Part VI: Summary of the risk management plan

Summary of risk management plan for Dicloxacillin Bluefish

This is a summary of the risk management plan (RMP) for Dicloxacillin Bluefish. The RMP details important risks of Dicloxacillin Bluefish, which can be minimized through routine pharmacovigilance activities. Data on missing information will be gathered.

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

I. The medicine and what it is used for

Dicloxacillin Bluefish is indicated for the infections caused by penicillinase forming staphylococci, e.g. wound infections, abscesses, osteomyelitis.

It contains dicloxacillin as active substance and it is given as oral tablets of dicloxacillin corresponding to 250 mg and 500 mg.

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

Important risks of Dicloxacillin Bluefish, together with measures to minimise such 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.

If important information that may affect the safe use of Dicloxacillin Bluefish is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

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

List of important risks and missing information	
Important identified risks	• Elevated serum creatinine • Clostridium difficile associated diarrhoea / Pseudo membranous colitis • Hypersensitivity
Important potential risks	• Interstitial nephritis • Drug-drug interactions with methotrexate and dicoumarol/warfarin
Missing information	• Use in children below 20kg • Use in neonates and new-borns

II.B Summary of important risks

The safety information in the latest approved product information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

Not applicable.