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Depakote

Generic Name: divalproex sodium (dye val PRO ex)
Brand Names: *Depakote*, *Depakote ER*, *Depakote Sprinkles*

What is Depakote?

Depakote affects chemicals in the body that may be involved in causing seizures.

Depakote is used to treat various types of seizure disorders. It is sometimes used together with other seizure medications. It is also used to treat the manic phase of bipolar disorders (manic-depressive illness), and to prevent migraine headaches.

Depakote may also be used for other purposes not listed in this medication guide.

Important information about Depakote

In rare cases, Depakote has caused life-threatening liver failure, especially in children younger than 2 years old. Children may be at even greater risk for liver problems if they use more than one seizure medication, if they have a metabolic disorder, or if they have a brain disease causing mental impairment (such as Creutzfeldt-Jacob disease, Huntington disease, multiple sclerosis, or a brain injury or infection). 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. Depakote can cause birth defects. Do not use this medication without your doctor's consent if you are pregnant. Use an effective form of birth control, and tell your doctor if you become pregnant during treatment.

You may have thoughts about suicide while taking Depakote. Your doctor will need to check you at regular visits. Do not miss any scheduled appointments.

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.

Before taking Depakote

In rare cases, Depakote has caused life-threatening liver failure, especially in children younger than 2 years old. Children of this age may be at even greater risk for liver problems if they use more than one seizure medication, if they have a metabolic disorder, or if they have a brain disease causing mental impairment (such as Creutzfeldt-Jacob disease, Huntington disease, multiple sclerosis, or a brain injury or infection). Depakote has also caused rare cases of life-threatening pancreatitis (inflammation of the pancreas). Pancreatitis can come on suddenly and symptoms may start even after you have been taking Depakote for several years. Do not take Depakote if you have liver disease or a urea cycle disorder.

If you have any of these other conditions, you may need a dose adjustment or special tests to safely take Depakote.

- a bleeding or blood clotting disorder;
- a history of head injury, brain disorder, or coma;

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- a family history of a urea cycle disorder;
- a family history of infant deaths with unknown cause; or
- HIV or CMV (cytomegalovirus) infection.

You may have thoughts about suicide while taking Depakote. Tell your doctor if you have new or worsening depression or suicidal thoughts during the first several months of treatment, or whenever your dose is changed.

Your family or other caregivers should also be alert to changes in your mood or symptoms. Your doctor will need to check you at regular visits. Do not miss any scheduled appointments.

FDA pregnancy category D. This medication can cause harm to an unborn baby. Do not use Depakote without your doctor's consent if you are pregnant. Tell your doctor if you become pregnant during treatment. Depakote can cause birth defects. Use an effective form of birth control while you are using this medication. Depakote passes into breast milk and could harm a nursing infant. Do not take this medication without telling your doctor if you are breast-feeding a baby.

How should I take Depakote?

Take Depakote 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.

Follow the instructions on your prescription label.

Drink plenty of water while you are taking Depakote. Your dose may need to be changed if you do not get enough fluids each day.

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 Depakote even if you feel better. It is important to take this medication 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. Do not crush, chew, break, or open a delayed-release or extended-release tablet or capsule. Swallow the pill whole. It is specially made to release medicine slowly in the body. Breaking or opening the pill would cause too much of the drug to be released at one time.

You may open the Depakote sprinkle capsule and sprinkle the medicine into a spoonful of pudding or applesauce to make swallowing easier. Swallow this mixture right away without chewing. Do not save the mixture for later use. Discard the empty capsule.

Carry an ID card or wear a medical alert bracelet stating that you are taking this medication, in case of emergency. Any doctor, dentist, or emergency medical care provider who treats you should know that you are taking Depakote. Store this medication at room temperature away from moisture and heat.

What happens if I miss a dose?

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take extra medicine to make up the missed dose.

What happens if I overdose?

Seek emergency medical attention if you think you have used too much of this medicine.

Overdose symptoms may include sleepiness or drowsiness, shallow breathing, weak pulse, or loss of consciousness.

What should I avoid while taking Depakote?

Avoid drinking alcohol, which can increase some of the side effects of Depakote.

Depakote can cause side effects that may impair your thinking or reactions. Be careful if you drive or do anything that requires you to be awake and alert. Avoid exposure to sunlight or artificial UV rays (sunlamps or tanning beds).

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Depakote can make your skin more sensitive to sunlight and sunburn may result. Use a sunscreen (minimum SPF 15) and wear protective clothing if you must be out in the sun.

Depakote side effects

Seek emergency medical attention if the person taking Depakote 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 to Depakote: 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 Depakote 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.

This is not a complete list of side effects and others may occur. Tell your doctor about any unusual or bothersome side effect. You may report side effects to FDA at 1-800-FDA-1088.

What other drugs will affect Depakote?

Cold or allergy medicine, narcotic pain medicine, sleeping pills, muscle relaxers, and medicine for depression or anxiety can add to sleepiness caused by Depakote. Tell your doctor if you regularly use any of these medicines, or any other

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seizure medication.

Before taking this medication, 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);

This list is not complete and there may be other drugs that can interact with Depakote. Tell your doctor about all the prescription and over-the-counter medications you use. This includes vitamins, minerals, herbal products, and drugs prescribed by other doctors. Do not start using a new medication without telling your doctor.

Where can I get more information?

- Your pharmacist can provide more information about Depakote.
- Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.
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