**FDA: Risk of oral birth defects in children born to mothers taking topiramate**

New data suggest that the drug Topamax (topiramate) and its generic versions increase the risk for the birth defects cleft lip and cleft palate in babies born to women who use the medication during pregnancy, the U.S. Food and Drug Administration said today.

Before prescribing topiramate, approved to treat certain types of seizures in people who have epilepsy, health care professionals should warn patients of childbearing age about the potential hazard to the fetus if a woman becomes pregnant while using the drug.   
Topiramate also is approved to prevent migraine headaches, but not to relieve the pain of migraines.

“Health care professionals should carefully consider the benefits and risks of topiramate when prescribing it to women of childbearing age,” said Russell Katz, M.D., director of the Division of Neurology Products in the FDA’s Center for Drug Evaluation and Research. “Alternative medications that have a lower risk of birth defects should be considered.”

Cleft lip and cleft palate, collectively called oral clefts, are birth defects that occur when parts of the lip or palate do not completely fuse together early in the first trimester of pregnancy, a time when many women do not know they are pregnant. The defects range from a small notch in the lip to a groove that runs into the roof of the mouth and nose, possibly leading to problems with eating, talking, and to ear infections. Surgery often is performed to close the lip and palate and most children do well after treatment.

Data from the North American Antiepileptic Drug (AED) Pregnancy Registry indicate an increased risk of oral clefts in infants exposed to topiramate during the first trimester of pregnancy. Infants exposed to topiramate as a single therapy experienced a 1.4 percent prevalence of oral clefts, compared with a prevalence of 0.38 percent – 0.55 percent in infants exposed to other antiepileptic drugs.

Infants of mothers who did not have epilepsy and were not being treated with other antiepileptic drugs had a prevalence of 0.07 percent. Similar data from the United Kingdom Epilepsy and Pregnancy Register supported the North American AED Pregnancy Registry data.

Based on the data, topiramate will have a stronger warning in its prescribing information (labeling). The pregnancy category will be changed to Pregnancy Category D. This means that there is positive evidence of human fetal risk based on human data, but the potential benefits of the drug in pregnant women may outweigh the risks in certain situations. The FDA previously designated the drug as Pregnancy Category C because of the lack of human data. More information about the Pregnancy Categories can be found in the [FDA’s Drug Safety Communication](http://www.fda.gov/Drugs/DrugSafety/ucm245085.htm)1.

The patient medication guide and prescribing information for Topamax and generic topiramate will be updated with the new information.

Before starting topiramate, pregnant women and women of childbearing potential should discuss other treatment options with their health care professional. Women taking topiramate should tell their health care professional immediately if they are planning to or become pregnant. Patients taking topiramate should not stop taking it unless told to do so by their health care professional.

Women who become pregnant while taking topiramate should talk to their health care professional about registering with the [North American Antiepileptic Drug Pregnancy Registry](http://www2.massgeneral.org/aed/)2, a group that collects information about outcomes in infants born to women treated with antiepileptic drugs during pregnancy.

For more information:

* [FDA Drug Safety Communication: Risk of oral clefts in children born to mothers taking Topamax (topiramate)](http://www.fda.gov/Drugs/DrugSafety/ucm245085.htm)3

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