Part VI: Summary of the risk management plan

Summary of risk management plan for Posaconazol Mylan 100 mg magensaftresistente Tabletten

This is a summary of the risk management plan (RMP) for Posaconazol Mylan 100 mg magensaftresistente Tabletten. The RMP details important risks of Posaconazol Mylan 100 mg magensaftresistente Tabletten, how these risks can be minimised, and how more information will be obtained about Posaconazol Mylan 100 mg magensaftresistente Tabletten risks and uncertainties (missing information).

Posaconazol Mylan 100 mg magensaftresistente Tabletten summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Posaconazol Mylan 100 mg magensaftresistente Tabletten should be used.

Important new concerns or changes to the current ones will be included in updates of Posaconazol Mylan 100 mg magensaftresistente Tabletten 100mg gastro-resistant tablets RMP.

I. The medicine and what it is used for

Posaconazol Mylan 100 mg magensaftresistente Tabletten are authorised for treatment of the following fungal infections in adults:

- 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.

Posaconazol Mylan 100 mg magensaftresistente Tabletten are also indicated for prophylaxis of invasive fungal infections in the following patients:

- Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (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 and who are at high risk of developing invasive fungal infections.

See SmPC for the full indication.

They contain posaconazole as the active substance and are taken orally.

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

Important risks of Posaconazol Mylan 100 mg magensaftresistente Tabletten, together with measures to minimise such risks and the proposed studies for learning more about Posaconazol Mylan 100 mg magensaftresistente Tabletten 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.

If important information that may affect the safe use of Posaconazol Mylan 100 mg magensaftresistente Tabletten is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Posaconazol Mylan 100 mg magensaftresistente Tabletten 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 Posaconazol Mylan 100 mg magensaftresistente Tabletten. 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	• Hepatic - elevated liver enzymes; hepatotoxicity; hepatic failure; hepatitis • Blood - thrombotic thrombocytopenia purpura; hemolytic uraemic syndrome • Cardiac - Torsade de Pointes • General - drug interaction
Important potential risks	• Blood - agranulocytosis; aplastic anaemia • Cardiac - QTc prolongation; heart failure; myocardial infarction • Psychiatric - depression; suicide • Endocrine - adrenal insufficiency • CNS - convulsion; cerebral ischemia; cerebral haemorrhage • Respiratory - pulmonary haemorrhage • Vascular- hypertension; venous thrombosis; arterial thrombosis • Metabolism – hypokalaemia • Visual - photopsia; visual brightness; visual disturbances • Neoplasms - occurrence of any neoplasm/malignancy, especially: hepatic adenoma; hepatic neoplasm; adrenal adenoma; adrenal neoplasm; phaeochromocytoma • Infections - fungal infections

List of important risks and missing information	
Missing information	• Experience in children

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 Posaconazol Mylan 100 mg magensaftresistente Tabletten.

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

There are no studies required for (Posaconazol Mylan 100 mg magensaftresistente Tabletten