

Part VI: Summary of the risk management plan

Summary of risk management plan for Cloxacillin Vital Pharma Nordic 2 g, powder for injection/infusion

This is a summary of the risk management plan (RMP) for 'Cloxacillin Vital Pharma Nordic, 2 g, powder for solution for injection/infusion'. The RMP details important risks of Cloxacillin Vital Pharma Nordic, how these risks can be minimised, and how more information will be obtained about Cloxacillin Vital Pharma Nordic's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of 'Cloxacillin Vital Pharma Nordic, 2 g, powder for solution for injection/infusion's RMP.

I. The medicine and what it is used for

'Cloxacillin Vital Pharma Nordic, 2 g, powder for solution for injection/infusion' is indicated for the treatment of infections caused by penicillinase-producing staphylococci.

Cloxacillin is indicated for the treatment of the following infections in adults and children:

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

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

Important risks of 'Cloxacillin Vital Pharma Nordic, 2 g, powder for solution for injection/infusion', together with measures to minimise such risks and the proposed studies for learning more about Cloxacillin Vital Pharma Nordic'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 Cloxacillin Vital Pharma Nordic is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Cloxacillin Vital Pharma Nordic 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 Vital Pharma Nordic.

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

Important potential risk

None

Missing information

None

II.C ***Post-authorisation development plan***

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

No studies are conditions of the marketing authorisation or specific obligation of Cloxacillin Vital Pharma Nordic.

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

No studies are conditions of the marketing authorisation or specific obligation of Cloxacillin Vital Pharma Nordic.