Part VI: Summary of the risk management plan

Summary of risk management plan for *Clarithromycin 500 mg Powder for concentrate for solution for infusion*

This is a summary of the risk management plan (RMP) for *Clarithromycin 500 mg Powder for concentrate for solution for infusion*. The RMP details important risks of *Clarithromycin 500 mg Powder for concentrate for solution for infusion*, how these risks can be minimised, and how more information will be obtained about the product's risks and uncertainties (missing information).

The summary of product characteristics (SmPC) for *Clarithromycin 500 mg Powder for concentrate for solution for infusion* and its package leaflet give essential information to healthcare professionals and patients on how clarithromycin should be used.

I. The medicine and what it is used for

Clarithromycin 500 mg Powder for concentrate for solution for infusion is authorised for the treatment of infections (see SmPC for the full indication). It contains clarithromycin as the active substance and it is given by the intravenous route of administration.

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

Important risks of *Clarithromycin 500 mg Powder for concentrate for solution for infusion*, together with measures to minimise such risks and the proposed studies for learning more about the risks associated with *Clarithromycin 500 mg Powder for concentrate for solution for infusion*, 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 a prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

If important information that may affect the safe use of *Clarithromycin 500 mg Powder for concentrate for solution for infusion* is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of *Clarithromycin 500 mg Powder for concentrate for solution for infusion* 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 *Clarithromycin 500 mg Powder for concentrate for solution for infusion*. 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 on the longterm use of the medicine);

Summary of safety concerns	
Important identified risks	• Known hypersensitivity to macrolide antibiotic drugs or to any of its excipients. • History of QT prolongation or ventricular cardiac arrhythmia, including torsades de pointes. • Severe hepatic failure in combination with renal impairment. • Hypokalaemia (risk of prolongation of QT-time). • Interactions • Resistance to antibiotics • Pregnancy (first trimester) • Pseudomembranous colitis
Important potential risks	None
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 a specific obligation of *Clarithromycin 500 mg Powder for concentrate for solution for infusion*.

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

There are no studies required for *Clarithromycin 500 mg Powder for concentrate for solution for infusion*