

# Cephalen®

Capsule/Suspension

## Description

Cephalen (Cefalexin) is a semisynthetic antibiotic of the cephalosporin group, intended for oral administration which has a bactericidal activity against a wide range of Gram-positive and Gram-negative organisms. Cephalen is acid stable and may be given regardless of meal. It is rapidly absorbed after oral administration and peak serum level is obtained after one hour. It is mainly excreted in the urine.

## Indications

Cephalen is indicated for the treatment of the following infections when caused by susceptible organisms.

*Respiratory tract infections* : Acute and chronic bronchitis and infected bronchiectasis.

*Genito-urinary tract infections* : Acute and chronic nephritis, cystitis, urethritis and prostatitis, prophylaxis of recurrent urinary tract infections.

*Skin and soft tissue infections* : Caused by staphylococci and/or streptococci.

*Ear, Nose and Throat infections* : Otitis media, mastoiditis, sinusitis, follicular tonsillitis and pharyngitis.

*Bone infections* : Caused by staphylococci and/or *P. mirabilis*.

## Dosage and Administration

*Adult* : The usual dose is 250 mg to 500 mg every 6 hour. For skin and soft tissue infections, streptococcal pharyngitis and uncomplicated cystitis, in patients over 15 years of age, 500 mg of the drug may be administered every 12 hour. In severe or deep seated infections the dose can be increased up to 3 g to 6 g daily.

*Children* : The dosage range is 25-100 mg/kg/day in divided doses to a maximum of 4 g daily (*please note the table*).

Children's Weight	Recommended Dose
10 kg ( 22 Ibs)	62.5 mg to 125 mg qid or 125 mg to 250 mg bid
20 kg ( 44 Ibs)	125 mg to 250 mg qid or 250 mg to 500 mg bid
40 kg ( 88 Ibs)	250 mg to 500 mg qid or 500 mg to 1 g bid

For streptococcal pharyngitis, skin and soft tissue infections and in patients over 1 year of age the total daily dose may be divided and administered every 12 hour. In the therapy of otitis media 75-100 mg/kg/day in four divided doses may be required. In the treatment of  $\beta$  haemolytic streptococcal infections a therapeutic dosage of the drug should be given at least for 10 days.

### **Contraindication**

Cephalexin is contraindicated in patients with known hypersensitivity to the cephalosporin group of antibiotics.

### **Precautions**

Cefalexin should be given with caution in patients with renal impairment. Under such condition, careful clinical observation should be made because safe dosage may be lower than the usually recommended. The urine of patients receiving Cefalexin may give a false positive reaction for glucose with copper reduction reagent. Positive results to Coombs' test have been reported.

Although there is no evidence of teratogenicity in animal tests, Cefalexin may be used during pregnancy when it is considered essential. Cefalexin is found in the milk of nursing mothers, hence caution should be taken when it is administered to nursing mothers.

### **Side Effects**

Side effects include nausea, vomiting, diarrhoea and abdominal discomfort. Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Skin rash, angio-oedema, rise in serum aminotransferases, eosinophilia, neutropenia have been reported very rarely. Superinfection with resistant micro-organisms, particularly candida may follow the treatment.

## **Commercial Packs**

Cephalen<sup>®</sup> 250 Capsule : Box containing 10 x 10's blister strips. Each capsule contains Cefalexin BP equivalent to anhydrous Cefalexin 250 mg.

Cephalen<sup>®</sup> 500 Capsule : Box containing 5 x 10's blister strips. Each capsule contains Cefalexin BP equivalent to anhydrous Cefalexin 500 mg.

Cephalen<sup>®</sup> Suspension : Dry powder in amber glass bottle for reconstitution into 100 ml suspension. After reconstitution each 5 ml contains Cefalexin BP equivalent to anhydrous Cefalexin 125 mg.