

Did you know Depakote poses serious health risks?

DID YOU OR A LOVED ONE TAKE DEPAKOTE?

EPILEPSY MEDICATION

Depakote[®]
—divalproex sodium

Linked to

Birth Defects!

- Spina bifida
- Cleft palate
- Facial dysmorphism
- Congenital cardiac defects
- Limb reduction

CRITICAL
Compensation
Evaluation

Valproate Semisodium, known by its brand name Depakote, is prescribed to patients as treatment for bipolar disorder, epilepsy, and for the prevention of migraine headaches. Depakote is a popular medication, and has helped millions of people with severe medical conditions. Recent studies, however, have shown that taking Depakote during pregnancy, and especially during the first trimester can have adverse effects on an infant, including a range of birth defects.

About Depakote

In 1983, Depakote became widely available in the United States as a means to treat epilepsy; more than two million prescriptions were filled within its first year. Created by Abbott Laboratories, the drug became popular extremely quickly, with many off-brand names following.

Eventually, during 2000-2002, Depakote was prescribed for both migraine headaches, pancreatitis, bipolar disorder, and adjunctive therapy for seizures. Over 27 million Americans were taking the medication by 2002.

In 2007, the United States Food and Drug Administration (FDA) issued a warning for pregnant women, stating that the drug has been linked with a heightened risk for serious birth defects. Consequently, the drug was then categorized as a Class D drug for pregnant women, meaning studies on animals taking Depakote resulted in adverse reactions. However, no official data is available for human babies since infants cannot be tested. Yet, several infants with mother who took the drug were born with a host of different birth defects. Pregnant women have also shown adverse reactions.

Risks Associated With Depakote While Pregnant

Along with the FDA's findings, a study performed by Lolkje T.W. de Jong-van den Berg, from the University of Groningen, and his colleagues, suggests that users of Depakote, including pregnant women, may experience not only an increased chance of having an infant with birth defects but also severe maternal side effects. While nausea and tremors are most common side effect, others side effects include:

- Headaches
- Diarrhea
- Impaired memory
- Hair loss
- Weight gain
- Nausea

In more severe instances, Depakote use can cause:

- Coma
- Osteoporosis
- Pancreatitis

Migraines, epilepsy, bipolar disorder, and seizures, however, are all serious conditions. When pregnant women are taken off medication that controls these conditions, additional risks may occur. It's always important to talk to your physician beforehand in order to determine the best course of action.

Risks Associated With Depakote and Infants

Recent studies indicate that mothers during the first trimester of pregnancy and taking Depakote put the fetus at risk of developing numerous birth defects and a level two to seven times the normal rate. The numerous potential issues that could affect the infant are:

Decreased IQ

According to a recent epidemiological study, children who were exposed to Depakote while in utero were linked to decreased IQ scores. In addition, the FDA released a warning after several studies were performed on children who were exposed to Depakote while in utero. The results of the studies is a major part of the reason that the FDA changed Depakote to a Class D Drug, meaning there is evidence of the risk of infant harm.

Atrial Septal Defect

Atrial septal defect (ASD) is a congenital heart defect marked by an unusual opening between the upper chambers of the heart. It's commonly referred to as "hole in the heart." Infants exposed to Depakote in utero are 2.5 times more likely to have the condition when compared to infants who aren't exposed to the drug.

Cleft Lip and Cleft Palate

Cleft lip and cleft palate are a type of birth defect that happens when an infant's lip or mouth fail to form properly during pregnancy. According to Lolkje T.W. de Jong-van den Berg's studies, infants exposed to Depakote during pregnancy are five times more likely to develop cleft lip or cleft palate.

"These findings provide further evidence to avoid valproic acid, if possible, in pregnant women and (for doctors) to discuss with girls and women of childbearing potential the risk of the drug for the unborn child," states Dr. Jong-van den Berg.

Spina Bifida

Per the Centers for Disease Control and Prevention (CDC), spina bifida is considered a serious birth defect as it affects an infant's spine, causing physical and sometime intellectual disabilities. Babies exposed to Depakote during pregnancy are 12.5 times more likely to develop spina bifida.

Other birth defects associated with Depakote include:

- Hypospadias
- Neural tube defects and malformation
- Anencephaly
- Polydactyl
- Craniosynotosis

Breastfeeding and Depakote

Since Depakote enters the bloodstream, it will also enter the maternal milk supply, yet the amount will vary according to each mother. In recent report published by the National Institutes of Health (NIH), infants experience sedation and drowsiness while breastfeeding. However, when the mothers stopped taking the drug, the sedation and drowsiness cleared.

In another instance, an 2-month-old infant who was exposed to Depakote via breastfeeding experienced not only sedation, but red spots on the skin, known as Petechiae, as well as anemia, thrombocytopenia, and hematuria. The infant's mother took 600 mg of Depakote twice a day.

However, it's important to note that the study also showed that some infants who were exposed to Depakote after breast feeding showed no adverse reactions. Each individual is different, and if you're considering taking Depakote while you breastfeed, be certain to talk with your physician beforehand.

Liability if Birth Defects Happen

Although the FDA warned the public of the dangers of birth defects associated with Depakote, physicians often still prescribe the medication if they feel that the benefits of treating the mother's health issues outweigh the risks of possible birth defects. However, physicians must always warn pregnant women of the hazards linked to Depakote and give them the option to choose whether to continue with the medication or not. If doctors fail to provide this important information, they may be liable for damages.

In addition, if the manufacturer of medications knowingly hide information regarding the risks and dangers linked to their drug, they may also be liable for any birth injuries or birth defects that occur.