MEDICATION GUIDE

Divalproex Sodium Extended-Release Tablets USP
[Divalproex (dye val PROE ex)]

Read this Medication Guide before you start taking divalproex sodium extended-release tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about divalproex sodium extended-release tablets?

Do not stop taking divalproex sodium extended-release tablets without first talking to your healthcare provider.

Stopping divalproex sodium extended-release tablets suddenly can cause serious problems.

Divalproex sodium extended-release tablets can cause serious side effects, including:

1. Serious liver damage that can cause death, especially in children younger than 2 years old. The risk of getting this serious liver damage is more likely to happen within the first 6 months of treatment.

Call your healthcare provider right away if you get any of the following symptoms:

- nausea or vomiting that does not go away
  - loss of appetite
  - pain on the right side of your stomach (abdomen)
  - dark urine
  - swelling of your face
  - yellowing of your skin or the whites of your eyes

In some cases, liver damage may continue despite stopping the drug.

2. Divalproex sodium extended-release tablets may harm your unborn baby.

- If you take divalproex sodium extended-release tablets during pregnancy for any medical condition, your baby is at risk for serious birth defects that affect the brain and spinal cord and are called spina bifida or neural tube defects. These defects occur in 1 to 2 out of every 100 babies born to mothers who use this medicine during pregnancy. These defects can begin in the first month, even before you know you are pregnant. Other birth defects that affect the structures of the heart, head, arms, legs, and the opening where the urine comes out (urethra) on the bottom of the penis can also happen.

- Birth defects may occur even in children born to women who are not taking any medicines and do not have other risk factors.

- Taking folic acid supplements before getting pregnant and during early pregnancy can lower the chance of having a baby with a neural tube defect.

- If you take divalproex sodium extended-release tablets during pregnancy for any medical condition, your child is at risk for having a lower IQ.

- There may be other medicines to treat your condition that have a lower chance of causing birth defects and decreased IQ in your child.
- Women who are pregnant must not take divalproex sodium extended-release tablets to prevent migraine headaches.
- **All women of child-bearing age should talk to their healthcare provider about using other possible treatments instead of divalproex sodium extended-release tablets. If the decision is made to use divalproex sodium extended-release tablets, you should use effective birth control (contraception).**
- Tell your healthcare provider right away if you become pregnant while taking divalproex sodium extended-release tablets. You and your healthcare provider should decide if you will continue to take divalproex sodium extended-release tablets while you are pregnant.
- **Pregnancy Registry:** If you become pregnant while taking divalproex sodium extended-release tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.

3. Inflammation of your pancreas that can cause death.

Call your healthcare provider right away if you have any of these symptoms:

- severe stomach pain that you may also feel in your back
- nausea or vomiting that does not go away

4. Like other antiepileptic drugs, divalproex sodium extended-release tablets may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Do not stop divalproex sodium extended-release tablets without first talking to a healthcare provider.

Stopping divalproex sodium extended-release tablets suddenly can cause serious problems. Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that do not stop (status epilepticus).

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

What are divalproex sodium extended-release tablets?

Divalproex sodium comes in different dosage forms with different usages.

Divalproex sodium extended-release tablets are prescription medicine used:

- to treat manic episodes associated with bipolar disorder.
- alone or with other medicines to treat:
  - complex partial seizures in adults and children 10 years of age and older
  - simple and complex absence seizures, with or without other seizure types
- to prevent migraine headaches

Who should not take divalproex sodium extended-release tablets?

Do not take divalproex sodium extended-release tablets if you:

- have liver problems
- have or think you have a genetic liver problem caused by a mitochondrial disorder (e.g., Alpers-Huttenlocher syndrome)
- are allergic to divalproex sodium, valproic acid, sodium valproate, or any of the ingredients in divalproex sodium extended-release tablets. See the end of this leaflet for a complete list of ingredients in divalproex sodium extended-release tablets.
- have a genetic problem called urea cycle disorder
- are pregnant for the prevention of migraine headaches

What should I tell my healthcare provider before taking divalproex sodium extended-release tablets?

