Topamax (topiramate) : Label change – risk for development of cleft lip and/or cleft palate in newborns

[Posted 03/04/2011]

婦女在懷孕期間使用 Topamax（topiramate），會增加新生兒有唇裂和/顎裂（唇顎裂）的風險，因此懷孕等級為 D。懷孕等級 D 代表：使用前須先評估胎兒有唇顎裂的風險和用藥的必要性，若潛在的好處大於風險，則仍可以使用 topiramte。

懷孕或可能懷孕的婦女在使用 topiramate 之前，必須先和醫療人願討論是否有其他的治療建議。若婦女正在使用 topiramate，必須立即告訴醫療人員是否計畫懷孕或已懷孕。若病患正在使用 topiramate，注意不可以自行停止，除非醫療人員建議停藥。

Topamax (topiramate) : Label change – risk for development of cleft lip and/or cleft palate in newborns

AUDIENCE: Neurology, OB/GYN

[Posted 03/04/2011]

FDA notified healthcare professionals and patients of an increased risk of development of cleft lip and/or cleft palate (oral clefts) in infants born to women treated with Topamax (topiramate) during pregnancy. Because of new human data that show an increased risk for oral clefts, topiramate is being placed in Pregnancy Category D. Pregnancy Category D means there is positive evidence of human fetal risk based on human data but the potential benefits from use of the drug in pregnant women may be acceptable in certain situations despite its risks.

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, a group that collects information about outcomes in infants born to women treated with antiepileptic drugs during pregnancy.