

driving an automobile or operating dangerous machinery, until it is known that they do not become drowsy from the drug.

Multiorgan Hypersensitivity Reactions

Instruct patients that a fever associated with other organ system involvement (rash, lymphadenopathy, etc.) may be drug-related and should be reported to the physician immediately [see *Warnings and Precautions (5.12)*].

Depakene Capsules

Mfd. by Banner Pharmacaps, Inc., High Point, NC 27265 U.S.A.

For AbbVie Inc., North Chicago, IL 60064, U.S.A.

Depakene Oral solution

Mfd. by AbbVie Inc., North Chicago, IL 60064, U.S.A.

OR by DPT Laboratories, Ltd., San Antonio, TX 78215, U.S.A.

For AbbVie Inc., North Chicago, IL 60064, U.S.A.

MEDICATION GUIDE

DEPAKOTE ER (dep-a-kOte)

(divalproex sodium)

Extended Release Tablets

DEPAKOTE (dep-a-kOte)

(divalproex sodium)

Tablets

DEPAKOTE (dep-a-kOte)

(divalproex sodium delayed release capsules)

Sprinkle Capsules

DEPAKENE (dep-a-keen)

(valproic acid)

Capsules and Oral Solution

Read this Medication Guide before you start taking Depakote or Depakene 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 Depakote and Depakene?

Do not stop taking Depakote or Depakene without first talking to your healthcare provider.

Stopping Depakote or Depakene suddenly can cause serious problems.

Depakote and Depakene 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. Depakote or Depakene may harm your unborn baby.

- If you take Depakote or Depakene 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 Depakote or Depakene 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 Depakote or Depakene to prevent migraine headaches.
- **All women of child-bearing age should talk to their healthcare provider about using other possible treatments instead of Depakote or Depakene. If the decision is made to use Depakote or Depakene, you should use effective birth control (contraception).**
- Tell your healthcare provider right away if you become pregnant while taking Depakote or Depakene. You and your healthcare provider should decide if you will continue to take Depakote or Depakene while you are pregnant.
- **Pregnancy Registry:** If you become pregnant while taking Depakote or Depakene, 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, Depakote or Depakene 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 Depakote or Depakene without first talking to a healthcare provider. Stopping Depakote or Depakene 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 Depakote and Depakene?

Depakote and Depakene come in different dosage forms with different usages.

Depakote Tablets and Depakote Extended Release Tablets are prescription medicines 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

Depakene (solution and liquid capsules) and Depakote Sprinkles are prescription medicines used 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

Who should not take Depakote or Depakene?

Do not take Depakote or Depakene 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 Depakote or Depakene. See the end of this leaflet for a complete list of ingredients in Depakote and Depakene.
- 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 Depakote or Depakene?

Before you take Depakote or Depakene, 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. Depakote or Depakene can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take Depakote or Depakene.
- 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 Depakote or Depakene 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 Depakote or Depakene?

- Take Depakote or Depakene exactly as your healthcare provider tells you. Your healthcare provider will tell you how much Depakote or Depakene to take and when to take it.
- Your healthcare provider may change your dose.
- Do not change your dose of Depakote or Depakene without talking to your healthcare provider.
- **Do not stop taking Depakote or Depakene without first talking to your healthcare provider.** Stopping Depakote or Depakene suddenly can cause serious problems.
- Swallow Depakote tablets, Depakote ER tablets or Depakene capsules whole. Do not crush or chew Depakote tablets, Depakote ER tablets, or Depakene capsules. Tell your healthcare provider if you cannot swallow Depakote or Depakene whole. You may need a different medicine.
- Depakote Sprinkle Capsules may be swallowed whole, or they may be opened and the contents may be sprinkled on a small amount of soft food, such as applesauce or pudding.

See the Patient Instructions for Use at the end of this Medication Guide for detailed instructions on how to use Depakote Sprinkle Capsules.

- If you take too much Depakote or Depakene, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking Depakote or Depakene?

- Depakote and Depakene can cause drowsiness and dizziness. Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking Depakote or Depakene, until you talk with your doctor. Taking Depakote or Depakene 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 Depakote or Depakene affect you. Depakote and Depakene can slow your thinking and motor skills.

What are the possible side effects of Depakote or Depakene?

- See “**What is the most important information I should know about Depakote or Depakene?**”

Depakote or Depakene 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 95°F, 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 Depakote or Depakene.

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

The common side effects of Depakote and Depakene 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 **Depakote or Depakene**. 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 Depakote or Depakene?

- Store Depakote Extended Release Tablets between 59°F to 86°F (15°C to 30°C).
- Store Depakote Delayed Release Tablets below 86°F (30°C).
- Store Depakote Sprinkle Capsules below 77°F (25°C).
- Store Depakene Capsules at 59°F to 77°F (15°C to 25°C).
- Store Depakene Oral Solution below 86°F (30°C).

Keep Depakote or Depakene and all medicines out of the reach of children.

General information about the safe and effective use of Depakote or Depakene

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Depakote or Depakene for a condition for which it was not prescribed. Do not give Depakote or Depakene to other people, even if they have the same symptoms that you have. It may harm them.

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

For more information, go to www.rxabbvie.com or call 1-800-633-9110.

What are the ingredients in Depakote or Depakene?

Depakote:

Active ingredient: divalproex sodium

Inactive ingredients:

- **Depakote Extended Release Tablets:** FD&C Blue No. 1, hypromellose, lactose, microcrystalline cellulose, polyethylene glycol, potassium sorbate, propylene glycol, silicon dioxide, titanium dioxide, and triacetin. The 500 mg tablets also contain iron oxide and polydextrose.
- **Depakote Tablets:** cellulosic polymers, diacetylated monoglycerides, povidone, pregelatinized starch (contains corn starch), silica gel, talc, titanium dioxide, and vanillin.

Individual tablets also 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.

- **Depakote Sprinkle Capsules:** cellulosic polymers, D&C Red No. 28, FD&C Blue No. 1 gelatin, iron oxide, magnesium stearate, silica gel, titanium dioxide, and triethyl citrate.

Depakene:

Active ingredient: valproic acid

Inactive ingredients:

- **Depakene Capsules:** corn oil, FD&C Yellow No. 6, gelatin, glycerin, iron oxide, methylparaben, propylparaben, and titanium dioxide.
- **Depakene Oral Solution:** FD&C Red No. 40, glycerin, methylparaben, propylparaben, sorbitol, sucrose, water, and natural and artificial flavors.

Depakote ER:

250 mg is Mfd. by AbbVie LTD, Barceloneta, PR 00617

500 mg is Mfd. by AbbVie Inc., North Chicago, IL 60064 U.S.A. or

AbbVie LTD, Barceloneta, PR 00617

For AbbVie Inc., North Chicago, IL 60064 U.S.A.

Depakote Tablets:

Mfd. by AbbVie LTD, Barceloneta, PR 00617

For AbbVie Inc., North Chicago, IL 60064, U.S.A.

Depakote Sprinkle Capsules:

AbbVie Inc., North Chicago, IL 60064, U.S.A.

Depakene Capsules:

Mfd. by Banner Pharmacaps, Inc., High Point, NC 27265 U.S.A.

For AbbVie Inc., North Chicago, IL 60064, U.S.A.

Depakene Oral solution:

Mfd. by AbbVie Inc., North Chicago, IL 60064, U.S.A.

OR by DPT Laboratories, Ltd., San Antonio, TX 78215, U.S.A.

For AbbVie Inc., North Chicago, IL 60064, U.S.A.

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