

Part VI: Summary of the risk management plan

Summary of risk management plan for Priminova (phenoxymethylpenicillin potassium)

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

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

I. The medicine and what it is used for

Priminova is authorised for infections caused by penicillin-sensitive bacteria (see SmPC for the full indication). It contains phenoxymethylpenicillin potassium 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 Priminova, together with measures to minimise such risks and the proposed studies for learning more about Priminova'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 of Priminova 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 Priminova. 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	- Cross-allergy between penicillins and cephalosporins - Colitis and pseudomembranous colitis
Important potential risks	- None
Missing information	- None

II.B Summary of important risks

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

Cross-allergy between penicillins and cephalosporins	
Evidence for linking the risk to the medicine	Clinical trials, post-marketing studies, published literature.
Risk factors and risk groups	Concomitant treatment with penicillins and cephalosporins.
Risk minimisation measures	Routine risk minimisation measures

Colitis and pseudomembranous colitis	
Evidence for linking the risk to the medicine	Clinical trials, post-marketing studies, published literature.
Risk factors and risk groups	Antibiotic treatment including phenoxymethylpenicillin.
Risk minimisation measures	Routine risk minimisation measures

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 Priminova.

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

There are no studies required for Priminova.