# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Keflex 125 mg/5 ml Powder for Oral Suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bottle when prepared as directed, contains as the active ingredient cefalexin equivalent to 125 mg / 5 ml cefalexin anhydrous.

Excipient(s) with known effect
Contains 3.119g of sucrose per 5ml.
Contains Allura Red AC (E129).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Powder for oral suspension

White, free flowing powder.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Cefalexin is a semisynthetic cephalosporin antibiotic for oral suspension.

Cefalexin is indicated in the treatment of the following infections due to susceptible micro-organisms:

Respiratory tract infections
Otitis media
Skin and soft tissue infections
Bone and joint infections
Genito-urinary tract infections, including acute prostatitis
Dental infections

### 4.2 Posology and method of administration

Keflex is administered orally.

*Adults:* The adult dosage ranges from 1-4g daily, in divided doses; most infections will respond to a dosage of 500mg every 8 hours. For skin and soft tissue infections, streptococcal pharyngitis and mild, uncomplicated urinary tract infections, the usual dosage is 250mg every 6 hours, or 500mg every 12 hours.

For more severe infections or those caused by less susceptible organisms, larger doses may be needed. If daily doses of Keflex greater than 4g are required, parenteral cephalosporins, in appropriate doses, should be considered.

*The elderly and patients with impaired renal function:* As for adults. Reduce dosage if renal function is markedly impaired (see 'Special warnings').

*Children:* The usual recommended daily dosage for children is 25-50mg/kg (10-20mg/lb), in divided doses. For skin and 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 schedule is suggested:

*Childrenunder5years:* 125mg every 8 hours.
*Children5yearsand over:* 250mg every 8 hours.

In severe infections, the dosage may be doubled. In the therapy of otitis media, clinical studies have shown that a dosage of 75 to 100mg/kg/day, in 4 divided doses, is required.

In the treatment of beta-haemolytic streptococcal infections, a therapeutic dose should be administered for at least 10 days.

**4.3 Contraindications**

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

**4.4 Special warnings and precautions for use**

Before instituting therapy with cefalexin, every effort should be made to determine whether the patient has had previous hypersensitivity reactions to the cephalosporins, penicillins or other drugs. Cefalexin should be given cautiously to penicillin-sensitive patients. There is some clinical and laboratory evidence of partial cross-allergenicity of the penicillins and cephalosporins. Patients have had severe reactions (including anaphylaxis) to both drugs.

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.

If an allergic reaction to cefalexin occurs, the drug should be discontinued and the patient treated with the appropriate agents.

Prolonged use of cefalexin may result in the overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Cefalexin should be administered with caution in the presence of markedly impaired renal function. Careful clinical and laboratory studies, including monitoring the serum levels of cefalexin, should be made because safe dosage may be lower than that usually recommended. If dialysis is required for renal failure, the daily dose of cefalexin should not exceed 500mg.

Reports of neurotoxicity have been identified in association with cephalosporin treatment. Symptoms may include encephalopathy, myoclonus and seizures. Elderly patients, patients with severe renal impairment or central nervous system disorders are particularly at risk. If cefalexin associated neurotoxicity is suspected, discontinuation of cefalexin should be considered (see Section 4.8).

Concurrent administration with certain other drug substances, such as aminoglycosides, other cephalosporins, or furosemide (frusemide) and similar potent diuretics, may increase the risk of nephrotoxicity.

Positive direct Coombs' tests have been reported during treatment with the 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 newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognised that a positive Coombs' test may be due to the drug.

A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets. Cefalexin may interfere with the alkaline picrate assay for creatinine.

Acute generalised exanthematous pustulosis (AGEP) has been reported in association with cefalexin treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, Keflex should be withdrawn immediately and an alternative treatment considered. Most of these reactions occurred most likely in the first week during treatment.

Excipients

This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. The sucrose content should be taken into account in patients who have diabetes mellitus. It may also be harmful to the teeth.

This medicinal product contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

This product contains Allura Red AC (E129) which may cause allergic reactions.

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

As with other beta-lactam drugs, renal excretion of cefalexin is inhibited by probenecid.

In healthy subjects given single 500mg doses of cefalexin and metformin, plasma metformin $C_{max}$ and AUC increased by an average of 34% and 24%, respectively, and metformin renal clearance decreased by an average of 14%. No information is available about the interaction of cefalexin and metformin following multiple dose administration.

Hypokalaemia has been described in patient taking cytotoxic drugs for leukaemia when they were given gentamicin and cefalexin.

**4.6 Fertility, pregnancy and lactation**

*Usage in pregnancy:* Although laboratory and clinical studies have shown no evidence of teratogenicity, caution should be exercised when prescribing for the pregnant patient.

