FDA: Risk of Oral Birth Defects in Children Born to Mothers Taking Topiramate

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SILVER SPRING, Md., March 4, 2011 /PRNewswire-USNewswire/ -- 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.

(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO [1])

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 percen
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