# Part VI: Summary of the risk management plan

## Summary of risk management plan for Cloxacillin 500 mg Powder for solution for injection / infusion, Cloxacillin 1 g Powder for solution for injection / infusion & Cloxacillin 2 g Powder for solution for injection / infusion (Cloxacillin)

This is a summary of the risk management plan (RMP) for Cloxacillin 500 mg Powder for solution for injection / infusion, Cloxacillin 1 g Powder for solution for injection / infusion and Cloxacillin 2 g Powder for solution for injection / infusion (hereinafter referred to as Cloxacillin Noridem). The RMP details important risks of Cloxacillin Noridem, how these risks can be minimised, and how more information will be obtained about Cloxacillin Noridem's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Cloxacillin Noridem’s RMP.

## I. The medicine and what it is used for

Cloxacillin Noridem is indicated in adults, adolescents and children for the treatment of following infections caused by susceptible staphylococci, including methicillin-susceptible Staphylococcus aureus (MSSA) and penicillinase-producing strains:

- Skin and soft tissue infections
- Endocarditis
- Osteomyelitis
- Septicaemia

Consideration should be given to official guidance on the appropriate use of antibacterial agents (see SmPC for the full indication).

It contains cloxacillin as the active substance and it is given intramuscularly or intravenously.

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

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

## *II.A List of important risks and missing information*

Important risks Cloxacillin Noridem 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 Cloxacillin Noridem. 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

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

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

There are no studies required for Cloxacillin Noridem.