Before you take divalproex sodium extended-release tablets, tell your healthcare provider if you:

- have a genetic liver problem caused by a mitochondrial disorder (e.g. , Alpers-Huttenlocher syndrome)
- drink alcohol
- are pregnant or breastfeeding. Divalproex sodium can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take divalproex sodium extended-release tablets.
- have or have had depression, mood problems, or suicidal thoughts or behavior

- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal supplements and medicines that you take for a short period of time.

Taking divalproex sodium extended-release tablets with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist each time you get a new medicine.

How should I take divalproex sodium extended-release tablets?

- Take divalproex sodium extended-release tablets exactly as your healthcare provider tells you. Your healthcare provider will tell you how much divalproex sodium to take and when to take it.
- Your healthcare provider may change your dose.
- Do not change your dose of divalproex sodium extended-release tablets without talking to your healthcare provider.
- **Do not stop taking divalproex sodium extended-release tablets without first talking to your healthcare provider**. Stopping divalproex sodium extended-release tablets suddenly can cause serious problems.
- Swallow divalproex sodium extended-release tablets whole. Do not crush or chew divalproex sodium extended-release tablets. Tell your healthcare provider if you cannot swallow divalproex sodium extended-release tablets whole. You may need a different medicine.
- If you take too much divalproex sodium, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking divalproex sodium extended-release tablets?

- Divalproex sodium extended-release tablets can cause drowsiness and dizziness. Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking divalproex sodium extended-release tablets, until you talk with your doctor. Taking divalproex sodium extended-release tablets with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not drive a car or operate dangerous machinery until you know how divalproex sodium extended-release tablets affect you. Divalproex sodium extended-release tablets can slow your thinking and motor skills.

What are the possible side effects of divalproex sodium extended-release tablets?

- **See "What is the most important information I should know about divalproex sodium extended-release tablets?"**

Divalproex sodium extended-release tablets may cause other serious side effects including:

- **Bleeding problems:** red or purple spots on your skin, bruising, pain and swelling into your joints due to bleeding or bleeding from your mouth or nose.
- **High ammonia levels in your blood:** feeling tired, vomiting, changes in mental status.

- **Low body temperature (hypothermia):** drop in your body temperature to less than 95ºF, feeling tired, confusion, coma.
- **Allergic (hypersensitivity) reactions:** fever, skin rash, hives, sores in your mouth, skin blistering and peeling of your skin, swelling of your lymph nodes, swelling of your face, eyes, lips, tongue, or throat, trouble swallowing or breathing.
- **Drowsiness or sleepiness in the elderly.** This extreme drowsiness may cause you to eat or drink less than you normally would. Tell your doctor if you are not able to eat or drink as you normally do. Your doctor may start you at a lower dose of divalproex sodium extended-release tablets.

Call your healthcare provider right away, if you have any of the symptoms listed above.

The common side effects of divalproex sodium extended-release tablets include:

- nausea
- headache
- sleepiness
- vomiting
- weakness
- tremor
- dizziness
- stomach pain
- blurry vision
- double vision
- diarrhea
- increased appetite
- weight gain
- hair loss
- loss of appetite
- problems with walking or coordination

These are not all of the possible side effects of **divalproex sodium extended-release tablets.** For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

How should I store divalproex sodium extended-release tablets?

- Store divalproex sodium extended-release tablets at 20° to 25°C (68° to 77°F).

Keep divalproex sodium extended-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of divalproex sodium extended-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use divalproex sodium extended-release tablets for a condition for which it was not prescribed. Do not give divalproex sodium extended-release tablets to other people, even if they have the same symptoms that you have. They may harm them.

This Medication Guide summarizes the most important information about divalproex sodium extended-release tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about divalproex sodium extended-release tablets that is written for health professionals.

For more information, call Northstar Rx LLC at 1-800-206-7821.

What are the ingredients in divalproex sodium extended-release tablets?

Active ingredient: divalproex sodium

Inactive ingredients: FD&C Blue #1, FD&C Blue #2, hypromellose, mannitol, polyacrylate dispersion 40 percent, polyethylene glycol, pregelatinised starch (maize), propylene glycol, shellac glaze in ethanol, silicified microcrystalline cellulose, silicon dioxide, titanium dioxide, and triacetin. In addition, 500 mg tablets contain iron oxide black, iron oxide yellow, and polydextrose.

Medication Guides available at www.northstarrxllc.com/products or call 1-800-206-7821.

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