Summary of risk management plan for Posaconazole AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets (Posaconazole)

This is a summary of the risk management plan (RMP) for Posaconazole AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets. The RMP details important risks of Posaconazole AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets, how these risks can be minimised, and how more information will be obtained about Posaconazole AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets risks and uncertainties (missing information).

Posaconazole AHCL 40 mg/mL oral suspension's/ Posaconazole Accord 100 mg gastro-resistant tablets product information and its package leaflet give essential information to healthcare professionals and patients on how Posaconazole AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets should be used.

This summary of the RMP for Posaconazole AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets 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 AHCL 40 mg/mL oral suspension’s/ Posaconazole Accord 100 mg gastro-resistant tablets RMP.

I. The medicine and what it is used for

Posaconazole Accord is indicated for use in the treatment of the following fungal infections in adults:

- Invasive aspergillosis
- 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.
- Oropharyngeal candidiasis: as first-line therapy in patients who have severe disease or are immunocompromised, in whom response to topical therapy is expected to be poor.

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 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.

It contains posaconazole as a active substance and given by oral route.

Further information about the evaluation of Posaconazole AHCL 40 mg/mL oral suspension's/ Posaconazole Accord 100 mg gastro-resistant tablets benefits can be found in Posaconazole AHCL 40 mg/mL oral suspension's/ Posaconazole Accord 100 mg gastro-resistant tablets' 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-ahcl 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 AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets, together with measures to minimise such risks and the proposed studies for learning more about Posaconazole AHCL 40 mg/mL oral suspension's/ Posaconazole Accord 100 mg gastro-resistant tablets 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 AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Posaconazole AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets 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 AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets. 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);

Important identified risks	• None

Important potential risks	• Medication error – related to substitution between different formulations (tablet and oral suspension)
Missing information	• Safety in children below 2 years of age

II.B Summary of important risks

Routine risk minimisation measures are sufficient to manage the safety concerns of the medicinal product and there is no additional risk minimisation measure required for posaconazole.

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 AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets.

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

There are no studies required for Posaconazole AHCL 40 mg/mL oral suspension/ Posaconazole Accord 100 mg gastro-resistant tablets.