

WOMEN WITH EPILEPSY: DRUG RISKS TO THE FETUS OR BABY DURING PREGNANCY



This fact sheet lists some of the risks of antiepileptic drugs (AEDs) when taken during pregnancy. To understand these risks better, please read the AAN Summary of [Evidence-based Guideline](#) for PATIENTS and their FAMILIES on WOMEN WITH EPILEPSY: DRUG RISKS AND SAFETY DURING PREGNANCY.

This information comes from scientific studies* of major health risks to the fetus or baby from AED exposure. For some drugs, there were not many high-quality studies.

Carbamazepine

- There is good evidence that carbamazepine (CBZ) use will probably *not* cause your child to develop poor thinking skills.
- There is weak evidence that CBZ use may be associated with a posterior cleft palate (a groove in the roof of the mouth).

Lamotrigine

- Consider limiting your lamotrigine (LTG) dose during the first trimester—but *only* if your doctor thinks it is safe to do so—because this might lower your risk of major birth defects.

Phenobarbital

- There is weak evidence that phenobarbital (PB) use may cause your fetus to develop heart problems.
- Weak evidence also suggests that PB might cause your child to develop poor thinking skills.

Phenytoin

- There is weak evidence that phenytoin (PHT) use may be associated with a cleft palate (a groove in the roof of the mouth).
- Weak evidence also suggests PHT use can cause your child to develop poor thinking skills.

Valproate

- Good evidence suggests valproate (VPA) use during the first trimester—whether alone or as part of multidrug therapy—can cause major birth defects.
- Good evidence suggests that VPA use is associated with neural tube defects and facial clefts.
- There is weak evidence that connects VPA use to hypospadias, a defect that occurs in boys. This defect causes the urinary opening to form below the tip or on the side of the penis.
- Good evidence suggests that VPA use can lead to poor thinking skills in your child.
- If VPA is the only drug that controls your seizures, then consider limiting your VPA dose during the first trimester—but *only* if your doctor thinks it is safe to do so. This might lower your risk of major birth defects.

The US Food and Drug Administration (FDA) writes “black-box” warnings for drugs that pose serious risks. The FDA has written a black-box warning on the risks of major birth defects from VPA. To read about this online, go to: http://www.fda.gov/MEDwatch/SAFETY/2002/Depakote_PI.pdf.

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

* After the experts review all of the published research studies, they describe the strength of the evidence supporting each recommendation:

Strong evidence = more than one high-quality scientific study

Good evidence = at least one high-quality scientific study or two or more studies of a lesser quality

Weak evidence = the studies, while supportive, are weak in design or strength of the findings

Not enough evidence = either different studies have come to conflicting results or there are no studies of reasonable quality

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