SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fenoximetylpenicillin EQL Pharma 800 mg film-coated tablets
Fenoximetylpenicillin EQL Pharma 1 g film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 800 mg or 1 g of phenoxymethylpenicillin potassium

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

800 mg: White to off white, capsule shaped, 19.5 x 8.5 mm, film-coated tablets debossed with ‘7’ and ‘3’ on either side of the break line on one side and ‘F’ on other side.
1 g: White to off white, capsule shaped, 21 x 9.5 mm, film-coated tablets debossed with ‘E’ and ‘86’ on either side of the break line on one side and plain on other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Fenoximetylpenicillin EQL Pharma is indicated for the treatment of the following infections if shown to be or considered very likely to be caused by bacteria susceptible to phenoxymethylpenicillin:

- pharyngotonsillitis,
- community acquired pneumonia
- uncomplicated skin and soft tissue infections (erysipelas),
- acrodermatitis
- cutaneous Lyme disease (erythema migrans),
- acute otitis media,
- acute sinusitis,
- dental abscess.

Local official guidelines regarding the use of antibacterial agents should be followed.

4.2 Posology and method of administration

Posology

Infection	Tablet strength	Dosage	Duration of treatment
Pharyngotonsillitis Weight > 40 kg	1 g	1 tablet 2-3 times daily	10 days
Community-acquired pneumonia			

Weight > 40 kg	1 g	1 tablet 2-3 times daily	7-10 days
Uncomplicated skin and soft tissue infections (*Erysipelas*) Weight >40 kg	1 g	1 tablet 2-3 times daily	7-10 days
Acrodermatitis, uncomplicated Adults	1 g	2 tablet 3 times daily	3 weeks
Cutaneus Lyme Disease (Erythema migrans) Adults and children over 12 years	1 g	1 tablet 3 times daily	10 days
Acute otitis media Weight 20-40 kg Weight > 40 kg	1 g 800 mg	1 tablet 2-3 times daily 2 tablets 2-3 times daily	5 days, when risk for complications 5-10 days, for recurrent acute otitis media 10 days
Acute sinusitis Weight 20-40 kg Weight > 40 kg	1 g 800 mg	1 tablet 2-3 times daily 2 tablets 2-3 times daily	7-10 days
Dental abscess Weight 20-40 kg Weight > 40 kg Additional antibiotics covering anaerobic bacteria are usually necessary in the treatment of dental abscesses	1 g 800 mg	1 tablet 2-3 times daily 2 tablets 2-3 times daily	7-10 days

General information on dosage
To avoid complications (rheumatic fever) are infections caused by beta-hemolytic streptococci treated for 10 days.

PK/PD data suggest that dosing three times a day gives a better clinical effect and is therefore always recommended.

The tablets should be taken on an empty stomach or one hour before or two hours after meals. The adherence is better for children if ingestion occurs with food.

4.3 Contraindications
Hypersensitivity to penicillin or any of the excipients.

4.4 Special warnings and precautions for use

Cross allergy between penicillins and cephalosporins occurs. Diarrhoea/pseudomembranous colitis caused by Clostridium difficile occurs. Patients with diarrhoea should be closely monitored.

4.5 Interaction with other medicinal products and other forms of interaction
The following combinations with Fenoximetylpenicillin EQL Pharma may require dose adjustment: contraceptives (oral contraceptives) and methotrexate.

Certain antibiotics may in rare cases reduce the effect of oral contraceptives by interfering with the reabsorption of unconjugated steroid in the intestine. This would reduce the plasma levels of active steroid. Pregnancies have primarily occurred in oral contraceptive-treated women who have concurrently taken ampicillin, amoxicillin or tetracyclines.

A serious case of severe toxic reaction to *methotrexate* has been described where the patient was concurrently being treated with furosemide and penicillin V, organic acids that can inhibit the tubular secretion of methotrexate. A suspected interaction is also described following the combination of methotrexate and mezlocillin, and another case following the combination of methotrexate and amoxicillin.

Probenecid slows the renal excretion of penicillin, which can give higher serum concentrations of phenoxymethylpenicillin for a longer period of time.

4.6 Fertility, pregnancy and lactation
Pregnancy: Comprehensive clinical data indicate that phenoxymethylpenicillin does not increase the risk of fetal damage.

Breastfeeding: Phenoxymethylpenicillin is excreted in breast milk, but an affect on the infant seems unlikely with therapeutic doses.

Fertility: Fertility data for phenoxymethylpenicillin are not available.

4.7 Effects on ability to drive and use machines
Fenoximetylpenicillin EQL Pharma has no influence on the ability to drive and use machines.

4.8 Undesirable effects
About 5% of treated patients are likely to experience side effects.
Most common is gastrointestinal problems with loose stools.

Estimated frequencies of adverse reactions are ranked as follows: Common (>1/100, <1/10), Uncommon (>1/1000, <1/100), Rare (>1/10 000, <1/1000), Very Rare (<1/10 000).

