V.2. Additional Risk Minimisation Measures

Part VI: Summary of the risk management plan

Summary of risk management plan for Posaconazole 300 mg concentrate for solution for infusion.

This is a summary of the risk management plan (RMP) for Posaconazole. The RMP details important risks of Posaconazole, risk minimisation measures needed to minimise these risks and routine pharmacovigilance activities needed to obtain more information about Posaconazole risks and uncertainties (missing information).

Posaconazole summary of product characteristics gives essential information to healthcare professionals and patients on how Posaconazole should be used.
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Important new concerns or changes to the current ones will be included in updates of

Posaconazole's RMP.

I. The medicine and what it is used for

Posaconazole concentrate for solution for infusion is indicated for use in the treatment of the following fungal infections in adults:

- Invasive aspergillosis

- Posaconazole concentrate for solution for infusion is indicated for use in the treatment of the following fungal infections in adult and paediatric patients from 2 years of age:

- Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;

- Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B;

- Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patients who are intolerant of itraconazole;

- Coccidioidomycosis in patients with disease that is refractory to amphotericin B, itraconazole or fluconazole or in patients who are intolerant of these medicinal products.

Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.

Posaconazole concentrate for solution for infusion is also indicated for prophylaxis of invasive fungal infections in the following adult and paediatric patients from 2 years of age:

- Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high-risk of developing invasive fungal infections;

- Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease (GVHD) and who are at high-risk of developing invasive fungal infections.

It contains Posaconazole as the active substance and it is given intravenously.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Posaconazole, together with measures to minimise such risks and learning more about Posaconazole 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 leaflets and SmPCs 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.

If important information that may affect the safe use of Posaconazole is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Posaconazole 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 Posaconazole. 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.***List of important risks and missing information***	
Important identified risks	None
Important potential risks	Injury, Poisoning, and Procedural Complications - Medication error related to substitution between different formulations (oral suspension and Gastro-Resistant Powder and Solvent for Oral Suspension)

Missing information	Safety in children below 2 years of age

II.B Summary of important risks

The safety information in the proposed Summary of product characteristics, Labelling and Package information leaflet is aligned to the reference medicinal product.

II.C Post-authorisation development plan

No post authorisation study is planned for this product.

II.C.1 Studies which are conditions of the marketing authorisation

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

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Posaconazole.