



Direct Healthcare Professional Communication

April 2024

Fluconazole - warnings regarding use during pregnancy

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you **warnings regarding use during pregnancy**.

Summary:

Following a periodic review of the safety information for fluconazole, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommends an update to the product information, with respect to warnings regarding use of fluconazole during pregnancy. Data suggests that the risk of spontaneous abortion and congenital malformations is also apparent for the use of fluconazole at lower doses. This also includes a single dose of 150 mg fluconazole.

The product information for medicinal products containing fluconazole will be revised to include recommended warnings regarding use during pregnancy. Please see Annex I for further details..

INSTRUCTIONS TO HEALTH CARE PROFESSIONALS:

- Fluconazole should not be used during pregnancy, unless clearly necessary. Women who are pregnant or who think they may be pregnant, or who are planning to have a baby, should consult their doctor before taking fluconazole.
- Women of childbearing potential should be informed about the potential risk to the fetus with fluconazole treatment during the first and second trimester of pregnancy.
- There is a risk with single-dose treatment, and with longer courses of treatment:
 - After the use of one single dose, a woman of childbearing potential is recommended to wait one week before becoming pregnant.
 - Women of childbearing potential should consider contraception throughout longer courses of treatment, and for 1 week after the final dose.

Reference:

Norway: https://www.dmp.no/globalassets/documents/bivirkninger-og-sikkerhet/kjare-helsepersonell-brev/2023/diflucan_dhpc_no_final_14dec2023.pdf



Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:

Hotline: 15301

