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Valproate: Patient drug information Lexicomp®

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(For additional information see "Valproate: Drug information" and see "Valproate: Pediatric drug information")

Brand Names: US Depacon; Depakene; Depakote; Depakote ER; Depakote Sprinkles; Stavzor [DSC]

Brand Names: Canada Apo-Divalproex; Apo-Valproic; Depakene; Dom-Divalproex; Dom-Valproic Acid; Dom-Valproic Acid E.C.; Epival; Mylan-Divalproex; Mylan-Valproic; Novo-Valproic; PHL-Valproic Acid; PHL-Valproic Acid E.C.; PMS-Divalproex; PMS-Valproic Acid; PMS-Valproic Acid E.C.; ratio-Valproic; Sandoz-Valproic; Teva Divalproex

Warning

All products:

- This drug may cause very bad and sometimes deadly liver problems. This most often happens within the
 first 6 months of using this drug. Call your doctor if you see dark urine, are feeling tired, are not hungry,
 have an upset stomach, are throwing up, or have yellowing of the skin or eyes. In patients who have
 seizures, loss of seizure control may happen. Have your blood work checked. Talk with your doctor.
- Children under 2 years are at greater risk of deadly liver problems. Those who take more than 1 seizure
 drug or who have a metabolic disorder, a very bad seizure disorder along with mental retardation, or
 certain brain problems are at highest risk. Talk with the doctor.
- There is a greater risk of liver failure and death in patients who have a genetic liver problem caused by a
 mitochondrial disorder like Alpers—Huttenlocher syndrome. You may need to have a genetic test to check
 for this health problem. If you have or may have mitochondrial disorders do not take this drug before
 talking with your doctor.
- This drug may cause very bad birth defects if you take it while you are pregnant. It can also cause the
 child to have a lower IQ. Do not take this drug to prevent migraine headaches if you are pregnant. If you
 are pregnant and take this drug for seizures or bipolar disorder, talk to your doctor to see if you need to
 keep taking this drug.
- If you are able to get pregnant, you must use birth control that you can trust while you take this drug. If
 you get pregnant while taking this drug, call your doctor right away.
- This drug may cause very bad and sometimes deadly pancreas problems (pancreatitis). This may happen soon after use as well as many years after use. Signs of pancreatitis include belly pain, upset stomach,

throwing up, or not feeling hungry. Call your doctor right away if you have any of these signs.

All oral products:

This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care each time
this drug is filled. If you have any questions about this drug, please talk with the doctor, pharmacist, or
other health care provider.

What is this drug used for?

- · It is used to treat seizures.
- · It is used to prevent migraine headaches.
- · It is used to treat bipolar problems.
- · It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to this drug or any part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Liver disease or a urea cycle disorder.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert or have clear eyesight until you see how this drug affects you.
- · Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Talk with your doctor before you drink alcohol or use other drugs and natural products that slow your actions.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- · You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- High blood levels of ammonia have happened with this drug. This can lead to certain brain problems. In some people, this has been deadly. Talk with the doctor.
- Some people have had certain brain problems without high blood levels of ammonia. Sometimes, these brain problems have gone back to normal after this drug was stopped. However, sometimes they have not

fully gone back to normal. Talk with the doctor.

- A very bad and sometimes deadly reaction has happened with this drug. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body organs like the liver, kidney, blood, heart, muscles and joints, or lungs. Talk with the doctor.
- Patients who take this drug may be at a greater risk of having thoughts or actions of suicide. The risk may
 be greater in people who have had these thoughts or actions in the past. Call the doctor right away if
 signs like low mood (depression), nervousness, restlessness, grouchiness, panic attacks, or changes in
 mood or actions are new or worse. Call the doctor right away if any thoughts or actions of suicide occur.
- This drug may affect how much of some other drugs are in your body. If you are taking other drugs, talk
 with your doctor. You may need to have your blood work checked more closely while taking this drug with
 your other drugs.
- Some other drugs may affect how much of this drug is in your body. Talk with your doctor or pharmacist to see if any of your other drugs may interact with this drug.
- If you are 65 or older, use this drug with care. You could have more side effects.
- · Use with care in children. Talk with the doctor.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or
 you get pregnant while taking this drug, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

Valproic acid capsules:

 Some brands of this drug have peanut oil in them. If you are allergic to peanuts, check with your pharmacist to see if your brand has peanut oil in it.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of high ammonia levels like a heartbeat that does not feel normal, breathing that is not normal, feeling confused, pale skin, slow heartbeat, seizures, sweating, throwing up, or twitching.
- · Chest pain.
- · Swelling in the arms or legs.
- · Change in eyesight.
- · Memory problems or loss.
- · Feeling very tired or weak.
- · Change in balance.
- Trouble walking.
- Any unexplained bruising or bleeding.
- · Purple spots or redness of the skin.

- · Not able to pass urine or change in how much urine is passed.
- · Swollen gland.
- · Muscle pain or weakness.
- · Joint pain or swelling.
- · Shakiness.
- · If seizures are worse or not the same after starting this drug.
- · Change in the way you act.
- · Not able to control eye movements.
- · Ringing in ears.
- · Feeling cold.
- · Feeling very sleepy.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- · Headache.
- · Upset stomach or throwing up.
- · Dizziness.
- Feeling sleepy.
- · Hard stools (constipation).
- · Loose stools (diarrhea).
- · Belly pain.
- · Not able to sleep.
- · Feeling more or less hungry.
- · Weight gain or loss.
- · Hair loss.
- Feeling tired or weak.
- · Feeling nervous and excitable.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All oral products:

- Take with or without food. Take with food if it causes an upset stomach.
- · To gain the most benefit, do not miss doses.

- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Do not stop taking this drug all of a sudden without calling your doctor. You may have a greater risk of seizures. If you need to stop this drug, you will want to slowly stop it as ordered by your doctor.
- If you take cholestyramine, you may need to take it at some other time than this drug. Talk with your pharmacist.

Tablets and capsules:

- · Swallow whole. Do not chew, break, or crush.
- · Take with a full glass of water.
- · If you have trouble swallowing, talk with your doctor.

Long-acting tablets:

· If you see parts of this drug in your stool, call your doctor.

Sprinkle capsule:

- You may swallow whole or mix the contents of the capsule with certain foods like applesauce. Take the
 mixture right away. Do not store for later use.
- · If you see parts of this drug in your stool, call your doctor.

Liquid:

Measure liquid doses carefully. Use the measuring device that comes with this drug. If there is none, ask
the pharmacist for a device to measure this drug.

Injection:

· It is given as an infusion into a vein over a period of time.

What do I do if I miss a dose?

All oral products:

- · Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

Injection:

· Call your doctor to find out what to do.

How do I store and/or throw out this drug?

All oral products:

- · Store at room temperature.
- Store in a dry place. Do not store in a bathroom.

Injection:

· If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

All products:

Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.

• Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- · Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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