MEDICATION GUIDE

Divalproex Sodium (dye val' proe ex soe' dee um)

Extended-Release Tablets USP, for oral use

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

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 will not stop (status epilepticus).

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 and patients with mitochondrial disorders.** 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:

- feeling very weak, tired, or uncomfortable (malaise)
- swelling of your face
- not feeling hungry
- nausea or vomiting that does not go away
- diarrhea
- pain on the right side of your stomach (abdomen)
- dark urine
- yellowing of your skin or the whites of your eyes
- loss of seizure control in people with epilepsy

In some cases, liver damage may continue even though the medicine is stopped. Your healthcare provider will do blood tests to check your liver before and during treatment with divalproex sodium extended-release tablets.

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 (such as spina bifida or neural tube defects). 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. Decreased hearing or hearing loss 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 lower IQ and may be at risk for developing autism or attention deficit/hyperactivity disorder.
   - There may be other medicines to treat your condition that have a lower chance of causing birth defects, decreased IQ, or other disorders in your child.
   - Women who are pregnant must not take divalproex sodium extended-release tablets to prevent migraine headaches.
   - **All women of childbearing age (including girls from the start of puberty) 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 (NAAED) Pregnancy Registry. You can enroll in this registry by calling toll–free 1-888-233-2334 or by visiting the website, http://www.aedpregnancyregistry.org/. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
3. **Swelling (Inflammation) and bleeding (hemorrhaging) 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
   - not feeling hungry
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.

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 extended-release tablets 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 other medications to treat:
  - patients with multiple seizure types that include absence seizures

Divalproex sodium extended-release tablets are also used to prevent migraine headaches.

Divalproex sodium extended-release tablets are also used to treat acute manic or mixed episodes associated with bipolar disorder with or without psychotic features.

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 such as 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 Medication Guide for a complete list of ingredients in divalproex sodium extended-release tablets.
- have a genetic problem called a urea cycle disorder.
- are taking it to prevent migraine headaches and are either pregnant or may become pregnant because you are not using effective birth control (contraception).

Before taking divalproex sodium extended-release tablets, tell your healthcare provider about all of your medical conditions including if you:

- have or have had liver problems.
- have or think you have a genetic liver problem caused by a mitochondrial disorder such as Alpers-Huttenlocher syndrome.
- drink alcohol.
- have or have had depression, suicidal thoughts or behavior, unusual changes in mood, or thoughts about self-harm
- are male and plan to father a child. Divalproex sodium extended-release tablets may cause fertility problems, which may affect your ability to father a child. Talk to your healthcare provider if this is a problem for you.
- are pregnant or may become pregnant. Divalproex sodium extended-release tablets may harm your unborn baby. See "**2. Divalproex sodium extended-release tablets may harm your unborn baby**" above for more information.
- are breastfeeding. Divalproex sodium can pass into breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take divalproex sodium extended-release tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Divalproex sodium extended-release tablets may affect the way other medicines work, and other medicines may affect how divalproex sodium extended-release tablets works. Using divalproex sodium extended-release tablets with other medicines can cause serious side effects. **Do not** start or stop other medicines without talking to your healthcare provider.

Especially tell your healthcare provider if you take:

- medicines that can affect how the liver breaks down other medicines (such as phenytoin, carbamazepine, felbamate, phenobarbital, primidone, rifampin)

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Customer	Camber	Market	USA
Dimensions (mm)	200 x 500 mm	Non Printing Colors	Die cut
Pharma Code No.	Front-NA & Back-NA		
Printing Colours	Black		
Others:	NA		

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- aspirin, carbapenem antibiotics, or estrogen-containing hormonal contraceptives
- methotrexate
- topiramate
- cannabidiol

You can ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

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?

- Divalproex sodium extended-release tablets comes in different dosage forms.
- 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, if needed.
- 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 them. Tell your healthcare provider if you cannot swallow divalproex sodium extended-release tablets whole. You may need a different medicine.
- If you miss a dose of divalproex sodium extended-release tablets, take it as soon as you remember unless it's almost time for your next dose. Take the next dose at your regular time. **Do not** take 2 doses at the same time.
- If you take too much divalproex sodium, call your healthcare provider or poison control center right away.

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

- **Do not** drink alcohol while taking divalproex sodium extended-release tablets. Divalproex sodium extended-release tablets and alcohol can affect each other causing side effects such as sleepiness and dizziness.
- Do not drive a car, or operate dangerous machinery, or do dangerous activities until you know how divalproex sodium extended-release tablets affect you. Divalproex sodium extended-release tablets can slow your thinking and motor skills and may affect your vision.

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

Call your healthcare provider right away if you have any of the symptoms listed below. Your healthcare provider may do additional tests before and during your treatment with divalproex sodium extended-release tablets. Your healthcare provider may reduce your dose, temporarily stop, or permanently stop treatment if you have certain side effects.

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

- See **"What is the most important information I should know about divalproex sodium extended-release tablets?"**
- **bleeding problems**. Call your healthcare provider if you have any symptoms of bleeding, including:

○ bruising or red or purple spots on your skin	○ vomiting blood or vomit that looks like coffee grounds
○ bleeding from your mouth or nose	○ blood in your stools or black stools (looks like tar)
○ cough up blood or blood clots	○ pain and swelling in your joints

- **increased ammonia levels in your blood.** High ammonia levels can seriously affect your mental activities, slow your alertness, make you feel tired, or cause vomiting (encephalopathy). This has happened when divalproex sodium extended-release tablets are taken alone or with a medicine called topiramate. Call your health care provider if you have any of these symptoms.
- **low body temperature (hypothermia).** A drop in your body temperature to less than 95°F can happen during treatment with divalproex sodium extended-release tablets. Call your healthcare provider if you have any of the following symptoms:

○ feeling tired	○ drowsiness
○ confusion	○ coma
○ memory loss	○ shivering

- **severe multiorgan reactions.** Treatment with divalproex sodium extended-release tablets may cause severe multiorgan reactions that can be life-threatening or may lead to death. Stop taking divalproex sodium extended-release tablets, and contact your healthcare provider or get medical help right away if you develop any of these symptoms of a severe skin reaction:

○ fever	○ blistering and peeling of your skin
○ skin rash	○ swelling of your lymph nodes
○ hives	○ swelling of your face, eyes, lips, tongue, or throat
○ sores in your mouth,	○ 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 healthcare provider if you are not able to eat or drink as you normally do. Your healthcare provider may start you at a lower dose of divalproex sodium extended-release tablets.
- **medicine residue in your stool.** Tell your healthcare provider if you have or think you may have medicine residue in your stool.

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

• headache	• loss of appetite
• weakness	• weight loss
• sleepiness	• increased appetite
• dizziness	• weight gain
• tremors	• nausea / vomiting
• difficulty walking or problems with coordination	• stomach pain
• ringing in your ears	• diarrhea
• blurred vision	• constipation
• double vision	• bronchitis
• unusual eye movement	• flu-like symptoms
• hair loss (alopecia)	• infection
• swelling of your arms or legs	

These are not all of the possible side effects of **divalproex sodium extended-release tablets.**

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 between 68° to 77°F (20° to 25°C).

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. It may harm them.

You can ask your pharmacist or healthcare provider for information about divalproex sodium extended-release tablets that is written for health professionals.

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

Active ingredient: divalproex sodium USP

Inactive ingredients: Hypromellose, microcrystalline cellulose, silicon dioxide. The film-coating contains lecithin, polyvinyl alcohol, talc, titanium dioxide and xanthan gum. The imprinting ink contains ammonium hydroxide, black iron oxide, propylene glycol and shellac glaze.

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