U.S. Food and Drug Administration

Drugs

Public Health Advisory: Paroxetine

12/8/2005

The Food and Drug Administration (FDA) has determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine's pregnancy category from C to D and added new data and recommendations to the *Warnings* section of paroxetine's prescribing information. Paroxetine is available as Paxil, Paxil CR, Pexeva, and generic paroxetine hydrochloride.

The FDA's conclusions and changes in paroxetine's prescribing information are based on preliminary analyses of two recent unpublished epidemiology studies.

- In a study using Swedish national registry data, women who received paroxetine in early pregnancy had an approximately 2-fold increased risk for having an infant with a cardiac defect compared to the entire national registry population (the risk of a cardiac defect was about 2% in paroxetine-exposed infants vs. 1% among all registry infants).
- In a separate study using a United States insurance claims database, infants of women who received paroxetine in the first trimester had a 1.5-fold increased risk for cardiac malformations and a 1.8-fold increased risk for congenital malformations overall compared to infants of women who received other antidepressants in the first trimester. The risk of a cardiac defect was about 1.5% in paroxetine-exposed infants vs. 1% among infants exposed to other antidepressants.
- Most of the cardiac defects observed in these studies were atrial or ventricular septal defects, conditions in which the wall between the right and left sides of the heart is not completely developed. In general, septal defects are one of the most common type of congenital malformations. They range from those that are symptomatic and may require surgery to those that are asymptomatic and may resolve on their own. It is of note that the data in these studies was limited to first trimester exposures only, and there are not currently data to address whether this or any other risk extends to later periods of pregnancy.

The FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to better characterize the risk for congenital malformations associated with paroxetine. In the interim FDA recommends the following:

Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. In individual cases, the benefits of continuing paroxetine may outweigh the potential risk to the fetus. If the decision is made to discontinue paroxetine and switch to another antidepressant or cease antidepressant therapy, paroxetine discontinuation should be undertaken only as directed in the prescribing information. Paroxetine should generally not be initiated in women who are in their first trimester of pregnancy or in women who plan to become pregnant in the near future.

Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do tha with their physician.

Related Information

- Paroxetine hydrochloride (marketed as Paxil) Information [1]

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