*Usage in nursing mothers:* 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. Caution should be exercised when cefalexin is administered to a nursing woman, since the neonate is presented with the risk of candidasis and CNS toxicity due to immaturity of the blood-brain barrier. There is a theoretical possibility of later sensitisation.

**4.7 Effects on ability to drive and use machines**

Keflex has no known influence on the ability to drive and use machines.

**4.8 Undesirable effects**

*Gastro-intestinal*: Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. The most frequent side-effect has been diarrhoea. It was very rarely severe enough to warrant cessation of therapy. Dyspepsia and abdominal pain have also occurred. As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.

*Hypersensitivity:* Allergic reactions have been observed in the form of rash, urticaria, angioedema and, rarely, erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis. These reactions usually subsided upon discontinuation of the drug, although in some cases supportive therapy may be necessary. Anaphylaxis has also been reported.

*Haemic and Lymphatic System:* Eosinophilia, neutropenia, thrombocytopenia, and haemolytic anaemia have been reported.

*Skin and subcutaneous tissue disorders:* Acute generalised exanthematous pustulosis (AGEP) has been reported with unknown frequency.

*Other*: These have included genital and anal pruritus, genital candidiasis, vaginitis and vaginal discharge, dizziness, fatigue, headache, agitation, confusion, hallucinations, arthralgia, arthritis and joint disorder. Reversible interstitial nephritis has been reported rarely. Slight elevations in AST and ALT have been reported.

There have been reports of neurological adverse reactions including encephalopathy, tremor, myoclonia and convulsions associated with the use of cephalosporins. Most cases occurred in patients with severe renal impairment (see Section 4.4).

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:

HPRA Pharmacovigilance
Website: www.hpra.ie

**4.9 Overdose**

Symptoms of oral overdose may include nausea, vomiting, epigastric distress, diarrhoea 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. It would be extremely unlikely that one of these procedures would be indicated.

Unless 5 to 10 times the normal total daily dose has been ingested, gastro-intestinal decontamination should not be necessary.

There have been reports of haematuria without impairment of renal function in children accidentally ingesting more than 3.5g of cefalexin in a day. Treatment has been supportive (fluids) and no sequelae have been reported.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: First generation cephalosporins, ATC code: J01DB01

*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 influenzae*
*Branhamella catarrhalis*

Most strains of enterococci (*Streptococcus faecalis*) and a few strains of staphylococci are resistant to cefalexin. It is not active against most strains of *Enterobacter* species, *Morganella morganii* and *Pr. vulgaris*. It has no activity against *Pseudomonas* or *Herellea* species or *Acinetobacter calcoaeticus*. Penicillin-resistant *Streptococcus pneumoniae* is usually cross resistant to beta lactam antibiotics. When tested by *in vitro* methods, staphylococci exhibit cross-resistance between cefalexin and methicillin-type antibiotics.

**5.2 Pharmacokinetic properties**

Cefalexin is acid stable.

Cefalexin is almost completely absorbed from the gastro-intestinal tract, and 75-100% is rapidly excreted in active form in the urine. Absorption is slightly reduced if the drug is administered with food. The half-life is approximately 60 minutes in patients with normal renal function. Haemodialysis and peritoneal dialysis will remove cefalexin from the blood.

Peak blood levels are achieved one hour after administration and therapeutic levels are maintained for 6-8 hours. Approximately 80% of the active drug is excreted in the urine within 6 hours. No accumulation is seen with dosages above the therapeutic maximum of 4g/day.

The half-life may be increased in neonates due to their renal immaturity, but there is no accumulation when given at up to 50mg/kg/day.

**5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Sucrose
Imitation Guarana Flavour
Allura Red AC (E129)
Sodium laurilsulfate (E487)
Methylcellulose
Dimeticone
Xanthan gum (E415)
Starch, pregelatinised

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

*Unreconstitutedproduct:* 3 years.
*Bottleofreconstitutedproduct:* 10 days.

**6.4 Special precautions for storage**

Powder: Do not store above 25°C.
Keep the bottle in the outer carton.
Keep the bottle tightly closed.

Suspension: After mixing the suspension should be stored at 2-8°C and used within 10 days.

**6.5 Nature and contents of container**

The powder is filled into 100 ml HDPE bottles with screw caps.

**6.6 Special precautions for disposal and other handling**

First invert the bottle and tap to loosen the powder then add a total of 60ml water in two portions, shaking after each addition until suspended.

The reconstituted product is coloured red. Shake well before use.

**7 MARKETING AUTHORISATION HOLDER**

Flynn Pharma Limited
5th Floor
40 Mespil Road

Dublin 4
D04 C2N4
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA1226/002/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 14 April 1977

Date of last renewal: 14 April 2007

**10 DATE OF REVISION OF THE TEXT**

November 2025