# Part VI: Summary of the risk management plan

# Summary of risk management plan for CEFIBACT

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

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

Important new concerns or changes to the current ones will be included in updates of CEFIBACT's RMP.

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

CEFIBACT is authorised is indicated in adults and children from 6 months of age, in treatment of infections caused by microorganisms sensitive to cefixime and in particular: upper respiratory tract infections (pharyngitis); ENT infections (otitis media, tonsillitis); lower respiratory tract infections (pneumonia, bronchitis); kidney and urinary tract infections. It contains cefixime as the active substance and it is given by oral route.

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

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

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

Important risks of CEFIBACT are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient evidence of a link with the use of CEFIBACT. 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** | Hypersensitivity reactions to cephalosporins and/or penicillin or any other beta-lactam antibiotics. |
| | Colitis, pseudomembranous colitis. |
| | Serious skin reactions. |
| | Renal toxicity (including interstitial nephritis) in concomitant use with aminoglycoside antibiotics, polymyxin B, colistin or high-dose loop diuretics (e.g. furosemide), especially in patients with restricted renal function. |
| | Hepatotoxicity. |
| | Serious hematological effects (agranulocytosis, pancytopenia, thrombocytopenia, haemolytic anaemia, neutropenia). |
| | Overgrowth of non-susceptible organisms and antibiotic resistance with prolonged use. |

| List of important risks and missing information | |
|---|---|
| **Important potential risks** | None |
| **Missing information** | Use in children under 6 months of age. |
| | Use in pregnancy and lactation. |

## *II.B Summary of important risks*

The safety information in the proposed Product Information is aligned to the reference medicinal 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 CEFIBACT.

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

There are no studies required for CEFIBACT.