

Part VI: Summary of the risk management plan

Summary of risk management plan for Risk Management Plan for Phenoxymethylpenicillin, film-coated tablets 800 mg and 1000 mg

This is a summary of the risk management plan (RMP) for Fenoximetylpenicillin EQL. The RMP details important risks of Fenoximetylpenicillin EQL, and how more information will be obtained about Phenoxymethylpenicillin EQL Pharma's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Fenoximetylpenicillin EQL, film-coated tablets, 800 and 1000 mg, is authorised for adults, children and adolescents from the age of 12 years or ≥ 20 kg for the treatment of the following infections if shown to be or considered very likely to be caused by bacteria susceptible to phenoxymethylpenicillin: pharyngotonsillitis, acute sinusitis, acute otitis media, community acquired pneumonia, uncomplicated skin and soft tissue infections, acrodermatitis, cutaneous *Borrelia* infection (erythema migrans), dental abscess (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 Fenoximetylpenicillin EQL's, together with measures to minimise such risks and the proposed studies for learning more about Fenoximetylpenicillin EQL'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 Fenoximetylpenicillin EQL's, 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 Fenoximetylpenicillin EQL's. 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

The safety information in the proposed product information is aligned to 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 Fenoximetylpenicillin EQL's.

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

There are no studies required for Fenoximetylpenicillin EQL's.