Summary of risk management plan for Posaconazole Accord gastro-resistant tablets (100 mg) (Posaconazole)

This is a summary of the risk management plan (RMP) for Posaconazole Accord gastro-resistant tablets (100 mg). The RMP details important risks of Posaconazole Accord gastro-resistant tablets (100 mg), how these risks can be minimised, and how more information will be obtained about Posaconazole Accord gastro-resistant tablets (100 mg)'s risks and uncertainties (missing information).

Posaconazole Accord gastro-resistant tablets (100 mg)'s product information and its package leaflet give essential information to healthcare professionals and patients on how Posaconazole Accord gastro-resistant tablets (100 mg) should be used.

This summary of the RMP for Posaconazole Accord gastro-resistant tablets (100 mg) should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Posaconazole Accord gastro-resistant tablets (100 mg)'s RMP.

I. The medicine and what it is used for

Posaconazole Accord gastro-resistant tablet (100 mg) is indicated for use in the 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.

Posaconazole Accord gastro-resistant tablet (100 mg) is 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.

Further information about the evaluation of Posaconazole Accord gastro-resistant tablets (100 mg)'s benefits can be found in Posaconazole Accord gastro-resistant tablets (100 mg)'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/posaconazole-accord link to product's EPAR summary landing page on the EMA webpage.

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

Important risks of Posaconazole Accord gastro-resistant tablet (100 mg), together with measures to minimise such risks and the proposed studies for learning more about Posaconazole Accord gastro-resistant tablet (100 mg)'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 Product Information (PI) 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, including PSUR assessment and signal management activity, 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 Accord gastro-resistant tablet (100 mg) is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

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

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 Posaconazole Accord gastro-resistant tablet (100 mg).

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

There are no studies required for Posaconazole Accord gastro-resistant tablet (100 mg).