PART VI- Summary of the risk management plan

Summary of risk management plan for Voxsill (Amylmetacresol and 2,4-Dichlorobenzyl alcohol)

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

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

I. The medicine and what it is used for

Voxsill is used for local, short-term symptomatic treatment of inflammatory and infectious diseases of the oral cavity, pharynx and to relieve sore throat, indicated for adults, adolescents, and children from 6 years of age. It contains 0.6mg of amylmetacresol and 1.20 mg of 2,4-dichlorobenzyl alcohol as actives substances,

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

Important risks of Voxsill, together with measures to minimise such risks and the proposed studies for learning more about Voxsill ´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.

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If important information that may affect the safe use of Voxsill is not yet available, it is listed under 'missing information' below

II.A List of important risks and missing information

Important risks of Voxsill 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 Voxsill 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);

Summary of safety concerns	
Important identified risks	- Hypersensitivity (eg. rash, urticaria, pruritus, mouth or pharyngeal oedema)
Important potential risks	- None
Missing information	- None

II.B Summary of important risks

Please see section - SVII.3 Details of important identified risks, important potential risks, and missing information.

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 Voxsill.

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

There are no studies required for Voxsill.