

FLOROBEX

BESIFLOXACIN INN

Compositions:

<p>Florobex Eye Suspension : Each ml eye drop (suspension) contains 6 mg Besifloxacin as Besifloxacin Hydrochloride INN.</p>

Pharmacology:

Besifloxacin is a fluoroquinolone antibacterial. The compound has activity against Gram-positive and Gram-negative bacteria due to the inhibition of both bacterial DNA gyrase and topoisomerase IV. DNA gyrase is an essential enzyme required for replication, transcription and repair of bacterial DNA. Topoisomerase IV is an essential enzyme required for partitioning of the chromosomal DNA during bacterial cell division.

Indications:

Besifloxacin (Besifloxacin ophthalmic suspension) 0.6%, is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria: CDC coryneform group G, *Corynebacterium pseudodiphtheriticum*, *Corynebacterium striatum*, *Haemophilus influenzae*, *Moraxella lacunata*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus hominis*, *Staphylococcus lugdunensis*, *Streptococcus mitis* group, *Streptococcus oralis*, *Streptococcus pneumoniae*, *Streptococcus salivarius*.

Dosage And Administration:

Invert closed bottle and shake once before use. Instill one drop in the affected eye(s) 3 times a day, four to twelve hours apart for 7 days.

Contraindications:

Besifloxacin ophthalmic solution is contraindicated in patients with a history of hypersensitivity to Besifloxacin, to other quinolones, or to any of the components in this medication.

Warning And Precaution:

Overgrowth of non-susceptible organisms including fungi. If super-infection occurs, discontinue use and institute alternative therapy. Patients should not wear contact lenses if they have signs or symptoms of bacterial conjunctivitis or during the course of therapy with Besifloxacin.

Side Effects:

The most frequently reported ocular adverse event was conjunctival redness, reported in approximately 2% of patients. Other adverse events reported in patients receiving occurring in approximately 1-2% of patients included: blurred vision, eye pain, eye irritation, eye pruritus and headache.

Use in Pregnancy and Lactation:

Pregnancy: Pregnancy Category C. Since there are no adequate and well-controlled studies in pregnant women, Besifloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Lactation: Besifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when Besifloxacin is administered to a nursing mother.

Drug Interaction:

No information provided.

Overdosage:

No data are available regarding the over dose of Besifloxacin.

Storage:

Store at 15°-25°C. Store in a cool and dry place, protect from light. Do not use longer than one month after first opening and keep out of the reach of children.

Packing:

Florobex Eye Suspension : Each plastic dropper bottle contains 5 ml of sterile eye drops.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.