

Date: 01 May 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)

Fluco-Sol (Fluconazole), a recommendation to use light-protection in order to avoid the risk of incorrect storage.

Dear Healthcare professional,

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

SUMMARY

- **Fluco-Sol (Fluconazole) should be stored in the outer carton to reduce incorrect storage risk. As a precaution, light-proof amber resistance bags are recommended when unable to store the product in the outer cartons to prevent photosensitivity.**
- **The Summary of Product Characteristics (SPC) will be updated as appropriate to reflect the latest data and recommendations.**

Background on the safety concern:

- Fluconazole is indicated in the following fungal infections: Cryptococcal meningitis, Coccidioidomycosis, Invasive candidiasis, Mucosal candidiasis including oropharyngeal, esophageal candidiasis, candiduria and chronic mucocutaneous candidiasis. The purpose of this letter is to encourage HCPs to use light-protection to prevent Fluco-sol from being incorrectly stored.
- Fluconazole belongs to the class of medicines known as triazole antifungals which it has a photosensitive activity lead to degradation of drug with potential toxic or allergizing effects for the human body, according on that should be **protected from light** to prevent the effect on light on such medication.
- A light-proof amber resistance bags are recommended when unable to store the product in the outer cartons to prevent photosensitivity.
- Storage temperatures do not exceed 25°C.

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: phvigilance@psi.com.sa

Company Contacts

Phone: +966126361383 Ext: 239

FAX: +966126379460

Website: <http://www.psilttd.com>

Yours sincerely,

Waad Alfahmi

Qualified person of Pharmacovigilance,

PSI – Saudi Arabia