CEFSIQ-O

Each tablet contains Cefixime 200 mg and Ofloxacin 200 mg

Dosage Form and Strength

Dosage Form: Tablets.
Dosage Strength: Cefixime 200 mg and Ofloxacin 200 mg per tablet.

Therapeutic Indication

CEFSIQ-O Tablets are indicated in bacterial infections of the skin, ears, lungs, prostate and urinary tract and for the treatment of typhoid fever and urinary tractinfections in adults.

Posology and Method of Administration

For oral administration.
Adults: One tablet of CEFSIQ-O to be administered twice daily for up to 14 days. CEFSIQ-O Tablets may be taken regardless of food. The tablet should be swallowedwhole with water and not to be cut, crushed or chewed.
Or, as prescribed by the physician.

Pharmacokinetic Properties

Cefixime

Absorption and Distribution: The absolute oral bioavailability of cefixime is in the range of22 to 54%. Absorption is not significantly modified by the presence of food. Cefixime may therefore be given without regard to meals. Typically, the peak serum levels following the recommended adult or pediatric doses are between 1.5 and 3 mcg/ml. Little or no accumulation of cefixime occurs following multiple dosing. Serum protein binding is concentration-independent with a bound fraction of approximately 65%. Cefixime is almost exclusively bound to the albumin fraction. Protein binding of cefixime is only concentration- dependent in human serum at very high concentrations which are not seen following clinical dosing.
Metabolism and Excretion: There is no evidence of metabolism of cefixime in vivo. Approximately 50% of the absorbed dose is excreted unchanged in the urine in 24 hours. In animal studies, it was noted that cefixime is also excreted in the bile in excess of 10% of the administered dose. The serum half-life of cefixime in healthy subjects is independent of dosage form and averages 3 to 4 hours, but may range up to 9 hours in some volunteers.

Ofloxacin

Absorption: Following oral administration, the bioavailability of ofloxacin in the tablet formulation is approximately 98%. Maximum serum concentrations are achieved 1 to 2 hoursafter an oral dose. Absorption of ofloxacin after single or multiple doses of 200 to 400 mg is predictable, and the amount of drug absorbed increases proportionately with the dose.
Distribution: The total clearance and volume of distribution are approximately similar aftersingle or

multiple doses. In vitro, approximately 32% of the drug in plasma is protein bound. **Metabolism and Excretion:** Elimination is mainly by renal excretion. Between 65 to 80% ofan administered oral dose of ofloxacin is excreted unchanged via the kidneys within 48 hoursof dosing. Studies indicate that less than 5% of an administered dose is recovered in the urineas the desmethyl or N-oxide metabolites. About 4 to 8% of ofloxacin dose is excreted in thefeces. Ofloxacin has biphasic elimination. Following multiple oral doses at steady-stateadministration, the half-lives are approximately 4 to 5 hours and 20 to 25 hours.Accumulation at steady-state can be estimated using a half-life of 9 hours.

Pharmacological Properties

Mechanism of Action

Cefixime

Cefixime is an oral third generation cephalosporin which has marked in vitro bactericidalactivity against a wide variety of Gram-positive and Gram-negative organisms.

Cefixime inhibits bacterial cell wall synthesis during cell multiplication and producesbactericidal action.

Ofloxacin

Ofloxacin is a quinolone antimicrobial agent. The mechanism of action of ofloxacin and other fluoroquinolone antimicrobials involves inhibition of bacterial topoisomerase IV and DNA gyrase (both of which are type II topoisomerases), enzymes required for DNA replication, transcription, repair and recombination. Ofloxacin has in vitro activity against a wide rangeof gram-negative and gram-positive microorganisms. Ofloxacin is often bactericidal at concentrations equal to or slightly greater than inhibitory concentrations.

Pharmacodynamic Properties

Cefixime

Cefixime has been shown to be active against most isolates of the following bacteria both invitro and in clinical infections:

Gram-positive bacteria

- Streptococcus pneumoniae
- Streptococcus pyogenes

Gram-negative bacteria

- Haemophilus influenzae
- Moraxella catarrhalis
- Escherichia coli
- Proteus mirabilis
- Neisseria gonorrhoeae

The following in vitro data are available, but their clinical significance is unknown. Cefixime exhibits in vitro MICs of 1 mcg/ml or less against most (≥ 90%) isolates of the following bacteria; however, the safety and effectiveness of cefixime in treating clinical infections due to these bacteria have not been established in adequate and well-controlled clinical trials.

Gram-positive bacteria

- Streptococcus agalactiae

Gram-negative bacteria

- Haemophilus parainfluenzae
- Proteus vulgaris
- Klebsiella pneumoniae
- Klebsiella oxytoca
- Pasteurella multocida
- Providencia species
- Salmonella species
- Shigella species
- Citrobacter amalonaticus
- Citrobacter diversus
- Serratia marcescens

Ofloxacin

Ofloxacin has been shown to be active against most strains of the following microorganismsboth in vitro and in clinical infections:

Aerobic gram-positive bacteria

- Staphylococcus aureus (methicillin-susceptible strains)
- Streptococcus pneumoniae (penicillin-susceptible strains)
- Streptococcus pyogenes

Aerobic gram-negative bacteria

- Citrobacter (diversus) koseri
- Enterobacter aerogenes
- Escherichia coli
- Haemophilus influenzae
- Klebsiella pneumoniae
- Neisseria gonorrhoeae
- Proteus mirabilis
- Pseudomonas aeruginosa

Other microorganisms

- Chlamydia trachomatis