FDA: Migraine drug ups risk for oral birth defects

Johnson & Johnson’s Topamax, are about 20 times more likely to have their infants develop cleft palate deformities than those who are not treated.

An epilepsy drug also used to help prevent migraines can increase the risk for oral birth defects in babies born to women taking the medication. The Food and Drug Administration said new data shows expecting mothers taking the drug, sold generically and as Johnson & Johnson’s Topamax, are about 20 times more likely to have their infants develop cleft lips or cleft palate deformities than those who are not treated.

Officials called on doctors to warn their female patients of childbearing age who are taking the medicine about the risks since the defects occur in the first three months of pregnancy, before women may know they are expecting. FDA’s Russell Katz, who heads the agency’s Division of Neurology Products, said doctors should think carefully before prescribing the drug to women of childbearing age and “alternative medications that have a lower risk of birth defects should be considered.” The conditions can lead to multiple development issues because they can make it nearly impossible for babies to get adequate nutrition. They can be corrected with surgery, although sometimes several operations are needed.

The data showed cleft lips or palates occurred in 1.4 percent of babies exposed to Topamax or generic rivals compared to between 0.38 percent and 0.55 percent in infants whose mothers took other drugs for epilepsy, FDA said. The defect occurs in about 0.07 percent of infants whose mothers are not on any such medication.

In a statement, J&J said Topamax’s label already notes the risks with pregnancy and “recommended cautious use in pregnant patients.” It said it would work with the FDA to clarify the drug’s use during pregnancy.

Topamax is expected to bring $569 million in worldwide revenue for the diversified drug maker in 2010, according to Thomson Reuters data. At its peak, the drug took in more than $2.7 billion in 2008, before rivals arrived in 2009.

FDA issued the warning based on data collected from the North American Antiepileptic Drug Pregnancy Registry.

Dentists at risk for hearing loss

Everyone knows there are certain jobs that carry a risk for loss of hearing. Rock musicians come immediately to mind. So do construction workers who use jackhammers. And don’t forget the people who use those yellow flashlights to direct planes at airports. According to a recent study, dentists can also consider themselves among those at risk for ear trouble.

Most individuals would not consider a dental office to be a place where noise is a problem, but the federal Occupational Safety and Health Administration (OSHA) warns that any workers exposed to noise levels in excess of 85 decibels are at risk.

The exposure to continuous high frequencies from a dental drill can degrade one’s hearing. According to the experts, dental