Divalproex Sodium

**CAS Number**: 76584-70-8  
**Molecular Weight**: 310.41 g/mol  
**Molecular Formula**: C₈H₁₆O₂C₈H₁₅O₂Na  
**Systematic (IUPAC)**: Pentanoic acid,2-propyl-, sodium salt (2:1);Abbott50711;Depakote;Epival;Sodium hydrogenbis(2-propylpentanoate);Sodium hydrogen bis(2-propylvalerate);Sodium hydrogendivalproate;Valdisoval;Valproate semisodium;

**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.

**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.

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.

**INTERACTION**

Divalproex sodium is broken down (metabolized) in the liver. Other drugs that are metabolized in the liver can have too low or too high concentrations in the body when taken with divalproex sodium. Levels of divalproex sodium may be increased when taken with felbamate, isoniazid, salicylates (aspirin-containing medications), clarithromycin, erythromycin, and troleandomycin.

Divalproex sodium may increase levels of carbamazepine, phenytoin, lamotrigine, nimodipine, phenobarbital, and zidovudine. Use with clonazepam may cause absence seizures. Cholestyramine and colestipol may reduce the absorption and the blood levels of divalproex sodium.

Cold or allergy medicine, narcotic pain medicine, sleeping pills, muscle relaxers, and medicine for
depression or anxiety can add to sleepiness caused by divalproex sodium. Tell your doctor if you regularly use any of these medicines, or any other seizure medication. Before taking divalproex sodium, tell your doctor if you are using any of the following drugs:

* topiramate (Topamax);
* tolbutamide (Orinase);
* a blood thinner such as warfarin (Coumadin);
* aspirin or acetaminophen (Tylenol);
* zidovudine (Retrovir);
* clozapine (Clozaril, FazaClo);
* diazepam (Valium);
* meropenem (Merrem);
* rifampin (Rifadin, Rimactane, Rifater); or
* ethosuximide (Zarontin).

**PHARMACOLOGY**

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

**CONSUMER INFORMATION**

This medication is used to treat seizure disorders, certain psychiatric conditions (manic phase of bipolar disorder), and to prevent migraine headaches. It works by restoring the balance of certain natural substances (neurotransmitters) in the brain.

This section contains uses of this drug that are not listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This drug may also be used for other mental disorders (e.g., schizophrenia).

Take this medication by mouth as directed by your doctor. You may take it with food if stomach upset occurs. Swallow the tablet whole. Do not crush or chew
the tablet, which can irritate the mouth or throat. Before taking divalproex sodium, tell your doctor or pharmacist if you are allergic to it; or to valproic acid or valproate sodium; or if you have any other allergies. MISSedd

DOSE: If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE: Store the US product at room temperature below 86 degrees F (30 degrees C) away from light and moisture. Do not store in the bathroom. Store the Canadian product at room temperature between 59 and 77 degrees F (15-25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

FIRST AID MEASURES

Ingestion
If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.

Inhalation
Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.

Skin Contact
Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.

**Eye Contact**
Flush eyes with plenty of water. Get medical attention.

**FIRE-FIGHTING MEASURES**

**Fire and Explosion Hazards**
Assume that this product is capable of sustaining combustion.

**Extinguishing Media**
Water spray, carbon dioxide, dry chemical powder or appropriate foam.

**Special Firefighting Procedures**
For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters.

**Hazardous Combustion Products**
Hazardous combustion or decomposition products are expected when the product is exposed to fire.

**ACCIDENTAL RELEASE MEASURES**

**Personal Precautions**
Wear protective clothing and equipment consistent with the degree of hazard.

**Environmental Precautions**
For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

**Clean-up Methods**
Collect and place it in a suitable, properly labeled container for recovery or disposal.

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