LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fenoximetylpenicillin EQL (phenoxymethylpenicillin potassium)

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Summary Public Assessment Report

Fenoximetylpenicillin EQL
phenoxymethylpenicillin potassium

Film-coated tablet, 800 mg, 1000 mg

This is a summary of the public assessment report (PAR) for Fenoximetylpenicillin EQL. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fenoximetylpenicillin EQL and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Kåvepenin.

The product is used in treatment of tonsillitis, tooth infections, pneumonia, sinus infections, infections in the ear (otitis), bacterial skin- and soft tissue infections (such as connective tissue infection and Borrelia infection).

How does Fenoximetylpenicillin EQL work?

The active substance in Fenoximetylpenicillin EQL, phenoxymethylpenicillin, is a penicillin (antibacterial medicine) that prevents the bacteria from building a normal cell wall. Without cell walls, the bacteria die fast.

How is Fenoximetylpenicillin EQL used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Fenoximetylpenicillin EQL have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Kåvepenin. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Fenoximetylpenicillin EQL?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Fenoximetylpenicillin EQL approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Kåvepenin, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Fenoximetylpenicillin EQL?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Fenoximetylpenicillin EQL

The full PAR for Fenoximetylpenicillin EQL can be found on the following website: MRI - Home. For more information about treatment with Fenoximetylpenicillin EQL, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-05.