2 September 2011
EMA/CHMP/478970/2011 Rev.1
EMEA/H/A-30/1156

Questions and answers on Diflucan and associated names (fluconazole, 50, 100, 150 and 200 mg capsules, oral solution 5 mg/ml, powder for oral suspension 10 mg/ml or 40 mg/ml, solution for infusion 2 mg/ml)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

The European Medicines Agency has completed a review of Diflucan. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that there is a need to harmonise the prescribing information for Diflucan in the European Union (EU).

What is Diflucan?

Diflucan is an antifungal medicine that belongs to the triazoles group. It contains the active substance fluconazole.

Diflucan works by preventing the formation of ergosterol, which is an important part of fungal cell walls. Without ergosterol, the fungus dies or is prevented from spreading. Diflucan is used to treat various fungal infections, including candidiasis (thrush) and fungus in the nails.

Diflucan is also available in the EU under other trade names: Fluconazole, Fungustatin, Fungata, Triflucan.

The company that markets these medicines is Pfizer.

Why was Diflucan reviewed?

Diflucan is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Diflucan was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

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On 18 February 2010, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Diflucan in the EU.

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Diflucan can be used for the following conditions: mucosal and invasive candidiasis, genital candidiasis (trush), crypotococcal meningitis, dermatomycosis, coccidiodomycosis and onychomycosis. The Committee harmonised the wording on the use of the medicine for these conditions, specifying when it is to be used for treatment and prophylaxis (prevention) and introducing restrictions for certain indications. The use in children was further clarified.

4.2 Posology and method of administration

The CHMP harmonised the dosing recommendations for the various indications to be in line with international guidelines.

4.3 Contraindications

The CHMP agreed that Diflucan should not be used in patients who are hypersensitive (allergic) to the active substance, to related azole substances, or to any of other ingredient of the medicine.

Medicines known to prolong the QT interval and which are metabolised via the cytochrome P450 (CYP) 3A4 such as cisapride, astemizole, pimozide, quinidine and erythromycin should also not be given to patients receiving Diflucan. Terfenadine must also not be used in patients receiving Diflucan at multiple doses of 400 mg per day or higher.

Other changes

Other sections harmonised by the CHMP include sections on special warnings, side effects, interactions, pharmacological properties and quality.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 2 September 2011.