DIVALPROEX SODIUM

TOP APS DRUGS -

DIVALPROEX SODIUM

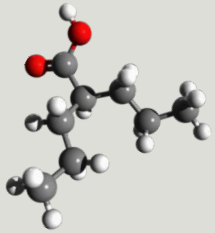
BRAND NAME: DEPAKOTE (ER)

Divalproex Sodium

Pharmacodynamics

study of what a drug does to the body

Divalproex sodium is chemically compounded from sodium valproate and valproic acid in a 1:1 ration.



Divalproex sodium dissociates to the valproate ion in the gastrointestinal tract.

The mechanisms by which valproate exerts its therapeutic effects have not been established.

It has been suggested that its activity in epilepsy is related to increased brain concentrations of gamma-aminobutyric acid (GABA).

Pharmacology

science of drug action on biological systems

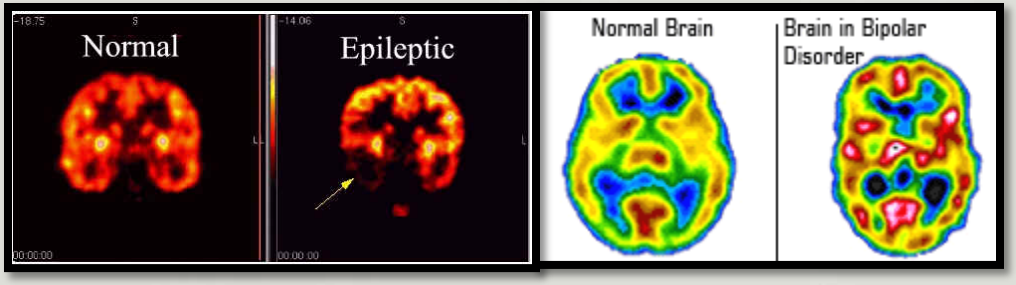
Usually given to those who suffer from epilepsy and bipolar disorder

Used to control certain types of seizures in the treatment of epilepsy.

Used to treat the manic phase of bipolar disorders (manic-depressive illness) and to prevent migraine headaches.

Divalproex delayed-release tablets are an anticonvulsant. It works by reducing or preventing the number of seizures by controlling the abnormal activity of nerve impulses in the brain and central nervous system.

Exactly how it works to treat bipolar disorder and migraine headache is not known.



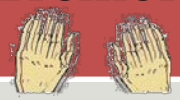
Divalproex Sodium

Side Effects

Common Side Effects

Mild nausea, vomiting, stomach pain & diarrhea

Tremors



Weight Gain

Hair Loss

Blurred or double vision

Problems with balance/ walking

Loss of menstrual periods

Severe Side Effects

Liver Failure

Pancreatitis

Encephalopathy

What is it? General term to describe abnormal brain functions, usually inflammation.

Hyperammonemia

What is it? Metabolic condition characterized by an excess of ammonia in blood.

Divalproex Sodium

Associated Risks

Patients who take divalproex delayed-release tablets may be at increased risk for suicidal thoughts or actions.

The risk may be greater in patients who have had suicidal thoughts or actions in the past.

Patients who have bipolar (manic-depressive) illness may also have an increased risk for suicidal thoughts or actions.

Certain brain problems have happened with the use of valproic acid products.

Divalproex Sodium

Contraindications

A specific situation in which a drug, procedure, or surgery should not be used because it may be harmful to the patient.

Patients should NOT take divalproex sodium tablets if they…

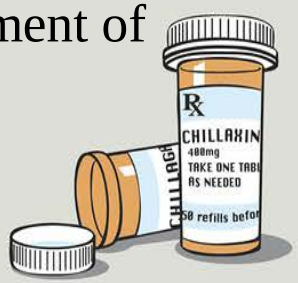
- have hepatic dysfunction
- have mitochondrial disorders caused by mutations in the mitochondrial DNA polymerase
- are known for their hypersensitivity to drug
- have urea cycle disorders
- are pregnant

Pregnancy Risks

Valproate can cause fetal harm when administered to a pregnant woman – causing neural tube defects and other structural abnormalities.

Valproate can also cause decreased IQ scores following in utero exposure. Published epidemiological studies have indicated that children exposed to valproate in utero have lower cognitive test scores than children exposed in utero to either another antiepileptic drug or to no antiepileptic drugs.

Because of the risk to the fetus of decreased IQ and major congenital malformations (including neural tube defects), which may occur very early in pregnancy, valproate should not be administered to a woman of childbearing potential unless the drug is essential to the management of her medical condition.



