Ceporin®

Cephalexin

First generation Cephalosporin

COMPOSITION

Ceporin® 250 capsule : Each capsule contains Cephalexin Monohydrate BP equivalent to 250 mg of Cephalexin Anhydrous.

Ceporin® 500 capsule : Each capsule contains Cephalexin Monohydrate BP equivalent to 500 mg of Cephalexin Anhydrous.

Ceporin® dry syrup : After reconstitution each 5 ml contains 125 mg of Cephalexin Anhydrous as Cephalexin Monohydrate BP.

Ceporin® DT 250 : Each tablet contains Cephalexin Monohydrate BP equivalent to 250 mg Cephalexin Anhydrous.

PHARMACOLOGY

Cephalexin is a semisynthetic analogue of Cephalosporin C. It kills bacteria by interfering in the synthesis of the bacterial cell wall. Peptidoglycan is a heteropolymeric structure that provides the cell wall with mechanical stability. The final stage in the synthesis of peptidoglycan involves the completion of the cross-linking and the terminal glycine residue of the Pentaglycine Bridge is linked to the fourth residue of the pentapeptide (d-alanin). The transpeptidase enzyme that performs this step is inhibited by penicillins and cephalosporins. As a result the bacterial cell wall is weakened, the cell swells and then ruptures. Cephalexin is a first generation cephalosporin that is active by mouth. It is active against *Streptococcus pneumoniae, Neisseria meningitidis* and *Neisseria gonorrhoeae* as well as against *Staphylococci*. It is less active against penicillinase-producing *Staphylococci* than other first generation drugs such as cephalothin. Cephalexin is also active against *Strep. viridans*. A few strains of *E. coli* are sensitive to cephalexin at clinically achievable concentrations.

Absorption of cephalexin from the gastrointestinal tract is almost complete, usually 80-100% of an orally administered dose. Cephalexin is excreted almost exclusively through the kidney. Mean plasma half-life is 1 hour.

INDICATION

Respiratory tract infections due to *Streptococcus pneumoniae* and group A β-*hemolytic streptococci*.

Otitis media caused by *S. pneumoniae, Haemophilus influenzae, Staphylococci, Streptococci and Moraxella catarrhalis*.

Skin and skin structure infections caused by *staphylococci or streptococci.*

Ceporin®

Bone infections caused by *staphylococci or Proteus Mirabilis*. genitourinary infections, including acute prostatis, caused by *Escherichia coli, P. mirabilis, and Klebsiella* sp.

DOSAGE AND ADMINISTRATION

Adults

1 to 4 g/day in divided doses. Usual dose is 250 mg every 6 hours. Streptococcal pharyngitis, skin and skin structure infections, uncomplicated cystitis in patients>15 years -500 mg every 12 hours. May need larger doses for more severe infections or less susceptible organisms.

Children

25 to 50 mg/kg/day in divided doses. For streptococcal pharyngitis in patients >1year old and for skin and skin structure infections, divide total daily dose and give every 12 hours. In sever infections, double the dose.

Otitis media: 75 to 100 mg/kg/day in 4 divided doses.

β-hemolytic streptococcal infections: Continue treatment for at least 10 days.

CONTRAINDICATION AND PRECAUTION

Cephalexin is contraindicated in patients with known hypersensitive to penicillins and cephalosporins. Cephalexin should be administered with caution to patients with impaired renal function; the frequency of dosage should be modified according to creatinine clearance values.

SIDE EFFECT

Symptomatic adverse effects include genital and anal pruritus, genital moniliasis, vaginitis and vaginal discharge, dizziness, and headache. Nausea, vomiting, dyspepsia, may occur. Diarrhoea is infrequent (1.1%). In rare instances the drug appears to have induced pseudomembranous colitis. Hypersensitivity reactions (rash, urticaria and angioedema) may occur. Slight elevation of AST (SGOT) and ALT (SGPT) have been detected. Eosinophilia, neutropenia, and a positive Coomb test have been reported.

DRUG INTERACTION

Administration of probenecid produces higher and more prolonged serum concentrations. Rate of clearance by the kidneys is reduced.

USE IN PREGNANCY AND LACTATION

Although there is no evidence of teratogenicity in animal tests, the drug should only be used during pregnancy if it is considered essential.

The drug enters breast milk and it is probably best for mothers taking the drug not to breast-feed, in order to avoid exposing the infant to the drug unnecessarily, though, apart from possible sensitization, such exposure is unlikely to be harmful.

HOW SUPPLIED

Ceporin® 250 capsule: Box containing 5 x 10 capsules in blister pack.

Ceporin® 500 capsule: Box containing 5 x 6 capsules in blister pack.

Ceporin® dry syrup : Bottle containing dry ingredients to make 100 ml syrup.

Ceporin® DT 250 : Box containing 5 x 10 tablets in blister pack.