# Besiflox

Besifloxacin 0.6%

**Sterile Ophthalmic Suspension**

**Composition:**
**Besiflox Sterile Ophthalmic Suspension:** Each ml contains Besifloxacin Hydrochloride INN equivalent to Besifloxacin 6 mg.

**Preservative:** Sodium Perborate BP 0.01%.

**Vehicle:** HPMC USP 0.45%.

**Pharmacology:**
Besifloxacin is an 8-chlorofluoroquinolone with a 3-aminohexahydro-azepinyl substituent at C-7 which shows antibacterial activity by inhibiting the bacterial enzyme DNA gyrase and topoisomerase IV.

**Indications:**
• **Besiflox** Sterile Ophthalmic Suspension is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:
Aerobic Gram-Positive Bacteria: *Corynebacterium pseudodiphtheriticum, Corynebacterium striatum, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus hominis, Staphylococcus lugdunensis, Streptococcus mitis, Streptococcus pneumoniae, Streptococcus oralis, Streptococcus salivarius and* CDC *coryneform* group G
Aerobic Gram-Negative Bacteria: *Moraxella lacunata*
• It is also indicated for the treatment of blepharitis, keratitis & surgical prophylaxis.

**Dosage & administration:**
For bacterial conjunctivitis & blepharitis:
Instill 1 drop in the affected eye (s) 3 times a day for 7 days.
For keratitis:
Instill higher doses in the affected eye(s) as per needed or directed by the phiysician.
For surgical prophylaxis:
Instill 1 drop in the affected eye(s) every 10 minutes for a total 4 doses beginning 1 hour before cataract surgery.

**Contraindications:**
None.

**Side effects:**
Reported side effect is conjunctival redness. Other side effects are blurred vision, eye irritation, eye pain, eye pruritis and headache.

**Precautions:**
- For topical ophthalmic use only and should not be injected subconjunctivally and should not be introduced directly into the anterior chamber of the eye.
- Prolonged use may result in overgrowth of non-susceptible organisms, including fungi.
- Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

**Use in special group:**
**Use in pregnancy:** Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Besifloxacin should be used during pregnancy only if the benefit justifies the potential risk to the fetus.
**Use in lactation:** Besifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. So, caution should be exercised when Besifloxacin is administered to a nursing woman.
**Use in children:** Safety and effectiveness in infants below the age of 1 year have not been established.
**Use in elderly patients:** No overall clinical differences in safety or effectiveness have been observed between elderly and younger patients.

**Storage:**
- Store in a cool and dry place, protect from light
- Do not use longer than one month after first opening
- Keep out of the reach of children

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**Packing:**
**Besiflox Sterile Ophthalmic Suspension:** Each plastic dropper bottle contains 5 ml/10 ml sterile ophthalmic suspension.

ARISTOVISION

Manufactured by:
ARISTOPHARMA LTD.
SHAMPUR-DHAKA-BANGLADESH