe liver problems, especially if they have metabolic problems, severe seizures with mental retardation, brain disease (organic) or if they take more than one drug for seizures. If divalproex sodium is being used in patients with these conditions, then it should not be taken with additional anti-seizure medications. Liver function tests should be performed before and during treatment.

Early signs of serious liver problems include vomiting, unusual tiredness, swelling of the face or loss of seizure control in patients with seizure disorder. Tell your doctor immediately if you develop any of these symptoms.

This medication has rarely caused severe (sometimes fatal) disease of the pancreas (pancreatitis). This problem may occur at any time during therapy and may worsen quickly. Tell your doctor immediately if you experience stomach/abdominal pain, nausea, vomiting, and loss of appetite while taking this medication.

This medication can cause birth defects. Discuss the risks and benefits of this medication with your doctor, especially if it is prescribed for a condition other than seizure disorder (e.g., migraine headache).

DRUG DESCRIPTION

Divalproex sodium is an anticonvulsant (antiseizure) drug. It is also used to treat mania and to help prevent migraine headaches. It is sold under multiple brand names in the United States, including Depacon, Depakene, Depakote, and Depakote sprinkle. Divalproex sodium is effective in the treatment of epilepsy, particularly for preventing simple, complex (petit mal), absence, mixed, and tonic-clonic (grand mal) seizures. Divalproex sodium is also used to treat the manic phase of bipolar disorder (also called manic-depressive disorder) in adults, and to prevent migraine headache in adults.Divalproex sodium is chemically compounded from sodium valproate and valproic acid in a 1:1 ratio.

Divalproex sodium is thought to work by increasing the levels of a brain neurotransmitter called gamma-aminobutyric acid (GABA). GABA is an inhibitory neurotransmitter, which means that its presence makes it harder for nerve cells (neurons) in the brain to become activated (fire). It is believed that increasing GABA's inhibitory action on brain neurons accounts for the ability of divalproex sodium to decrease seizures, curb manic behaviors, and decrease the frequency of migraine headaches.

Divalproex sodium was discovered to decrease the likelihood of seizure in 1963. In 1978, the United States Food and Drug Administration approved it for this use. Other uses for divalproex sodium were researched and approved subsequently, including use against mania (1995) and use to decrease migraine headache frequency.

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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