

Patient Education

DIVALPROEX SODIUM EXTENDED RELEASE TABLET - ORAL

IMPORTANT NOTE: The following information is intended to supplement, not substitute for, the expertise and judgment of your physician, pharmacist or other healthcare professional. It should not be construed to indicate that use of the drug is safe, appropriate, or effective for you. Consult your healthcare professional before using this drug.

DIVALPROEX SODIUM EXTENDED RELEASE TABLET - ORAL

(dye-VAL-pro-ex)

COMMON BRAND NAME(S): Depakote ER

WARNING: 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. Read the patient information leaflet provided with this medication. Consult your doctor or pharmacist for more information. (See also Precautions section)

USES:

This medication is used to treat seizure disorder in adults and children (age 10 years or older). It is also used to prevent migraine headaches in adults. This medication works by restoring the balance of certain natural substances (neurotransmitters) in the brain.

OTHER USES:

This drug may also be used to treat certain psychiatric conditions (e.g., manic phase of bipolar disorder, schizophrenia) in adults.

HOW TO USE:

Take this medication by mouth once daily or 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 destroy the long action of the drug and increase side effects.

Dosage is based on your weight, medical condition, and response to therapy. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day to keep the amount of medication in your blood constant.

If this medication is used for seizures, do not stop taking it without consulting your doctor. Your condition may become worse if the drug is suddenly stopped. Your dose may need to be gradually decreased.

Divalproex sodium does not relieve acute migraine headaches. Take other medications as directed by your doctor for acute attacks.

Inform your doctor if your condition does not improve.

SIDE EFFECTS:

See also Warning section.

Diarrhea, dizziness, drowsiness, hair loss, blurred/double vision, change in menstrual periods, ringing in the ears, shakiness (tremor), unsteadiness, weight changes may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

Tell your doctor immediately if any of these serious side effects occur: mental/mood changes, signs of infection (e.g., fever, persistent sore throat).

Tell your doctor immediately if any of these unlikely but serious side effects occur: chest pain, easy bruising/unexplained bleeding, fast/irregular heartbeat, swelling of hands/feet, uncontrolled eye movement (nystagmus).

Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: dark urine, persistent nausea/vomiting, severe stomach/abdominal pain, yellowing eyes or skin.

Severe (sometimes fatal) brain disorder (encephalopathy) has rarely occurred, particularly in patients with certain metabolic disorders (urea cycle disorders). Tell your doctor immediately if you develop unexplained weakness and vomiting or sudden mental changes.

A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing.

If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS:

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 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.

DRUG INTERACTIONS:

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: certain antidepressants (e.g., amitriptyline, nortriptyline, phenelzine), certain benzodiazepines (e.g., clonazepam, diazepam), mefloquine, other medications for seizure (e.g., carbamazepine, ethosuximide, felbamate, lamotrigine, phenobarbital, phenytoin), rifampin, warfarin, zidovudine.

Low-dose aspirin, as prescribed by your doctor for specific medical reasons such as heart attack or stroke prevention (usually these dosages are 81-325 mg per day), should be continued. Consult your doctor or pharmacist if you are using aspirin for any reason.

Tell your doctor or pharmacist if you also take drugs that cause drowsiness such as: antihistamines that cause drowsiness (e.g., diphenhydramine), medicine for sleep (e.g., sedatives), muscle relaxants, narcotic pain relievers (e.g., codeine), psychiatric medicines (e.g., phenothiazines such as chlorpromazine), tranquilizers.

Check the labels on all your medicines (e.g., cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about the safe use of those products.

This drug may affect certain lab tests (e.g., urine ketones). Make sure laboratory personnel and your doctors know you use this medication.

Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE:

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: excessive drowsiness, coma, irregular/slowed/skipped heart beats (heart block).

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (e.g., drug levels, liver function tests, complete blood counts, clotting tests) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED 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 at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

MEDICAL ALERT: Your condition can cause complications in a medical emergency. For enrollment information call MedicAlert at 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).