

Oxcin-D Ophthalmic Solution

(Moxifloxacin HCl + Dexamethasone Sodium Phosphate)

COMPOSITION:
Moxifloxacin (as HCl) BP 0.5%w/v
Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone Phosphate 0.1%w/v

CLINICAL PHARMACOLOGY

Pharmacokinetics:

The mean steady-state C_{max} (2.7 ng/mL) and estimated daily exposure AUC (45 ng hr/mL) values are 1,600 and 1,000 times lower than the mean C_{max} and AUC reported after therapeutic 400 mg oral doses of moxifloxacin. The plasma half-life of moxifloxacin is estimated to be 13 hours. Dexamethasone suppresses the inflammatory response to a variety of agents and it probably delays or slows healing.

Oxcin-D Ophthalmic Solution is a combination of Moxifloxacin 0.5% and Dexamethasone 0.1%. Moxifloxacin is a fourth generation fluoroquinolone controls infection by inhibiting the DNA gyrase and topoisomerase IV. Dexamethasone a potent corticosteroid effectively controls the inflammation by inhibiting the release inflammatory mediators.

Microbiology:

Moxifloxacin is an 8-methoxy fluoroquinolone with a diazabicyclononyl ring at the C7 position. The antibacterial action of moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division.

The mechanism of action for quinolones, including moxifloxacin, is different from that of macrolides, aminoglycosides, or tetracyclines. Therefore, moxifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to moxifloxacin. There is no cross-resistance between moxifloxacin and the aforementioned classes of antibiotics.

Resistance to moxifloxacin develops via multiple-step mutations. Resistance to moxifloxacin occurs at a general frequency of between 1.3×10^{-9} to $< 1 \times 10^{-11}$ for Gram-positive bacteria.

Moxifloxacin has been shown to be active against most strains of the following microorganisms.

Aerobic Gram-positive microorganisms:

Corynebacterium species*
*Micrococcus luteus**
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis
*Staphylococcus warneri**
Streptococcus pneumoniae
Streptococcus viridans group

Aerobic Gram-negative microorganisms:

*Acinetobacter baumannii**
Haemophilus influenzae
*Haemophilus parainfluenzae**

Other microorganisms:

Chlamydia trachomatis
*The efficacy of moxifloxacin for this organism is studied in fewer than 10 infections.

The following organisms are considered susceptible when evaluated using systemic breakpoints. However, a correlation between the systemic breakpoint and ophthalmological efficacy has not been established. The list of organisms is provided as guidance only in assessing the potential treatment of conjunctival infections. Moxifloxacin exhibits minimal inhibitory concentrations (MICs) of 2 µg/ml or less (systemic susceptible breakpoint) against most (>90%) of strains of the following ocular pathogens

Aerobic Gram-positive microorganisms:

Listeria monocytogenes
Staphylococcus saprophyticus
Streptococcus agalactiae
Streptococcus mitis
Streptococcus pyogenes
Streptococcus Group C, G and F

Aerobic Gram-negative microorganisms:

Acinetobacter baumannii
Achromobacter calcoaceticus
Citrobacter freundii
Citrobacter Koseri
Enterobacter aerogenes
Enterobacter cloacae
Enterobacter coli
Klebsiella oxytoca
Klebsiella pneumoniae
Moraxella ostenhalsii
Morganella morganii
Neisseria gonorrhoeae
Proteus mirabilis
Proteus vulgaris
Pseudomonas slutzneri

Anaerobic microorganisms:

Clostridium perfringens
Fusobacterium species
Prevotella species
Propionibacterium acnes
Other microorganisms:
Chlamydia pneumoniae
Legionella pneumophila
Mycobacterium avium
Mycobacterium marinum
Mycoplasma pneumoniae

INDICATION AND USAGE

Oxcin-D Ophthalmic Solution is indicated for steroid responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists. The combination can also be used for post-operative inflammation associated with infection.