

#### Presentation

**Besigen:** Each ml sterile ophthalmic suspension contains Besifloxacin 6 mg (as Besifloxacin Hydrochloride INN).

**Preservative:** Benzalkonium Chloride 0.01%

Vehicle: Hypromellose 0.5%

## Pharmacological Action

The antibacterial action of Besifloxacin results from inhibition of 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. Through inhibiting these processes Besifloxacin shows bactericidal activity.

#### Indications

Besifloxacin 0.6% ophthalmic suspension is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:

CDC coryneform group G

Corynelorm group G Corynelorm group G Corynebacterium striatum\*, Haemophilus influenzae, Moraxella lacunata\*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus hominis\*, Streptococcus mitis group, Streptococcus oralis, Streptococcus pneumoniae.

\*Efficacy for this organism was studied in fewer than 10 infections.

### **Dosage and Application**

Instill one drop in the affected eye(s) 3 times a day, four to twelve hours apart for 7 days.

#### Contraindications

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

# Side Effects

Blurred vision, watery eyes, headache, eye irritation/pain/dryness/redness etc.

# Precautions

Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

## **Drug Interactions**

No specific drug-drug interaction studies were conducted.

## **Use in Pregnancy and Lactation**

In Pregnancy

Pregnancy Category C.

Because there are no adequate and well-controlled studies in pregnant women, Besifloxacin 0.6% ophthalmic suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### In Lactation

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Besifloxacin is administered to a nursing woman.

# Over Dose

An overdose of this medication is unlikely to threaten life.

#### Storage Conditions

Store in a cool and dry place away from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. Do not use after one month of first opening.

## Commercial Pack

**Besigen:** Each plastic dropper bottle containing 5 ml sterile ophthalmic suspension.

## Manufactured by :



