Summary of risk management plan for Roxithromycin Medical Valley 150 mg, film-coated tablets (Roxithromycin)

This is a summary of the risk management plan (RMP) for Roxithromycin Medical Valley 150 mg, film-coated tablets. The RMP details important risks of Roxithromycin Medical Valley, how these risks can be minimised, and how more information will be obtained about Roxithromycin Medical Valley's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Roxithromycin Medical Valley is authorised for pneumonia caused by Mycoplasma pneumoniae, Chlamydia psittaci (hornitos) or Chlamydia pneumoniae (TW AR). Pharyngotonicillitis. Acute otitis media. Socially acquired pneumonia. Skin and soft tissue infections (see SmPC for the full indication). It contains roxithromycin as the active substance and it is given by the oral route of administration.

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

Important risks of Roxithromycin Medical Valley, together with measures to minimise such risks and the proposed studies for learning more about Roxithromycin Medical Valley'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 Roxithromycin Medical Valley is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Roxithromycin Medical Valley 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 Roxithromycin Medical Valley. 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	1. Severe Cutaneous Adverse Reactions (SCARs), including acute generalised exanthematous pustulosis (AGEP) 2. Pseudomembranous colitis
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk: Severe Cutaneous Adverse Reactions (SCARs), including acute generalised exanthematous pustulosis (AGEP)	
Evidence for linking the risk to the medicine	Post-marketing experience.
Risk factors and risk groups	Patients with a history of hypersensitivity to macrolide antibiotics
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.4 and 4.8 Relevant PL sections Additional risk minimisation measures No risk minimisation measures

Important identified risk: Pseudomembranous colitis	
Evidence for linking the risk to the medicine	Post-marketing experience.
Risk factors and risk groups	Use of such broad-spectrum antibiotics leads to increased patient susceptibility to C. difficile infection and decreased 'herd immunity', particularly in health care facilities such as hospitals and nursing homes.
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.4 and 4.8 Relevant PL sections Additional risk minimisation measures No risk minimisation measures

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 Roxithromycin Medical Valley.

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

There are no studies required for Roxithromycin Medical Valley.

Part VII: Annexes

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Annex 1 – EudraVigilance Interface

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable.

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable.

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable.

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not applicable.

Annex 7 - Other supporting data (including referenced material)

Not applicable.

Annex 8 – Summary of changes to the risk management plan over time

Not applicable.