Otic Solution 0.3% (Sterile)

DESCRIPTION:
Otic Solution 0.3% is a sterile aqueous anti-infective (antibacterial) solution for otic use. Chemically, ofloxacin has three condensed 6-membered rings made up of a fused carbocyclic aromatic with a 1,2,4 thiazine ring. The chemical name of ofloxacin is 1-(2-Fluoro-4-Methyl-phenoxy)-4-methyl-6-oxo-1,4-Dihydro-7-(1H)-pyridinone (1:1.5:1:4:4-Benzodiazepine sodium salt). and its molecular weight is 361.38. The structural formula is:

Each mL contains: Active: ofloxacin 0.3% (0.9 mg/mL); inactive: benzalkonium chloride (0.02%), sodium chloretate (0.8%), and purified water. Hydrochloric acid and sodium hydroxide may be added to adjust the pH 5.0 ± 0.5.

CLINICAL PHARMACOLOGY:
Drug concentrations in serum (in subjects with tympanostomy tubes and perforated tympanic membranes) 30 minutes after otic administration of a 0.3% solution in subjects with chronic suppurative otitis media and perforated tympanic membranes. The maximum serum drug level of ofloxacin detected was 18 ng/mL after administration of a 0.3% solution. Concentrations in serum were maintained for at least 5 days.

Pharmacokinetics:
Each mL contains:
ofloxacin 0.3% (3 mg/mL); starch; propylene glycol; methylparaben; and propylene glycol.

INDICATIONS AND USAGE:
Otic Solution 0.3% is indicated for the treatment of infections caused by susceptible organisms in the following conditions:

Chronic Suppurative Otitis Media
Aerobes, gram-positive:
Staphylococcus aureus
Streptococcus pneumoniae
Aerobes, gram-negative:
Haemophilus influenzae
Moraxella catarrhalis

Middle Ear Infection
Aerobes, gram-positive:
Staphylococcus aureus
Streptococcus pneumoniae
Aerobes, gram-negative:
Haemophilus influenzae
Moraxella catarrhalis

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including ofloxacin. In most instances, anaphylaxis was preceded by constitutional symptoms (e.g., rash, fever, malaise, myalgias, asthenia, abdominal pain, and diarrhea).

WARNINGS:
OFLOXACIN Otic Solution 0.3% is contraindicated in patients with a history of hypersensitivity to ofloxacin, to other quinolones, or to any of the components in this medication.

OXYGEN AND AIRWAY MANAGEMENT:
In adults with perforated tympanic membranes, the maximum serum drug level of ofloxacin detected was 10 ng/mL after administration of a 0.3% solution.

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ofloxacin 0.3% (3 mg/mL); starch; propylene glycol; methylparaben; and propylene glycol.

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**Applications**

Otitis Externa

**ADVERSE REACTIONS**

In clinical trials of clinical efficacy, the most common adverse event reported in subjects with intact tympanic membranes was otitis externa with intact tympanic membranes (0.2%). For otitis externa with intact tympanic membranes, the adverse event rate was 0.8%.

**Chronic Suppurative Otitis Media with perforated tympanic membranes:**

The most common adverse event reported in subjects with perforated tympanic membranes was inflammation of the external ear (0.6%). For inflammation of the external ear, the adverse event rate was 0.2%.

**Post-Marketing Adverse Events**

The following treatment-related adverse events occurred in a single subject in post-marketing surveillance:

- Hypoaesthesia (0.1%)
- Tinnitus, dyspepsia, hot flushes, flushing, and otorrhagia (0.1%)
- Fungal infection (0.1%)

**Subjects with Acute Otitis Media with Tympanostomy Tubes (AOM TT) and Subjects with Chronic Suppurative Otitis Media (CSOM) with Perforated Tympanic Membranes**

In these trials, the most common adverse event reported in subjects with intact tympanic membranes was otitis externa with intact tympanic membranes (0.6%). For otitis externa with intact tympanic membranes, the adverse event rate was 0.2%.

**Subjects with Acute Otitis Media with Tympanostomy Tubes (AOM TT) and Subjects with Acute Otitis Externa**

The most common adverse event reported in subjects with intact tympanic membranes was otitis externa with intact tympanic membranes (0.2%). For otitis externa with intact tympanic membranes, the adverse event rate was 0.8%.

**Subjects with Acute Otitis Externa**

The most common adverse event reported in subjects with intact tympanic membranes was otitis externa with intact tympanic membranes (0.2%). For otitis externa with intact tympanic membranes, the adverse event rate was 0.8%.

**Subjects with Acute Otitis Externa with intact tympanic membranes**

The most common adverse event reported in subjects with intact tympanic membranes was otitis externa with intact tympanic membranes (0.2%). For otitis externa with intact tympanic membranes, the adverse event rate was 0.8%.

**Other treatment-related adverse events reported in subjects with intact tympanic membranes included: dizziness (0.3%), nausea (0.3%), vomiting (0.3%), dry mouth (0.3%), headachness (0.3%), vertigo (0.5%), erythema (0.5%), tinnitus (0.3%), fever (0.3%).**

The following treatment-related adverse events were each reported in a single subject with intact tympanic membranes:

- Hypoaesthesia (0.1%)
- Tinnitus, dyspepsia, hot flushes, flushing, and otorrhagia (0.1%)
- Fungal infection (0.1%)

**Subjects with Acute Otitis Media with Tympanostomy Tubes (AOM TT) and Subjects with Acute Otitis Externa**

The most common adverse event reported in subjects with intact tympanic membranes was otitis externa with intact tympanic membranes (0.2%). For otitis externa with intact tympanic membranes, the adverse event rate was 0.8%.

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