Blood and lymphatic system	Uncommon	Eosinophilia.
Gastrointestinal Disorders	Common	Loose stools, nausea.
Skin and subcutaneous tissue	Common	Exanthema
	Uncommon	Urticaria
Immune system	Uncommon	Generalized hypersensitivity reaction with fever and/or joint pain.
	Rare	Anaphylactic reaction.

Fungal overgrowth in the oral cavity and genital area may occur.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V

4.9 Overdose
Toxicity: Large doses are generally well tolerated. Acute reactions are mainly due to hypersensitivity. A certain risk of hyperkalemia in case of very severe overdose of penicillins in potassium salt.

Symptoms: Toxic reactions; nausea, vomiting, diarrhoea, electrolyte imbalance, decreased consciousness, muscle fasciculations, myoclonus, seizures, coma, hemolytic reactions, renal failure, acidosis.

In exceptional cases, anaphylactic shock may occur within 20-40 minutes.

Treatment: If necessary, gastric emptying, charcoal. Symptomatic treatment. In severe cases, haemoperfusion or hemodialysis. *Treatment of anaphylactic reaction:* epinephrine (adrenaline) 0.1 - 0.5 mg slowly intravenously, hydrocortisone 200 mg intravenously, possibly promethazine 25 mg intravenously, fluid, acidosis correction.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: antibacterial beta-lactams, penicillins
ATC code: J01CE02

Mode of action
Phenoxymethylpenicillin is a beta-lactam antibiotic, which functions by inhibiting bacterial cell wall synthesis. The effect is bactericidal.

Resistance

Mechanisms of resistance: Resistance may occur due to bacterial synthesis of a large number of beta-lactamases that hydrolyse the penicillin. Several of these can be inhibited by clavulanic acid. In addition, resistance may occur due to production of altered penicillin-binding proteins (PBP). The resistance is often mediated by plasmids.

Cross-resistance occurs in the betalactam group (penicillins and cephalosporins).

The resistance situation varies geographically and information on the local resistance situation should be sought from the local microbiological laboratory.

Susceptibility testing breakpoints
EUCAST clinical MIC breakpoints to separate susceptible (S) pathogens from resistant (R) pathogens are:

The susceptibility of streptococci Groups A, C and G and S. pneumoniae to phenoxymethylpenicillin is inferred from the susceptibility to benzylpenicillin.

EUCAST Species-related breakpoints (Susceptible≤/Resistant>) Units: mg/L	
Staphylococcus	≤0.12/>0.12
Streptococcus A, C, G	≤0.25/>0.25
S. pneumoniae	≤0.06/>2

Staphylococci: Most staphylococci are penicillinase-producers. Penicillinase-producing strains are resistant. The benzylpenicillin breakpoint (shown) will mostly, but not unequivocally, separate beta-lactamase producers from non-producers.

Commonly susceptible species
Streptococcus A, C, G
Species for which acquired resistance may be a problem
Staphylococcus aureus
Streptococcus pneumoniae
Staphylococcus epidermidis

5.2 Pharmacokinetic properties

Phenoxymethylpenicillin potassium is water soluble and acid stable and absorbed to approximately 50%. Following single doses of 800 mg given to adults in the fasting state maximum serum concentrations are reached after 0.5 - 1 hour at an average of about 10 micrograms/ml. Concurrent administration with food results in decreased absorption and lower peak serum concentration. The biological half-life in serum is approximately 30 minutes and the degree of protein binding is approximately 80%. Phenoxymethylpenicillin is primarily excreted in urine, where 30-50% of the administered dose can be detected in an anti-bacterial active form within 8 hours.

PK/PD relationship

Available knowledge on the pharmacokinetics and pharmacodynamics displays that for beta-lactam antibiotics the effect is primarily dependent on the duration of time when the free antibiotic concentration in serum is above the minimum inhibitory concentration for the relevant bacteria (T> MIC). Based on this knowledge shorter dosing interval should be considered for maximum clinical efficacy.

5.3 Preclinical safety data

There are no preclinical data of relevance for the safety evaluation beyond that of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Povidone
Cellulose, microcrystalline
Talc
Silica, Colloidal anhydrous
Magnesium Stearate
Hypromellose
Macrogol
Titanium Dioxide (E 171)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years.

6.4 Special precautions for storage
Store below 30°C.

6.5 Nature and contents of container
Clear PVC/PE/PVdC -Aluminium foil blister packs.

Tablets 800 mg and 1 g: 14, 20, 30, 40 and 100 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER

EQL Pharma AB
Stortorget 1
222 23 Lund
Sverige

8 MARKETING AUTHORISATION NUMBERS

To be completed nationally

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 January 2013
Date of latest renewal: 11 January 2018

10 DATE OF REVISION OF THE TEXT

2023-03-24