

Patient Information Leaflet

Important Information for Women Who Could Become Pregnant About the Use of DEPAKOTE®, DEPAKOTE® ER, DEPAKOTE® Sprinkle Capsules, and DEPAKENE®.

Please read this leaflet carefully before you take any of these medications. This leaflet provides a summary of important information about taking these medications to women who could become pregnant. If you have any questions or concerns, or want more information about these medications, contact your doctor or pharmacist.

Information For Women Who Could Become Pregnant

These medications can be obtained only by prescription from your doctor. The decision to use any of these medications is one that you and your doctor should make together, taking into account your individual needs and medical condition.

Before using any of these medications, women who can become pregnant should consider the fact that these medications have been associated with birth defects, in particular, with spina bifida and other defects related to failure of the spinal canal to close normally. Approximately 1 to 2% of children born to women with epilepsy taking DEPAKOTE in the first 12 weeks of pregnancy had these defects (based on data from the Centers for Disease Control, a U.S. agency based in Atlanta). The incidence in the general population is 0.1 to 0.2%.

These medications have also been associated with other birth defects such as defects of the heart, the bones, and other parts of the body. Information suggests that birth defects may be more likely to occur with these medications than some other drugs that treat your medical condition.

Information For Women Who Are Planning to Get Pregnant

- Women taking any of these medications who are planning to get pregnant should discuss the treatment options with their doctor.

Information For Women Who Become Pregnant

- If you become pregnant while taking any of these medications, you should contact your doctor immediately.

Other Important Information

- Your medication should be taken exactly as prescribed by your doctor to get the most benefit from your medication and reduce the risk of side effects.
- If you have taken more than the prescribed dose of your medication, contact your hospital emergency room or local poison center immediately.
- Your medication was prescribed for your particular condition. Do not use it for another condition or give the drug to others.

Facts About Birth Defects

It is important to know that birth defects may occur even in children of individuals not taking any medications or without any additional risk factors.

This summary provides important information about the use of DEPAKOTE®, DEPAKOTE® ER, DEPAKOTE® Sprinkle Capsules, and DEPAKENE® to women who

could become pregnant. If you would like more information about the other potential risks and benefits of these medications, ask your doctor or pharmacist to let you read the professional labeling and then discuss it with them. If you have any questions or concerns about taking these medications, you should discuss them with your doctor.

Abbott Laboratories

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

DEPAKOTE®
Sprinkle Capsules
DIVALPROEX SODIUM
COATED PARTICLES IN CAPSULES

Patient Information Guide

Administration Guide

DEPAKOTE® Sprinkle Capsules (divalproex sodium coated particles in capsules) may be swallowed whole or the capsule contents may be sprinkled onto soft food such as applesauce or pudding.

Serving Suggestions

DEPAKOTE® Sprinkle Capsules (divalproex sodium coated particles in capsules) provide the medicine that your doctor has prescribed. The sprinkles are flavorless. Soft foods such as applesauce or pudding are best to use for mixing and taking DEPAKOTE Sprinkles.

TO
 ADMINISTER
 WITH FOOD:

1



Hold the capsule so that the end marked "THIS END UP" is straight up and the arrow on the capsule is up. The capsule is extra large to help prevent spilling the DEPAKOTE Sprinkles, but it still must be handled carefully.

2



To open the capsule, hold it carefully. As shown in the picture, gently twist the capsule apart to separate the top from the bottom. It may be helpful to hold the capsule over the food to which you will add the sprinkles. If you spill any of the capsule contents, start over with a new capsule and a new portion of food.

3



Place all the sprinkles onto a small amount (about a teaspoonful) of soft food such as applesauce or pudding.

4



Make sure that all of the sprinkle and food mixture is swallowed right away. Do not chew the sprinkle and food mixture. Drinking water right after taking the sprinkle and food mixture will help make sure all sprinkles are swallowed. Throw away any unused sprinkle and food mixture; do not store any sprinkle and food mixture for future use. Mix it each time, right before it is taken.

Make sure this medicine is taken exactly as your doctor prescribed it. If you have any questions, please contact your doctor or pharmacist. Keep all of your of your doctor's appointments as scheduled. Make sure that DEPAKOTE Sprinkle Capsules and all other medicines are kept out of the reach of children.

Note

You may see the specially coated particles in DEPAKOTE Sprinkle Capsules in stool; this is normal. Ask your doctor or pharmacist about possible side effects with DEPAKOTE Sprinkle Capsules.

Store DEPAKOTE Sprinkle Capsules below 77⁰F (25⁰C).

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