



Fluconazole (Diflucan): Drug Safety Communication - FDA Evaluating Study Examining Use of Oral Fluconazole (Diflucan) in Pregnancy

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FDA 檢視丹麥的研究結果，發布一則安全警訊：口服抗黴菌藥物 Fluconazole 可能增加流產、胎兒異常的風險。FDA 也正檢視其他的研究資料，評估完成後會再給予結論和建議。

目前美國仿單標示，懷孕女性只使用一次 150mg 劑量的 Fluconazole 並不會增加胎兒發育異常的風險，除非是大劑量(400-800 mg/day)且一段時間的使用才會增加風險。然而丹麥的研究結果顯示，即使是一或兩次 150mg 的劑量，懷孕女性的流產或是胎兒發育異常的風險都有明顯的增加。

建議：

FDA 建議懷孕婦女應該謹慎的使用口服 Fluconazole。

醫療人員應該遵循美國疾病控制與預防中心(Centers for Disease Control and Prevention)的治療準則，懷孕女性陰道念珠菌感染建議使用局部抗黴菌藥物，即使感染較為嚴重或者是復發的懷孕婦女也應該使用局部抗黴菌藥物。

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AUDIENCE: Internal Medicine, Family Practice, OB/GYN

ISSUE: FDA is evaluating the results of a Danish study that conclude there is a possible increased risk of miscarriage with the use of oral fluconazole (Diflucan) for yeast infections. FDA is also reviewing additional data and will communicate final conclusions and recommendations when the review is complete.

The current FDA drug label states that data available from studies in people do not suggest an increased risk of problems during pregnancy or abnormalities in developing babies when women are exposed to a single 150 mg dose of oral fluconazole to treat vaginal yeast infections. However, high doses of oral fluconazole (400-800 mg/day) taken by pregnant women for much longer than a single dose have resulted in reports of abnormalities at birth. In the Danish study, most of the oral fluconazole use appeared to be one or two doses of 150 mg.

BACKGROUND: Oral fluconazole is used to treat yeast infections of the vaginal area, mouth, and esophagus. It is also used to treat a fungal infection of the brain and spinal cord called cryptococcal meningitis that most often affects people with weakened immune systems, and used to prevent yeast infections that can spread to the rest of the body in cancer patients who have a weakened immune system. It is available under the brand name Diflucan and also as generics.

RECOMMENDATION: Until FDA's review is complete and more is understood about this study and other available data, FDA advises cautious prescribing of oral fluconazole in pregnancy.

Health care professionals should be aware that the Centers for Disease Control and Prevention guidelines recommend only using topical antifungal products to treat pregnant women with vulvovaginal yeast infections, including for longer periods than usual if these infections persist or recur.

Patients who are pregnant or actively trying to get pregnant should talk to their health care professionals about alternative treatment options for yeast infections.