TERATOGENIC EFFECTS ASSOCIATED WITH LONG-TERM, HIGH-DOSE FLUCONAZOLE

This special issue is prompted by a FDA safety alert cautioning practitioners about the chronic use of high dose fluconazole in pregnant females. This usage pattern in pregnant women during their first trimester may be associated with rare birth defects in the fetus that has been identified in case report data, including: a short broad head shape or abnormal looking face, an oral cleft, bowing of thigh bones, thin ribs and long bones, muscle weakness and congenital heart disease. A verbatim copy of the FDA safety alert is posted below. If you need further information please contact the Samford University Global Drug Information Service at (205) 726-2659.

ISSUE: FDA is informing the public that treatment with chronic, high doses (400-800mg/day) of Diflucan (fluconazole) during the first trimester of pregnancy may be associated with a rare and distinct set of birth defects in infants. This risk does not appear to be associated with a single, low dose of fluconazole 150mg to treat vaginal yeast infection (candidiasis). Based on this information, the pregnancy category for fluconazole indications (other than vaginal candidiasis) has been changed from category C to category D. The pregnancy category for a single, low dose of fluconazole has not changed and remains category C.

BACKGROUND: Diflucan is used to treat yeast infections of the vagina, mouth, throat, esophagus and other organs. It is also used to prevent yeast infections in patients who are likely to become infected because they are being treated with chemotherapy or radiation therapy before bone marrow transplant. Diflucan is also used to treat meningitis caused by a certain type of fungus. 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 with serious or life-threatening conditions may be acceptable despite its risks.

RECOMMENDATION: Healthcare professionals should counsel patients if the drug is used during pregnancy or if a patient becomes pregnant while taking the drug. Patients should notify their healthcare professionals if they are or become pregnant while taking fluconazole. If a patient uses fluconazole during pregnancy, the patient should be informed of the potential risk to the fetus.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA’s MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA Drug Safety Communication, at:


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