



**The FDA Safety Information and
Adverse Event Reporting Program**

Diflucan (fluconazole): Drug Safety Communication – Long-term, High-dose Use During Pregnancy May Be Associated With Birth Defects

[Posted 08/03/2011]

FDA 公告：懷孕前三個月的婦女長期使用大劑量的 fluconazole (Diflucan) (400~800/day)，可能造成嬰兒缺陷。使用單一劑量 150 mg 治療陰道念珠菌感染的婦女，則沒有此風險。根據此訊息，fluconazole 用於陰道念珠菌感染以外的適應症時，懷孕分級由 C 改為 D。單一劑量 150 mg fluconazole 的懷孕分級仍為 C。

醫療人員須詢問使用 fluconazole (Diflucan) 的患者，是否有懷孕或即將懷孕；若懷患者於懷孕期間接受長期且大劑量的 fluconazole，應被告知對胎兒的危險。

Diflucan (fluconazole): Drug Safety Communication – Long-term, High-dose Use During Pregnancy May Be Associated With Birth Defects

AUDIENCE: OBGYN, Pharmacy, Infectious Disease

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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.

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.