Divalproex Sodium

Potential Dangers

Alcohol:

- Drinking alcohol may increase certain side effects of divalproex sodium such as dizziness, drowsiness and difficulty concentrating.

General Applications:

- Divalproex sodium may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be alert.

Sunlight/Tanning Beds:

- Avoid exposure to sunlight or tanning beds. Divalproex sodium can make you sunburn more easily. Wear protective clothing and use sunscreen (SPF 30 or higher) when you are outdoors.

Potential dangers continued

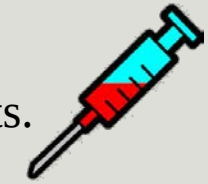
Other prescriptions: (Some MEDS MAY INTERACT with divalproex)

Most Common	Less Common	Risks
• Benzodiazepines (Diazepam, Clonazepam, Lorazepam & Alprazolam) • Salicylates (Aspirin)	• Felbamate	- Risk of seizures may be increased - Increase valproic acid blood levels significantly
• Topiramate		Risk of high ammonium levels, brain problems or an unusual drop in body temp. may be increased
• Carbamazepine (Tegretol, Carbatrol & Equetro) • Hydantoins (Phenytoin) • Birth control pills	• Carbapenem antibiotics • Mefloquine • Rifampin • Ritonavir	Decreases levels of valproic acid & effectiveness
• Anticoagulants (Warfarin) • Methylphenidate • Quetiapine (Seroquel) • Tricyclic antidepressants (Tofrantil & Norpramin)	• Barbiturates (Phenobarbital & Primidone) • Ethosuximide • Lamotrigine • Rufinamide • Tolbutamide • Zidovudine	Risk of increased side effects

Laboratory Monitoring

Lab tests (including complete blood cell counts, blood ammonia levels, and liver function) may be performed while you use divalproex delayed-release tablets.

These tests may be used to monitor your condition or check for side effects.



Divalproex delayed-release tablets may interfere with certain lab tests, including thyroid function.

People with diabetes should be aware that valproate semisodium can cause false positive results in urine tests for ketones.

NOTE: Wear a medical alert tag or carry an ID card stating that you take divalproex sodium. Any doctor, dentist, or emergency medical care provider who treats you should know that you are taking a seizure medication.

(Self) Administration Instructions

Follow all directions on your prescription label. Your doctor may occasionally change your dose to make sure you get the best results. Do not take this medicine in larger or smaller amounts or for longer than recommended.

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.

Do not crush, chew, break, or open a **delayed-release** or **extended-release tablet or capsule**. Swallow it whole.

For the divalproex sodium sprinkle capsule: Sprinkle the medicine into a spoonful of pudding or applesauce to make swallowing easier. Swallow this mixture right away.

Divalproex Sodium

Dosage

Valproic acid is available in many different forms (for example, liquid, sprinkle capsules, “long–acting”).

The recommended starting dose is between 750 and 1500 mg daily taken in divided doses. (The starting dose should be lower in elderly patients.)

Dosages are adjusted based on response and blood level. One person may need a higher dose to get a therapeutic blood level compared to another individual.

The usual effective dose range is between 1000 and 2000 mg daily, although lower or higher doses are needed in some cases.

Management & Planning

Do not stop using divalproex sodium suddenly even if you feel fine. ***Stopping suddenly may cause a serious, life-threatening type of seizure.***

Miss a dose? Call a pharmacist or doctor.

Overdose? Seek emergency medical attention or call the Poison Help line @ 1-800-222-1222

Changing dose? Consult with a doctor and follow your doctor's instructions about tapering your dose.

Take valproic acid with food to minimize stomach cramping, nausea, and vomiting .

Always take valproic acid at the same time every day.

Store at room temperature away from moisture and heat.

Nonadherence & Withdrawal

Stopping <u>suddenly</u> and taking <u>inconsistently</u> may cause a serious life-threatening type of seizure that does not stop, a.k.a. status epilepticus.

Missing doses of valproate may increase your risk for a relapse in your mood symptoms.

Divalproex Sodium

Diet/Exercise

This medication does not interact with food or caffeine.

Cigarette smoking does not affect the use of medication.

Medications can affect different patients in various ways - not everyone will react the same way.

Follow a healthy diet and exercise plan to help manage with your symptoms.

Consult your doctor to ensure you establish the proper regime for your circumstances.

Divalproex Sodium

Additional Resources

abbvie PATIENT ASSISTANCE FOUNDATION

Abbvie offers a variety of assistance programs to meet the needs of the specific people who are prescribed AbbVie medications.

http://www.abbviepaf.org/index.cfm

800-222-6885