

825. Fixed Drug Eruption Induced by Fluconazole

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Introduction: A Fixed Drug Eruption (FDE) is a sharply demarcated erythema, oval or circular in shape, which recurs in exactly the same place after following exposure to a specific drug. Usually there is only one lesion, but two or more may be present. The size varies from a few millimetres to 10–20 cm in diameter. Initially it is a lesion of dusky erythema and edema, sometimes followed by development of vesiculae or bullae. Healing takes place with pigmentation. The FDE may be localized on skin and mucous membranes.

Histologically, lesions show mononuclear infiltrate along the dermo-epidermal junction.

Drugs most frequently implicated are barbiturates, paracetamol, pyrazolon derivatives, sulphonamides and tetracyclines. Among the antifungal agents griseofulvin, ketoconazole and nystatin had already been associated with the occurrence of FDE.

Aim of the study: Description of several cases of fixed drug eruptions caused by fluconazole, reported to the Netherlands Pharmacovigilance Centre Lareb.

Methods: Analysis of the adverse event reports, followed by a literature search.

Results: Lareb has received five reports of FDE in association with fluconazole. One patient had used fluconazole once monthly for vaginal candidiasis for several months, when the first episode of FDE appeared. On the day of exposure she experienced redness and swelling on the left side of the lower lip. Afterwards the lesion became pigmented. Each month, after intake of a tablet fluconazole, the lesion recurred. After discontinuation of fluconazole a postinflammatory hyperpigmentation remained.

In the other reports, twice the inner part of the hand was affected, once the right forearm and once the tongue was involved.

Three articles of fixed drug eruption in association with fluconazole have been published. In one of these a patient suffered from 15 episodes of FDE on the extensor surfaces of his elbows.

The WHO combinations database contains 17 reports of FDE disproportionately associated with the use of fluconazole (Odds ratio 4.55, 95% Confidence Interval 2.82–7.33).

Conclusion: Lareb has received five reports of fixed drug eruption on fluconazole. The association between fixed drug eruption and fluconazole is supported by publications in the literature and findings in the WHO database.)