

Summary of risk management plan for Cefixime FrostPharma 20 mg/ml granules for oral suspension (cefixime)

This is a summary of the risk management plan (RMP) for Cefixime FrostPharma 20 mg/ml granules for oral suspension (hereafter referred to as Cefixime FrostPharma). The RMP details important risks of Cefixime FrostPharma, how these risks can be minimised, and how more information will be obtained about Cefixime FrostPharma's risks and uncertainties (missing information). Cefixime FrostPharma's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Cefixime FrostPharma should be used.

I. The medicine and what it is used for

Cefixime FrostPharma is authorised for use indicated for the treatment of the following infections caused by susceptible microorganisms in children above 6 months, adolescents and adults:

- Acute exacerbations of chronic bronchitis
- Community-acquired Pneumonia
- Lower urinary tract infections
- Pyelonephritis
- Otitis media
- Sinusitis
- Pharyngitis

(see SmPC for the full indication). It contains cefixime as the active substance and it is given orally.

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

Important risks of Cefixime FrostPharma, together with measures to minimise such risks and the proposed studies for learning more about Cefixime FrostPharma'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 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 of Cefixime FrostPharma 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 proof of a link with the use of Cefixime FrostPharma. 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

No important risk has been identified for Cefixime FrostPharma.

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 Cefixime FrostPharma.

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

There are no studies required for Cefixime FrostPharma.