Part VI: Summary of the risk management plan

For NL/H/1707/001-002/MR

Summary of risk management plan for Amoxicillin/Clavulanic acid Aurobindo 500 mg/125 mg and 875 mg/125 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Amoxicillin/Clavulanic acid Aurobindo 500 mg/125 mg and 875 mg/125 mg film-coated tablets (hereinafter referred to as Amoxicillin/Clavulanic acid). The RMP details important risks of Amoxicillin/Clavulanic acid, how these risks can be minimised, and how more information will be obtained about Amoxicillin/Clavulanic acid's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Amoxicillin/Clavulanic acid's, RMP

I. The medicine and what it is used for

Amoxicillin/Clavulanic acid is used in adults and children to treat the following infections such as middle ear and sinus infections, respiratory tract infections, urinary tract infections, skin and soft tissue infections including dental infections, bone and joint infections (See SmPC for the full indication). It contains Amoxicillin and Clavulanic acid as the active substance and is given orally.

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

Important risks of amoxicillin/clavulanic acid together with measures to minimise such risks and the proposed studies for learning more about amoxicillin/clavulanic acid'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 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 the adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

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 amoxicillin/clavulanic acid. 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	None
Important potential risks	Bacterial resistance development leading to lack of efficacy
Missing information	None

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 amoxicillin/clavulanic acid.

II.C.2 Other studies in post-authorisation development plan There are no studies required for amoxicillin/clavulanic acid.