Part VI: Summary of the risk management plan

Summary of risk management plan for Fluconazole 2 mg/mL Solution for infusion (Fluconazole)

This is a summary of the risk management plan (RMP) for Fluconazole 2 mg / mL Solution for infusion (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 in the following fungal infections:

In adults 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.

In adults for the prophylaxis of:

- Relapse of cryptococcal meningitis in patients with high risk of recurrence.

- Relapse of oropharyngeal or oesophageal candidiasis in patients infected with HIV who are at high risk of experiencing relapse.

- Prophylaxis of candidal infections in patients with prolonged neutropenia (such as patients with haematological malignancies receiving chemotherapy or patients receiving Hematopoietic Stem Cell Transplantation).

In term newborn infants, infants, toddlers, children and adolescents aged from 0 to 17 years old is used for the treatment of mucosal candidiasis (oropharyngeal, oesophageal), invasive candidiasis, cryptococcal meningitis and the prophylaxis of candidal infections in immunocompromised patients. FLUCONAZOLE can be used as maintenance therapy to prevent relapse of cryptococcal meningitis in children with high risk of reoccurrence (see SmPC for the full indication).

It contains fluconazole as the active substance and it is given orally and by intravenous infusion.

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, 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 administered. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

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.