



This information has been gathered by The Cleft Lip & Palate Foundation of Smiles. We are responding to the fact that a number of our members have questions concerning the safety of medications that they had taken during pregnancy, or may take during a future pregnancy. These medications may be the cause of craniofacial differences. Our goal is to ensure that our families have resources and facts about the medications that may be taken during pregnancy, so you can have informed discussions with the treating doctors.

Online at www.cleftsmile.org

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The Cleft Lip & Palate Foundation of Smiles provides research on craniofacial causes (genetics, environmental, prescription drugs), treatments (cleft palate teams, medical devices, therapies), and available support for families.

This PDF is about Depakote valproate birth defect risks for women who get pregnant. This article is by no means conclusive but generally outlines some of the more common birth defects from the more well known brands of Depakote. As with any prescription drug, do not stop taking or reduce the dosage without discussing the repercussions with your doctor first.

RESEARCH AND RECENT STUDIES

Causes of Cleft Lip and Palate: DEPAKOTE



Depakote valproate neural tube birth defects

[Valproate use during pregnancy increases the risk of major malformations, including neural tube defects.](#) In the United States, about 1 in 1,500 babies is born with a neural tube defect. The risk of neural tube defects is much higher in babies born to mothers treated with valproate during the first 12 weeks of pregnancy, with the risk increasing to one in 20 babies.

What are neural tube defects?

[Neural tube defects](#) are birth defects of the brain and spinal cord. The two most common neural tube defects are spina bifida and anencephaly. In spina bifida, the fetal spinal column doesn't close completely during the first month of pregnancy. In anencephaly, the brain doesn't develop. Babies with anencephaly are either stillborn or die shortly after birth.

What medical conditions are Depakote / valproate used for?

The FDA-approved Depakote to treat seizures, and manic or mixed episodes associated with bipolar disorder / manic-depressive disorder, and to prevent migraine headaches. Depakote is also used off-label for unapproved uses for other psychiatric conditions.

What are some brand names for valproate?

Depacon (valproate sodium), Depakote, Depakote CP, and Depakote ER (divalproex sodium), Depakene and Stavzor (valproic acid)



What are Depakote side effects?

The most dangerous Depakote side effects involve damage to the unborn fetus. Consequently, women who are pregnant, likely to become pregnant or want to get pregnant or are of childbearing age, or are nursing should not take Depakote because it may cause the following conditions:

- Spina bifida
- Cleft palate
- Hand malformations
- Abnormally developed ribs
- Hypospadias (a condition in male babies that causes the opening of the urethra to occur in the wrong place)
- Undescended testicles
- And the most recently reported [a/o June 2011—lower cognitive test scores](#)

Is the FDA doing enough about dangerous Depakote / valproate side effects?

FDA first approved Depakene (valproic acid) in 1978 for the treatment of epilepsy. More recently, FDA approved valproate for the treatment of bipolar disorder and migraine headaches. As valproate's indications for use expand, it is critical that all healthcare professionals caring for women of childbearing potential and taking valproate for any indication be informed that valproate causes an [increased risk of major birth defects](#).

Data from the [NAAED Pregnancy Registry](#) show that the rate of major malformations in babies born to women with epilepsy taking valproate (monotherapy) is almost 4 times higher than the rate of major malformations in babies born to women with epilepsy taking a different antiepileptic drug.

How were lower cognitive test scores evaluated?

In the primary epidemiologic study upon which FDA's conclusion is based, cognitive tests were performed at age three. Several published epidemiological studies have indicated that children exposed to Depakote in utero have lower cognitive test scores than children exposed to either another antiepileptic drug in utero or to no antiepileptic drugs in utero. The largest of these studies is a prospective cohort study conducted in the United States and United Kingdom that found children with prenatal exposure to Depakote (valproate) throughout pregnancy had lower Differential Ability Scale (D.A.S) scores at age 3 than children with prenatal exposure to the other evaluated antiepileptic drug monotherapy treatments—Lamictal (lamotrigine), Tegretol (carbamazepine), and Dilantin (phenytoin).

In supportive studies, cognitive tests were performed at ages five to 16. Cognitive tests are commonly used to assess development in a variety of areas, including intelligence, abstract reasoning, and problem solving.

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Is Depakote the only drug available for my medical condition?

This is a discussion you have to have between you and your doctor. The benefits and risks of Depakote should be carefully considered when prescribing this drug to women of child bearing age and to women who want to get pregnant. Ask your doctor if there are alternative medications that do not have the same risks for birth defects.

Should I stop taking Depakote or related products if it's harmful to my baby or if I want to get pregnant?

No! Do not stop taking Depakote or related drugs without first talking to your doctor. If you suddenly stop taking a prescription drug, it may cause an entirely different array of side effects which could be more harmful to your well being

Do you have more questions? Do you need resources?

For questions and resources about cleft lip and cleft palate, please contact: [The Cleft Lip and Palate Foundation of Smiles](#). Cleft lip or palate is one of the most common birth defects, currently affecting one in 600 children in the United States. The Foundation was formed by a young mother of twins both born with cleft lip and palate. The Foundation offers positive support to parents of children with craniofacial differences by offering news, information on cleft palate teams, [state by state resources](#), [birth registry listings](#), and a [support group](#) where you can meet other families in your local area who are going through the same or similar concerns and where you can share and express useful information.

References

Information for Healthcare Professionals: Risk of Neural Tube Birth Defects following prenatal exposure to Valproate, Food & Drug Administration, December 3, 2009

Meador KJ, Baker GA, Browning N, et al. Cognitive function at 3 years of age after fetal exposure to antiepileptic drugs; N Engl J Med 2009; 360:1597-605.

Epilepsy.com: [Introduction to valproic acid](#)

Pregnant women using Depakote / valproate or other anti-epileptic drugs should be encouraged to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry; 1-888-233-2334; www.aedpregnancyregistry.org

Other Research from The Cleft Lip & Palate Foundation of Smiles

Research and Recent Studies:

[Causes of Cleft Lip and Palate: Birth Defects](#)

[Causes of Cleft Lip and Palate: Clomid](#)

[Causes of Cleft Lip and Palate: Fluconazole](#)

[Causes of Cleft Lip and Palate: Health Insurance](#)

[Causes of Cleft Lip and Palate: Hydrocodone](#)

[Causes of Cleft Lip and Palate: Special Education](#)

[Causes of Cleft Lip and Palate: SSRIs](#)

[Causes of Cleft Lip and Palate: Topamax](#)

