Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for FLUCONAZOLE 50 mg, 100 mg, 150 mg, 200 mg, capsules

This is a summary of the risk management plan (RMP) for FLUCONAZOLE 50 mg, 100 mg, 150 mg, 200 mg, capsules (hereinafter referred to as Fluconazole). The RMP details important risks of Fluconazole, how these risks can be minimised, and how more information will be obtained about Fluconazole's risks and uncertainties (missing information).

Fluconazole's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fluconazole should be used.

Important new concerns or changes to the current ones will be included in updates of Fluconazole's RMP.

I. The Medicine and What It is used for

Fluconazole is authorised for the treatment of: cryptococcal meningitis; coccidioidomycosis; invasive candidiasis; mucosal candidiasis including oropharyngeal, oesophageal candidiasis, candiduria and chronic mucocutaneous candidiasis; chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment are insufficient; vaginal candidiasis, acute or recurrent; when local therapy is not appropriate; candidal balanitis when local therapy is not appropriate; dermatomycosis including tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal candida infections when systemic therapy is indicated; tinea unguium (onychomycosis) when other agents are not considered appropriate (see SmPC for the full indication). It contains Fluconazole as the active substance and it is taken orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Fluconazole, together with measures to minimise such risks and the proposed studies for learning more about Fluconazole's risks, if any, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of Important Risks and Missing Information

Important risks of Fluconazole are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Fluconazole. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table 4: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	• Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP)
Important potential risks	• Congenital Anomalies in infants born to pregnant women taking high doses (400-800 mg) fluconazole for long periods (3 or more months) for the treatment of coccidioidomycosis • Congenital malformations with low-dose fluconazole exposure during the first trimester of pregnancy • Development of fluconazole resistance
Missing information	• Use in paediatric patients with genital candidiasis • Pregnancy/ Lactation

II.B Summary of Important Risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Fluconazole.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Fluconazole.