**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use Besivance safely and effectively. See full prescribing information for Besivance.

**INDICATIONS AND USAGE**

Besivance® (besifloxacin ophthalmic suspension) 0.6% is a quinolone antimicrobial indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following bacteria:

- Aerococcus viridans
- CDC coryneform group C
- CDC coryneform group G
- Corynebacterium striatum
- Haemophilus influenzae
- Moraxella catarrhalis
- Moraxella lacunata
- Pseudomonas aeruginosa
- Staphylococcus epidermidis
- Staphylococcus hominis
- Staphylococcus lugdunensis
- Staphylococcus warneri
- Streptococcus mitis
- Streptococcus pneumoniae
- Strep. pseudobahcinus lenses

**CONTRAINDICATIONS**

- **Pregnancy**
- **Nursing Mothers**
- **Geriatric Use**

**WARNINGS AND PRECAUTIONS**

- **Avoidance of Contact Lenses**
- **Growth of Resistant Organisms with Prolonged Use**
- **Topical Ophthalmic Use Only**

**ADVERSE REACTIONS**

- **Ocular**
- **Systemic**

**DOSE AND ADMINISTRATION**

- Install one drop of Besivance into the eye 3 times a day; for 3 days.

**DOSE FORMS AND STRENGTHS**

- 7.5 mL, size bottle filled with 5 mL of besifloxacin ophthalmic suspension 0.6% (3)

**CONTRAINDICATIONS**

None (4)

**WARNINGS AND PRECAUTIONS**

Topical Ophthalmic Use Only. (5.1)

**ADVERSE REACTIONS**

To report SUSPECTED ADVERSE REACTIONS, contact Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 06/2016

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3 DOSAGE FORMS AND STRENGTHS
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Efficacy for this organism was studied in fewer than 10 infections. (1)

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**CONTRAINDICATIONS**

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- **Geriatric Use**

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**WARNINGS AND PRECAUTIONS**

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**ADVERSE REACTIONS**

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**WARNINGS AND PRECAUTIONS**

Topical Ophthalmic Use Only. (5.1)

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**CONTRAINDICATIONS**

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**DOSE FORMS AND STRENGTHS**

- 7.5 mL, size bottle filled with 5 mL of besifloxacin ophthalmic suspension 0.6% (3)

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**CONTRAINDICATIONS**

None (4)

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Topical Ophthalmic Use Only. (5.1)

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See 17 for PATIENT COUNSELING INFORMATION.

Revised: 06/2016
Besifloxacin is an 8-chloro dihydroquinoline-3-carboxylic acid hydrochloride. Besifloxacin hydrochloride is a white to pale yellowish solid.

Each mL contains:
- Active: besifloxacin 0.6% (6 mg/mL); 0.6%, is supplied as a sterile ophthalmic suspension in a white low density polyethylene (LDPE) bottle with a controlled dropper tip and tip polysulfone cap. Tamper evident stopper with a shrink band around the cap and neck area of the package.
- Inactive:
  - Chemical Name: (+)-7-[(3R)-3-aminohexahydro-1H-azepino[1,2-b]thiazol-1-yl]-9-(1H-pyrrolin-2-yl)cyclopropyl-6-fluro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid hydrochloride.
  - Preservative: benzalkonium chloride 0.01%

Besifloxacin is a fluoroquinolone antibacterial [see Clinical Pharmacology (12.4)].

**CLINICAL PHARMACOLOGY**

**12.1 Mechanism of Action**
Besifloxacin is a fluorinated analog of nalidixic acid with activity against Gram-negative and Gram-positive bacteria due to the inhibition of DNA topoisomerases IV and II. Replication, transcription, and repair of bacterial DNA are essential for bacterial cell division. Besifloxacin is bactericidal with minimum bactericidal concentrations (MBCs) generally within one dilution of the minimum inhibitory concentrations (MICs).

The mechanism of action of fluoroquinolones, including besifloxacin, is different from that of aminoglycosides, macrolides, and β-lactam antibiotics. Therefore, besifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to besifloxacin.

In vitro resistance to besifloxacin develops via multiple mechanisms. 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 bacterial chromosome partitioning of the chromosomal DNA during bacterial cell division. Besifloxacin is bactericidal with minimum bactericidal concentrations (MBCs) generally within one dilution of the minimum inhibitory concentration (MICs).

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**12.2 Microbiology**
Besifloxacin is an 8-chloro dihydroquinoline with a 1-N-cyclohexyl-2-oxo-3-thiazolinone ring that bears a quinolone moiety and has activity against Gram-positive and Gram-negative bacteria due to the inhibition of both bacterial DNA gyrase and topoisomerase IV.

Beef heart DNA gyrase is an enzyme required for replication, transcription and repair of bacterial DNA. Topoisomerase IV is an essential enzyme required for bacterial chromosome partitioning of the chromosomal DNA during bacterial cell division. Besifloxacin is bactericidal with minimum bactericidal concentrations (MBCs) generally within one dilution of the minimum inhibitory concentration (MICs).

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**12.3 Pharmacokinetics**
Plasma concentrations of besifloxacin were measured in adult patients with suspected bacterial conjunctivitis who received Besivance bilaterally three times a day (16 doses total). Following the first and last dose, the maximum plasma besifloxacin concentration in each patient was less than 1.3 ng/mL. The mean besifloxacin Cmax was 0.37 ng/mL on day 1 and 0.43 ng/mL on day 6.

**12.4 Pharmacodynamics**
Besifloxacin is an 8-chloro dihydroquinoline-3-carboxylic acid hydrochloride. Besifloxacin hydrochloride is a white to pale yellowish solid.

Each mL contains:
- Active: besifloxacin 0.6% (6 mg/mL);
- Inactive:
  - Benzalkonium chloride 0.01%

Besifloxacin is an 8-chloro dihydroquinoline-3-carboxylic acid hydrochloride. Besifloxacin hydrochloride is a white to pale yellowish solid.

Each mL contains:
- Active: besifloxacin 0.6% (6 mg/mL);
- Inactive:
  - Benzalkonium chloride 0.01%