DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)

DIFLUCAN (FLUCONAZOLE) - WARNINGS REGARDING USE DURING PREGNANCY – LABEL VARIATION OCTOBER 2022

Date 01 February 2024

Dear Healthcare professional,

In agreement with the Saudi Food and Drug Authority (SFDA), Pfizer as the marketing authorization holder for Diflucan would like to inform you of the following:

SUMMARY

This letter is implemented because of the presence of new safety data, 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.

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.

CALL FOR REPORTING

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via the following:

The National Pharmacovigilance Centre (NPC) at Saudi Food and Drug Authority (SFDA)

SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: http://ade.sfda.gov.sa/

Pharmacovigilance Department in the company

E-mail: SAU.AEReporting@pfizer.com

Company Contacts
For more information, please contact Pfizer Medical Information: MedInfoMEandAfrica@pfizer.com

This letter is approved by the Executive Directorate of Pharmacovigilance at SFDA

Yours sincerely,

Amr Khardaly
Medical Manager,
Pfizer – Saudi Arabia