

October 15, 2015

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Depakote

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Depakote

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Depakote

(divalproex sodium) Tablets

Patient Information

WARNING

LIFE THREATENING ADVERSE REACTIONS

Hepatotoxicity

Hepatic failure resulting in fatalities has occurred in patients receiving valproate and its derivatives. Children under the age of two years are at a considerably increased risk of developing fatal hepatotoxicity, especially those on multiple anticonvulsants, those with congenital metabolic disorders, those with severe seizure disorders accompanied by mental retardation, and those with organic brain disease. When Depakote is used in this patient group, it should be used with extreme caution and as a sole agent. The benefits of therapy should be weighed against the risks. The incidence of fatal hepatotoxicity decreases considerably in progressively older patient groups.

These incidents usually have occurred during the first six months of treatment. Serious or fatal hepatotoxicity may be preceded by non-specific symptoms such as malaise, weakness, lethargy, facial edema, anorexia, and vomiting. In patients with epilepsy, a loss of seizure control may also occur. Patients should be monitored closely for appearance of these symptoms. Liver function tests should be performed prior to therapy and at frequent intervals thereafter, especially during the first six months [see WARNINGS AND PRECAUTIONS].

Fetal Risk

Valproate can cause major congenital malformations, particularly neural tube defects (e.g., spina bifida). In addition, valproate can cause decreased IQ scores following in utero exposure.

Valproate is therefore contraindicated in pregnant women treated for prophylaxis of migraine [see CONTRAINDICATIONS]. Valproate should only be

REVIEWED*By Chris Tighe at 12:56 pm, Oct 15, 2015*

Psoriasis

Symptoms, Causes and Treatment?

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Magnesium
Melatonin
N-Acetyl Cysteine



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Tool

used to treat pregnant women with epilep-, or bipolar disorder if other medications have failed to control their symptoms or are otherwise unacceptable.

Valproate should not be administered to a woman of childbearing potential unless the drug is essential to the management of her medical condition. This is especially important when valproate use is considered for a condition not usually associated with permanent injury or death (e.g., migraine). Women should use effective contraception while using valproate [see WARNINGS AND PRECAUTIONS].

A Medication Guide describing the risks of valproate is available for patients [see PATIENT INFORMATION].

Pancreatitis

Cases of life-threatening pancreatitis have been reported in both children and adults receiving valproate. Some of the cases have been described as hemorrhagic with a rapid progression from initial symptoms to death. Cases have been reported shortly after initial use as well as after several years of use. Patients and guardians should be warned that abdominal pain, nausea, vomiting, and/or anorexia can be symptoms of pancreatitis that require prompt medical evaluation. If pancreatitis is diagnosed, valproate should ordinarily be discontinued. Alternative treatment for the underlying medical condition should be initiated as clinically indicated [see WARNINGS AND PRECAUTIONS].

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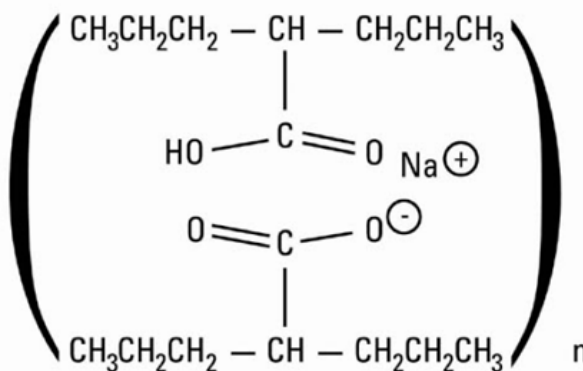
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DRUG DESCRIPTION

Divalproex sodium is a stable co-ordination compound comprised of sodium valproate and valproic acid in a 1:1 [molar](#) relationship and formed during the partial neutralization of valproic acid with 0.5 equivalent of sodium hydroxide. Chemically it is designated as sodium [hydrogen](#) bis(2-propylpentanoate). Divalproex sodium has the following structure:



Divalproex sodium occurs as a white powder with a characteristic odor.

Depakote tablets are for oral administration. Depakote tablets are supplied in three dosage strengths containing divalproex sodium equivalent to 125 mg, 250 mg, or 500 mg of valproic acid.

Inactive Ingredients

Depakote tablets: cellulosic polymers, diacetylated monoglycerides, povidone, pregelatinized starch (contains corn starch), [silica](#) gel, talc, titanium dioxide, and vanillin.

In addition, individual tablets contain:

125 mg tablets: FD&C Blue No. 1 and FD&C Red No. 40.

250 mg tablets: FD&C Yellow No. 6 and iron oxide.

500 mg tablets: D&C Red No. 30, FD&C Blue No. 2, and iron oxide.

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Vaccine Safety

**What are the possible side effects of divalproex sodium (Depakote, Depakote ER, Depakote Sprinkles)?**

Seek emergency medical attention if the person taking this medicine has nausea, vomiting, upper 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 or pancreatitis.

Report any new or worsening symptoms to your doctor, 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...

[Read All Potential Side Effects and See Pictures of Depakote »](#)

What are the precautions when taking divalproex sodium delayed release tablets (Depakote)?

See also Warning section.

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 product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, pancreatitis, certain metabolic disorders (such as urea cycle disorders, Alpers-Huttenlocher syndrome), alcohol abuse, bleeding problems, brain disease (dementia), kidney disease, low body water (dehydration), poor nutrition.

To lower the chance of getting cut, bruised, or injured, use caution with sharp objects like razors...

[Read All Potential Precautions of Depakote »](#)

Last reviewed on RxList: 7/16/2013

This monograph has been modified to include the generic and brand name in many instances.

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Next: [Indications & Dosage](#)

Depakote FDA Prescribing Information

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Additional Depakote Information

- Depakote Drug Interactions Center: [divalproex oral](#)
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- [Depakote FDA Approved Prescribing Information including Dosage](#)

Depakote - User Reviews**Depakote User Reviews**

Now you can gain knowledge and insight about a drug treatment with Patient Discussions.

Here is a collection of user reviews for the medication Depakote sorted by most helpful. ?

[See User Reviews](#)

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit the [FDA MedWatch](#) website or call 1-800-FDA-1088.

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