Part VI: Summary of the risk management plan

Summary of risk management plan for Xilmac

This is a summary of the risk management plan (RMP) for Xilmac 1000 mg/ 200 mg powder for solution for injection/infusion. The RMP details important risks of Xilmac, how these risks can be minimised and how more information will be obtained about Xilmac risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Xilmac is authorised for the treatment of the following infections in adults and children:

- Severe infections of the ear, nose and throat (such as mastoiditis, peritonsillar infections, epiglottitis, and sinusitis when accompanied by severe systemic signs and symptoms)
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community acquired pneumonia
- Cystitis
- Pyelonephritis

- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis
- Bone and joint infections, in particular osteomyelitis
- Intra-abdominal infections
- Female genital infections

Xilmac is authorised for the prophylaxis against infections associated with major surgical procedures in adults, such as those involving the:

- Gastrointestinal tract
- Pelvic cavity
- Head and neck
- Biliary tract surgery

It contains 1000 mg amoxicillin and 200 mg clavulanic acid as the active substances, and it is given by injection or infusion.

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

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

II.A List of important risks and missing information

Important risks of Xilmac are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or 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 Xilmac. 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 risk	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

There are no studies which are conditions of the marketing authorisation or specific obligation of Xilmac.

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

There are no studies required for Xilmac, powder for solution for injection/infusion.