SUMMARY OF RISK MANAGEMENT PLAN FOR ASCOPAN (PSACONAZOLE) – VERSION 0.1

This is a summary of the risk management plan (RMP) for Ascopan. The RMP details important risks of Ascopan, how these risks can be minimized, and how more information will be obtained about Ascopan's risks and uncertainties (missing information).

Ascopan's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ascopan should be used.

Important new concerns or changes to the current ones will be included in updates of Ascopan's RMP.

I. The medicine and what it is used for

Ascopan is authorised for the treatment of the following.

- 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.

Ascopan is also indicated for prophylaxis of invasive fungal infections in adults (tablet, IV and oral suspension formulations) and paediatric patients aged 2 years and above (tablet for patients who weigh greater than 40 kg, IV and PFS formulations):

- 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.

II. Risks associated with the medicine and activities to minimize or further characterize the risks.

Important risks of Ascopan, together with measures to minimize such risks and the proposed studies for learning more about Ascopan's risks, are outlined below.

Measures to minimize 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 public (e.g. with or without prescription) can help to minimizes its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including PSUR assessment, 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 Ascopan are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered by patients. 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 Ascopan. 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/use in special patient populations etc.);

List of important risks and missing Information	
Important identified risks	None
Important potential risks	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

Important potential risk: Medication error – related to substitution between different formulations	
Evidence for linking the risk to the medicine	There is a risk for medication errors since the 2 oral suspension formulations have different dosage recommendations.
Risk factors and risk groups	None identified
Risk minimization measures	Communication via healthcare provider and patient product information Listed under SmPC Sections 4.2 (Posology and method of administration) Package leaflet- Section 3 (How to take Ascopan) Outer carton A one-time Direct Healthcare Professional Communication will be distributed to healthcare providers to alert them of the new formulation and that the formulations are not interchangeable. Design of product and packaging

Missing Information: Safety in children below 2 years of age	
Risk minimization measures	Communication via healthcare professional and patient product information Listed under SmPC Section 4.2 (Posology and method of administration) and 5.2 (Pharmacokinetic properties) Package leaflet –Section 2, What you need to know before you use Ascopan
Additional Pharmacovigilance	There are no additional pharmacovigilance activities for this safety concern.

II.C Post-authorization development plan

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

No studies are conditions of the marketing authorization or specific obligations of Ascopan.

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

Not applicable.