

Brightside Specialty Pharmacy

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Patient Education for DIVALPROEX SOD DR 500 MG TAB



Teratogenic in pregnant women; Use effective birth control measures. Report sx c/w pancreatitis stat: radiating abdominal pain, or n/v Many drug-drug interactions possible with this drug May cause drowsiness or dizziness Use caution driving. Swallow whole. Do not break, chew, crush, or dissolve. Dispense & explain patient package insert and medication guide. Liver failure signs: lethargic, anorexia/emesis/weakness/fatigue Depression or thoughts of suicide should be reported to MD ASAP.

Do not get pregnant; Use effective birth control. Tell Dr if abdominal pain mild to severe, or nausea Review all drugs you are taking with your doctor May make you drowsy or dizzy. Drive with caution Swallow whole. Do not break/chew/crush/dissolve Important to read patient package insert& med guide Call MD if lethargic, no appetite, vomiting & weak Immediately report to MD any thoughts of suicide.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

DIVALPROEX SODIUM ENTERIC-COATED TABLET - ORAL
(dye-VAL-pro-ex SO-dee-um)

COMMON BRAND NAME(S):

Depakote

WARNING:

Rarely, this medication has caused serious (sometimes

fatal) liver problems, usually within the first 6 months of starting treatment. Laboratory tests should be performed before you start treatment and periodically during treatment, especially within the first 6 months, to monitor this side effect.

The risk of serious liver problems is increased in children younger than 2 years, especially if they have an inherited metabolic disorder, severe seizure disorder with mental retardation, organic brain disease, or if they take more than one seizure medication. Talk with the doctor about the risks and benefits of using this medication in children younger than 2 years.

Due to an increased risk for liver problems, people with certain inherited metabolic disorders (such as Alpers-Huttenlocher syndrome) should not use this medication. Children younger than 2 years who might have these disorders should not use this medication. Children older than 2 years who might have these disorders should be closely monitored during treatment with divalproex sodium. Talk to your doctor for details.

This medication has rarely caused severe (sometimes fatal) disease of the pancreas (pancreatitis). This may occur at any time during treatment and can quickly worsen.

Tell your doctor right away if you develop symptoms of liver problems or pancreatitis such as nausea/vomiting that doesn't stop, unusual tiredness, weakness, swelling of the face, stomach/abdominal pain, loss of appetite, dark urine, or yellowing eyes/skin.

Taking this medication during pregnancy can cause birth defects, may lower your child's IQ, and may increase the risk of your child having certain brain/mental disorders (such as autism, attention deficit/hyperactivity disorder). Women of childbearing age should discuss the risks and benefits of this medication, other treatment options, and use of reliable forms of birth control with their doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately talk to your doctor. If you are taking divalproex sodium only to prevent migraine headaches, this medication must not be used during pregnancy. If you are taking divalproex sodium to treat seizures or mental/mood problems (such as bipolar disorder), do not stop taking this medication unless directed by your doctor. Untreated seizures and mental/mood problems (such as bipolar disorder) are serious conditions that can harm both a pregnant woman and her unborn baby.

USES:

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.

HOW TO USE:

Read the Medication Guide and, if available, the

Patient Information Leaflet provided by your pharmacist before you start taking divalproex sodium and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

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.

The dosage is based on your age, weight, medical condition, response to treatment, and other medications you may be taking.

Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). 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 last or get worse, tell your doctor or pharmacist promptly.

You may rarely see partial tablets in your stool. This may occur if you have certain intestinal disorders (such as ileostomy, colostomy). Tell your doctor right away if you see partial tablets in your stool.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

A small number of people who take anticonvulsants for any condition (such as seizure, bipolar disorder, pain) may experience depression, suicidal thoughts/attempts, or other mental/mood problems. Tell your doctor right away if you or your family/caregiver notice any unusual/sudden changes in your mood, thoughts, or behavior including signs of depression, suicidal thoughts/attempts, thoughts about harming yourself.

Severe (sometimes fatal) brain disorder (encephalopathy) has rarely occurred, particularly in patients with certain metabolic disorders (urea cycle disorders). Tell your doctor right away if you develop unexplained weakness, vomiting, or sudden mental/mood changes (such as confusion).

Get medical help right away if you have any very serious side effects, including: chest pain, easy bruising/unexplained bleeding, fast/slow/irregular heartbeat, swelling of hands/feet, uncontrolled eye movement (nystagmus), feeling cold/shivering, rapid breathing, loss of consciousness.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: fever, swollen lymph nodes, rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at

www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

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 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, dehydration, poor nutrition.

To lower the chance of getting cut, bruised, or injured, use caution with sharp objects like razors and nail cutters, and avoid activities such as contact sports.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

This drug may make you dizzy or drowsy or blur your vision. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness or clear vision until you can do it safely. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

Children younger than 6 years may be at greater risk for liver problems and pancreatitis.

Older adults may be more sensitive to the side effects of this drug, especially drowsiness, dizziness, unsteadiness, or tremor. Drowsiness, dizziness, unsteadiness can increase the risk of falling.

Tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while using divalproex sodium. Divalproex sodium may harm an unborn baby. If you become pregnant, talk to your doctor right away about the risks and benefits of this medication. See also Warning section.

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:

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: certain antidepressants (such as amitriptyline, nortriptyline, phenelzine), certain antibiotics (carbapenems such as imipenem),

irinotecan, mefloquine, orlistat, other medications for seizure (such as ethosuximide, lamotrigine, rufinamide, topiramate), rifampin, warfarin, vorinostat, zidovudine.

Low-dose aspirin, as prescribed by your doctor for specific medical reasons such as heart attack or stroke prevention (usually 81-162 milligrams a day), should be continued. Consult your doctor or pharmacist if you are using aspirin for any reason.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, marijuana (cannabis), antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), and opioid pain relievers (such as codeine, hydrocodone).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

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

OVERDOSE:

If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: excessive drowsiness, coma, irregular/slow heartbeat.

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (such as drug levels, liver function tests, complete blood counts, clotting tests) should be performed before you start treatment, periodically to monitor your progress, or to 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. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

MEDICAL ALERT:

Your condition can cause complications in a medical emergency. For information about enrolling in MedicAlert,

call 1-888-633-4298 (US) or 1-800-668-1507 (Canada).
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