QUINODEX

EAR DROPS

(Ciprofloxacin 0.3% + Dexamethasone 0.1%)

COMPOSITION

Each mL contains Ciprofloxacin 0.3% (equivalent to 3 mg ciprofloxacin) and Dexamethasone 0.1% (equivalent to 1 mg dexamethasone). Other ingredients: according to the approved finished-product formula.

DESCRIPTION

Quinodex combines a fluoroquinolone antibacterial agent with a corticosteroid for topical otic use. It is intended for the treatment of susceptible bacterial ear infections accompanied by inflammation.

CLINICAL PHARMACOLOGY

Ciprofloxacin inhibits bacterial DNA gyrase and topoisomerase IV, interfering with bacterial DNA replication and producing bactericidal activity. Dexamethasone is a potent glucocorticoid that reduces inflammatory responses, swelling and related symptoms.

INDICATIONS

Reference ciprofloxacin 0.3% / dexamethasone 0.1% otic products are indicated for acute otitis externa caused by susceptible organisms in adults and children aged 6 months or older, and for acute otitis media in children aged 6 months or older with tympanostomy tubes. Use only for locally approved indications.

DOSAGE AND ADMINISTRATION

The reference regimen is 4 drops in the affected ear twice daily for 7 days, for acute otitis externa or acute otitis media with tympanostomy tubes, as applicable. Follow the prescriber's directions and locally approved product labeling.

METHOD OF ADMINISTRATION

For ear use only. Wash hands. Warm the bottle in the hand for 1-2 minutes to minimize dizziness from cold drops. Shake well immediately before use if the approved formulation is a suspension. Do not touch the dropper tip to the ear, fingers or other surfaces.

Lie with the affected ear facing upward and instill the prescribed number of drops. For otitis externa, remain in this position for approximately 60 seconds. In a patient with tympanostomy tubes, gently pump the tragus inward 5 times after instillation. Repeat for the other ear if prescribed.

Complete the prescribed course even if symptoms improve. Do not use in the eyes or inject. Use the product only for the prescribed patient.

CONTRAINDICATIONS

Known hypersensitivity to ciprofloxacin, other quinolones, dexamethasone or any formulation ingredient. Contraindicated in fungal otic infections and viral infections of the external ear canal, including herpes simplex infection.

WARNINGS

Serious hypersensitivity reactions, including anaphylaxis, have been reported with quinolones. Stop administration and seek prompt medical help for rash, facial swelling, difficulty breathing or other allergic reactions.

PRECAUTIONS

Long-term use may cause overgrowth of non-susceptible bacteria or fungi. If infection persists after one week, or drainage continues or recurs, the patient should be reassessed for alternative causes and appropriate additional treatment. Two or more episodes of otorrhea within 6 months may warrant further investigation.

Do not contaminate the applicator tip. Use with caution when the diagnosis is uncertain. Persistent pain, fever, severe swelling, hearing problems or worsening discharge require medical evaluation. Use only as prescribed.

DRUG INTERACTIONS

Specific interaction studies with otic ciprofloxacin/dexamethasone are limited. Systemic exposure after prescribed otic administration is low. Inform the physician about all other medicines, including topical ear treatments.

PREGNANCY

Adequate clinical data in pregnant women are unavailable. Systemic absorption after otic administration is minimal, but the prescriber should assess benefits and potential risks before use during pregnancy.

LACTATION

It is unknown whether the low systemic exposure after otic administration results in detectable concentrations in human milk. Consider the benefits of breastfeeding, the need for treatment, and any potential risk to the infant.

PEDIATRIC USE

Reference otic combination products have established use for specific indications in patients aged 6 months or older. Safety and effectiveness below 6 months of age have not been established.

ADVERSE REACTIONS

Reported reactions include ear discomfort or pain, ear itching, ear residue or debris, ear congestion, irritation, redness, altered taste, dizziness and occasional superimposed infection. Rare reports include rash, auricular swelling, discharge and hypersensitivity reactions.

Discontinue treatment and consult a physician if severe irritation, allergic manifestations or worsening symptoms develop.

OVERDOSAGE

Significant systemic toxicity is unlikely after normal otic administration. If excessive drops are applied, wipe away the excess. Following accidental ingestion, contact a healthcare professional or poison information service for assessment and supportive care.

STORAGE CONDITIONS

Store as specified in the approved product label. Reference otic suspensions are stored at controlled room temperature, protected from light and freezing. Keep the container tightly closed and out of reach of children. Follow the approved in-use period after first opening.

PRESENTATION

Quinodex Ear Drops: Ciprofloxacin 0.3% + Dexamethasone 0.1%, 5 mL in a dropper bottle.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.