

## Part VI : Summary of the risk management plan

### Summary of risk management plan for Posaconazole 40 mg/ml oral suspension

This is a summary of the risk management plan (RMP) for Posaconazole 40 mg/ml oral suspension. The RMP details important risks of Posaconazole, how these risks can be minimised, and how more information will be obtained about Posaconazole's risks and uncertainties (missing information).

Posaconazole's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Posaconazole should be used.

#### *I. The medicine and what it is used for*

Posaconazole is authorised for the treatment of the following fungal infections in adults: invasive aspergillosis, fusariosis, chromoblastomycosis and mycetoma, coccidioidomycosis and oropharyngeal candidiasis. Posaconazole is also indicated for prophylaxis against invasive fungal infections (see SmPC for the full indication). It contains posaconazole as the active substance and it is given as an oral suspension.

#### *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 the proposed studies for learning more about Posaconazole'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 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 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 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 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 (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	<ul style="list-style-type: none"> <li>• Hepatic events – elevated liver enzymes, hepatotoxicity, hepatic failure, hepatitis</li> <li>• Blood - thrombotic thrombocytopenic purpura, haemolytic uraemic syndrome</li> <li>• Cardiac – Torsades de pointes</li> <li>• General – drug interaction</li> <li>• Injury, poisoning and procedural complications – medication error related to potential substitution between different formulations (tablet and oral suspension)</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• Blood – agranulocytosis, aplastic anaemia</li> <li>• Cardiac – QTc prolongation, heart failure, myocardial infarction</li> <li>• Psychiatric – depression, suicide</li> <li>• Endocrine – adrenal insufficiency</li> <li>• CNS – convulsions, cerebral ischaemia, cerebral haemorrhage</li> <li>• Respiratory – pulmonary haemorrhage</li> <li>• Vascular – hypertension, venous thrombosis, arterial thrombosis</li> <li>• Metabolism – hypokalaemia</li> <li>• Neoplasms – Occurrence of any neoplasm/malignancy, especially: Hepatic adenoma; Hepatic neoplasm; Adrenal adenoma; Adrenal neoplasm; Pheochromocytoma</li> <li>• Infections – Fungal infections</li> <li>• Visual – photopsia, visual brightness, visual disturbances</li> </ul>
Missing information	<ul style="list-style-type: none"> <li>• Experience in children</li> </ul>

### *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.

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

There are no studies required for Posaconazole.