

FDA warns pregnant women about migraine drugs

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Medicines containing valproate linked to lower IQs in children, agency says.

(HealthDay)—Pregnant women who struggle with migraine headaches should never use medicines containing the ingredient valproate because they can lower the IQ scores of their children, the U.S. Food and Drug Administration said Monday.

The new warning will be included on the labels of medicines that contain valproate. These medicines already carry a boxed warning about fetal risk, including birth defects. Valproate products include valproate sodium (Depacon); divalproex sodium (Depakote, Depakote CP, and Depakote ER); valproic acid (Depakene and Stavzor); and their generic versions.

"Valproate medications should never be used in pregnant women for the prevention of [migraine headaches](#) because we have even more data now that show the risks to the children outweigh any treatment benefits for this use," Dr. Russell Katz, director of the division of neurology products in the FDA's Center for Drug Evaluation and Research, said in an agency news release.

Valproate medicines have several FDA-approved uses including: prevention of migraines, treatment of epileptic seizures and treatment of bipolar disorder.

This new warning was issued after a study found that children whose mothers took valproate drugs to protect against epilepsy during pregnancy scored eight to 11 points lower on [IQ tests](#) at age 6 than children who were exposed to other [antiepileptic drugs](#) in the womb.

It's not known if there's a specific time during pregnancy when valproate can result in decreased IQ in children. The women in the study took the antiepileptic valproate drugs throughout their pregnancies, the FDA said.

Valproate may have some value in treating bipolar disorder and [epileptic seizures](#) in pregnant women, but should only be taken if other medications have failed to control the symptoms or are otherwise unacceptable, according to the agency.

The FDA also said that:

- Women who can become pregnant should not use valproate unless it is essential to managing their medical condition.
- Women of childbearing age taking valproate products should use effective birth control.
- Women who are pregnant or who become pregnant while taking

[valproate](#) medications should talk to their health-care professional immediately. Women should not stop taking their medication without talking to their health-care professional because stopping treatment suddenly can cause serious and life-threatening medical problems for the woman or the fetus.

More information: The Nemours Foundation outlines [pregnancy hazards](#).

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