Part VI: Summary of the risk management plan

Summary of risk management plan for AZYTER (azithromycin)

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

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

I. The medicine and what it is used for

AZYTER is authorised in children (aged from birth to 17 years) and adults for the local antibacterial curative treatment of conjunctivitis caused by susceptible strains: purulent bacterial conjunctivitis and trachomatous conjunctivitis caused by *Chlamydia trachomatis*. It contains azithromycin as the active substance and it is given by ocular route.

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

Important risks of AZYTER together with measures to minimise such risk and the proposed studies for learning more about AZYTER's risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly.

Together, these measures constitute routine risk minimisation measures.

II.A List of important risks and missing information

Important risks of AZYTER 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 AZYTER. 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	None
Missing information	None

II.B Summary of important risks

Not applicable.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

None.

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

None