

Part VI: Summary of the risk management plan

Summary of risk management plan for Cloxacillin Macure

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

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

I. The medicine and what it is used for

Cloxacillin Macure is authorised for the treatment of infections due to penicillinase producing staphylococci related to skin and soft tissue infections, bone and joint infections such as osteomyelitis and pulmonary infections, endocarditis, septicaemia and for prophylaxis in orthopaedic surgery.

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

Important risks of Cloxacillin Macure, together with measures to minimise such risks and the proposed studies for learning more about Cloxacillin Macure'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.

II.A List of important risks and missing information

Important risks of Cloxacillin Macure 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 Cloxacillin Macure. 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 longterm use of the medicine)

List of important risks and missing information	
Important identified risk	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

No important risks have been identified for the 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 Cloxacillin Macure.

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

There are no studies required for Cloxacillin Macure.