Summary of Product Characteristics

1. Name of the medicinal product

Cefalexin Oral Suspension BP

125mg/ml

2. Qualitative and quantitative composition

Each 5 ml reconstituted suspension contains:

Cefalexin monohydrate	BP
Eq. to Cefalexin (Anhydrous)	125 mg
Excipients	q.s.
Approved Colour used	

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Oral Solid Dosage Form (Dry powder for suspension)

Visual/ Physical description of FPP:

Off white powder flavouring powder filled in HDPE bottle which gives orange colour suspension on reconstitution.

4. Clinical particulars

4.1 Therapeutic indications

Cefalexin is a semi synthetic cephalosporin antibiotic for oral administration.

Cefalexin is indicated in the treatment of the following infections: Respiratory tract infections; otitis media; skin and soft tissue infections; bone and joint infections; genito-urinary infections, including acute prostatitis and dental infections. Cefalexin is active against the following organisms in vitro: Bhaemolytic streptococci; staphylococci, including coagulase-positive, coagulase-negative and penicillinase-producing strains; Streptococcus pneumoniae; Escherichia coli; Proteus mirabilis; Klebsiella species, Haemophilus influenza; Branhamella catarrhalis.

4.2 Posology and method of administration Adults

1-4 g daily in divided doses; most infections will respond to a dosage of 500 mg every 8 hours. For skin and soft tissue infections, streptococcal pharyngitis and mild, uncomplicated urinary tract infections, the usual dosage is 125 mg every 6 hours or 500 mg every 12 hours.

Children

The recommended daily dosage for children is 25-50 mg/kg (10-20mg/lb) in divided doses.

For skin, soft tissue infections, streptococcal pharyngitis and mild, uncomplicated urinary tract infections, the total daily dose may be divided and administered every 12 hours

For most infections, the following is suggested Children under 5 years: 125 mg every 8 hours Children 5 years and over: 125 mg every 8 hours. Or as directed by the physician

Method of administration:

For Oral Use Only

4.3 Contraindications.

Cefalexin is contra-indicated in patients with known allergy to the cephalosporin group of antibiotics.

Cefalexin should be given cautiously to patients who have shown hypersensitivity to other drugs. Cephalosporins should be given with caution to penicillin-sensitive patients, as there is some evidence of partial cross-allergenicity between the penicillins and the cephalosporins. Patients have had severe reactions (including anaphylaxis) to both drugs.

4.4 Special warnings and precautions for use

Cefalexin should be given cautiously to penicillin-sensitive patients. There is some evidence of partial cross-allergenicity of the penicillins and cephalosporins.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics, including macrolides, semisynthetic penicillins and cephalosporins. It is important, therefore, to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening. Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, appropriate measures should be taken. Cefalexin should be administered with caution in the presence of markedly impaired renal function. Positive direct Coombs' tests have been

reported during treatment with cephalosporin antibiotics, In haematological studies, or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side, or in Coombs' testing of new-borns whose mothers have received cephalosporin antibiotics before parturition.

4.5 Interaction with other medicinal products and other forms of interaction.

Probenecid causes reduced excretion of cefalexin leading to increased plasma concentration. Cephalosporins may have an increased risk of nephrotoxicity in the presence of amphotericin, loop diuretics, aminoglycosides, capreomycin or vancomycin.

4.6 Fertility, pregnancy and lactation Pregnancy:

Cefalexin have shown no evidence of teratogenicity.

Lactation:

The excretion of cefalexin in human breast milk increased up to 4 hours following a 500mg dose. The drug reached a maximum level of 4 micrograms/ml then decreased gradually and had disappeared 8 hours after administration.

4.7 Effects on ability to drive and use machines.

None

4.8 Undesirable effects

These have included genital and anal pruritus, genital candidiasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, fever, arthralgia, arthritis and joint disorder. Hyperactivity, nervousness, sleep disturbances and hypertonia.

Reporting of suspected adverse reactions:

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) **mailto:https://pv.pharmacyboardkenya.org'**

4.9 Overdose

Symptoms of overdosage may include nausea, vomiting, epigastric distress and haematuria.

In the event of severe overdosage, general supportive care is recommended including close clinical and laboratory monitoring of haematological, renal and hepatic functions and coagulation status until the patient is stable. Forced

diuresis, peritoneal dialysis, haemodialysis, or charcoal haemoperfusion have not been established as beneficial for an overdose of cefalexin

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

Cephalosporin **ATC Code:** J01DB01

Cefalexin is bactericidal and has antimicrobial activity similar to that of cephaloridine or cephalothin against both gram- positive and gram-negative organisms.

In vitro tests demonstrate that cephalosporins are bactericidal because of their inhibition of cell-wall synthesis.

Cefalexin is active against the following organisms in vitro:

Beta haemolytic streptococci Staphylococci, including coagulase positive, coagulase negative and penicillinase producing strains.

Streptococcus pneumoniae, Escherichia coli, Proteus mirabilis, Klebsiella species, Haemophilus influenza, Branhamella catarrhalis.

5.2 Pharmacokinetic properties

Cefalexin is acid stable and may be given without regard to meals.

Cefalexin is rapidly absorbed from the gastro-intestinal tract and produces peak plasma concentrations about 1 hour after administration. Cefalexin is almost completely absorbed from the gastro-intestinal tract, and 75-100% is rapidly excreted in active form in the urine by glomerular filtration and tubular secretion.

5.3 Preclinical safety data

At doses far higher than the human therapeutic range teratogenicity has been observed in animal studies. There is further no information of relevance to the safety assessment in addition to what is stated in other part.

6. Pharmaceutical particulars

6.1 List of excipients

- Methyl Hydroxybenzoate BP
- Color Sunset Yellow Supra IH
- Purified Talc BP
- Flavour Strawberry (Dry) IH

- Propyl Hydroxybenzoate BP
- Colloidal Anhydrous Silica BP
- Sodium Carboxy Methyl Cellulose BP
- Sucrose BP
- Aspartame BP
- Sodium Benzoate BP

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 30°C. Protected from light.

6.5 Nature and contents of container

Pack Size: 100 ml HDPE bottle packed in a unit carton along with pack insert.

6.6 Special precautions for disposal and other handling

No special requirement.

7. Marketing Authorisation holder And Manufacturing

site Addresses Marketing Authorisation holder

Crown Healthcare

CrownPlex, Mombasa Rd, Opp. JKIA Flyover, P O Box 40449-00100 Nairobi, Kenya

Manufacturing Site Address

Laborate Pharmaceuticals India Limited

Unit-II, 31, Rajban Road,

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8. Marketing authorisation number(s)

CTD5047

9. Date of first authorisation/renewal of the authorisation

10. September 29 2025 Date of revision of the text

2025 September 29