SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 800 mg or 1 g phenoxymethylpenicillin potassium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

800 mg: White to off-white, capsule-shaped 18x8 mm filmcoated tablets, with break line and embossing P/0.8 on the same side.

1 g: White to off-white, capsule-shaped 21x9 mm filmcoated tablets, with break line and embossing P/1.0 on the same side.
The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[Invented name] 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
- acute sinusitis
- acute otitis media
- community acquired pneumonia
- uncomplicated skin and soft tissue infections
- cutaneous Borrelia infections
- dental abscess

Consideration should be given to official guidance on the appropriate use of antimicrobial agents.

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 Weight >40 kg	1 g	1 tablet 2-3 times daily	7-10 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
Cutaneus Borrelia infection Adults and children over 12 years	1 g	1 tablet 3 times daily	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 daily improves the clinical efficacy and therefore it is always recommended in severe infections such as pneumonia and erysipelas and at least in the initial phase of other infections (see section 5.1).

Pediatric population
Other pharmaceutical forms/strengths of phenoxymethylpenicillin are available and may be more appropriate for administration to children below 12 years of age or below 20-40 kg.

Method of administration
The tablets should be taken fasting, one hour before or two hours after a meal.

4.3 Contraindications

Hypersensitivity to the active substance(s), to other penicillin's or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Cross-allergy exists between penicillins and cephalosporins.

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 [Invented name] may require dose adjustment: methotrexate.

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
Extensive clinical data indicate that phenoxymethylpenicillin does not increase the risk of foetal damage.

Breastfeeding
Phenoxymethylpenicillin passes into breast milk, but if administered in therapeutic doses the risk is not unlikely to occur but affection of the child is unlikely to occur.

4.7 Effects on ability to drive and use machines

[Invented name] has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Approximately 5% of the treated patients can be expected to experience adverse events.
The most common events are gastrointestinal events with loose stools.

The following undesirable effects have been observed with the following frequencies: Very common ≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

Infections and infestations	Now known	Fungal overgrowth in the oral cavity and genital area
Blood and lymphatic system disorders	Uncommon Very rare	Eosinophilia. Haemolytic anaemia, leukopenia, thrombocytopenia, agranulocytosis.
Immune system disorders	Rare	Anaphylactic reaction including anaphylactic shock.

Gastrointestinal disorders	Common Uncommon Not known	Loose stools, nausea. Vomiting, stomatitis, glossitis, indigestion. Pseudomembranous colitis
Skin and subcutaneous tissue disorders	Common Uncommon Very rare	Exanthema. Urticaria, angioedema, erythema multiforme, exfoliative dermatitis. Itching.
Musculoskeletal and connective tissue disorders	Uncommon	Arthralgia.
General disorders and administration site conditions	Uncommon	Fever.
Investigations	Very rare	Positive Coomb's test.

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 usually well tolerated. Acute reactions are mainly due to hypersensitivity. Certain risk for hyperkalaemia occurs in the event of very severe overdosing of potassium salts of penicillin.

Symptoms:
Toxic reactions: nausea, vomiting, diarrhoea, electrolyte disorders, decreased level of consciousness, muscular fasciculations, myoclonus, cramps, coma, haemolytic reactions, renal failure and acidosis.

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

Treatment:
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

Mechanism of action
Phenoxymethylpenicillin is a β-lactam antibiotic, which works by inhibiting bacteria's ability to synthesize cell walls. The effect is bactericidal.

Pharmacodynamic effects
Available pharmacokinetic and pharmacodynamic knowledge shows that for betalactam antibiotics the efficacy is mainly dependent on the time of free antibiotic concentration above the minimum inhibitory concentration in serum for the microorganism (T>MIC). Based on this knowledge, shorter dosing intervals should be considered to achieve maximum clinical efficacy.

Mechanism(s) of resistance
Resistance may evolve because of bacterial synthesis of a large number of betalactamases that hydrolyze the penicillin. Several of these are inhibited by clavulanic acid. In addition, resistance may occur because of production of deviating penicillin binding proteins (PBP). This resistance is often plasmide mediated.

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

Development of resistance
Penicillin-resistant pneumococci are resistant to phenoxymethylpenicillin. These strains are rare in Sweden, but common in some areas of Europe.

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

Antibacterial spectrum

Susceptible	Streptococci and pneumococci *Corynebacterium diphteriae* *Pasteurella multocida* Peptococci Peptostreptococci Actinomyces Fusobacteria *Capnocytophaga canimorsus* *Borrelia burgdorferi* *Borrelia Vincenti*
Intermediate	*Haemophilus influenzae*
Resistant	Staphylococci Enterococci *Moraxella catarrhalis* Gram-negative intestinal bacteria Pseudomonas Legionella *Bacteroides fragilis* *Clostridium difficile* Mycoplasma *Chlamydia*

Resistance occurs (1-10%) in pneumococci. Resistance is common (>10%) with *Haemophilus influenzae*.

Non-betalactamase producing *Haemophilus* influenzae is therapeutically reachable with high dose phenoxymethylpenicillin.

Susceptibility testing breakpoints
MIC (minimum inhibitory concentration) interpretive criteria for susceptibility testing have been established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for phenoxymethylpenicillin and are listed here: https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx.

5.2 Pharmacokinetic properties

Phenoxymethylpenicillin potassium is soluble in water and acid-stable, and approximately 50% is absorbed. After single doses of 800 mg, given to fasting adults mean peak serum concentrations of 10 microg/ml are achieved after 0.5 – 1 hour. Concomitant intake of food results in a lower degree of absorption and lower peak serum concentration. The biological half-life in serum is approximately 30 minutes and the protein binding is approximately 80%. Phenoxymethylpenicillin is mainly excreted in urine, where 30 – 50% of a given dose can be detected in the active form within 8 hours.

5.3 Preclinical safety data

There are no available pre-clinical data of relevance for the safety assessment that have not already been considered in this Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Povidone (E1201)
Magnesium stearate (E470b)

Film-coating:
Hypromellose
Titanium dioxide (E171)
Macrogol 400

[Invented name] have a saliva resistant coating to preserve the normal flora in the oral cavity and in the throat.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

No special storage conditions

6.5 Nature and contents of container

Aluminium –OPA/Alu/PVC blisters packed into cardboard boxes.

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

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD month YYYY}
Date of latest renewal: {DD month YYYY}

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2025-04-23