OTODEX

Ear Drops

Composition

Each ml contains:

Dexamethasone Sodium Phosphate	1 mg
Neomycin Sulphate	5 mg
Polymyxin B Sulphate	10.000 I.U

Action

Corticoids suppress the inflammatory response to a variety of agents and they probably delay or slow healing. Since corticoids may inhibit the body's defence mechanism against infection, a concomitant antimicrobial drug may be used when this inhibition is considered clinically significant in a particular case.

The anti-infective component in the combination is included to provide action against specific organisms susceptible to it. Neomycin Sulfate considered active against the following microorganisms: Staphylococcus aureus, Corynebacterium diphteriae, Streptococcus viridans, Escherichia coli, Klebsiella pneumoniae, Proteus vulgaris, Aerobacter aerogenes, and Haemophilus influenzae.

Polymyxin B Sulfate is considered active against the following microorganisms: Pseudomonas aeruginosa, Aerobacter aerogenes, Escherichia coli, Klebsiella pneumoniae and Koch-Weeks bacillus.

Indications

Inflammatory conditions and superficial bacterial infections of the external auditory canal, caused by staphylococci, Pseudomonas, Proteus and other Gram-positive and Gram-negative bacteria susceptible to these antibiotics.

Contraindications

- Known hypersensitivity to any of the components or to the preparation.
- Topical corticosteroids are contraindicated in fungal infections, tuberculosis of the skin, vaccinia, varicella and herpes simples.

Warnings

Ototoxicity and nephrotoxicity have been reported with the topical use of neomycin. The likelihood of their occurrence may be increased if the patient is being concurrently treated with and aminoglycoside antibiotic.

Pregnancy

Topical corticosteroids should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.
Infants born to mothers, who have been treated during pregnancy with large amounts of corticosteroids or for prolonged periods, should be observed carefully for signs of hypoadrenalism.

Nursing Mothers

It is not known whether topical application of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk. Therefore, caution should be exercised when topical corticosteroids are applied to nursing women.

Adverse Reactions

This preparation is usually well tolerated. Stinging and burning may occur if the preparation gains access to the middle ear.
Signs of a sensitivity reaction to neomycin may also appear, usually in the form of a low-grade reddening with swelling dry scaling or itching, or simply as a failure to heal. During long-term use of neomycin-containing preparation, periodic examination for such signs is recommended. If they occur, patients should be advised to discontinue treatment.

Allergic cross-reactions may occur which could prevent the future use of any or all of the following antibiotics for the treatment of infections kanamycin, paromomycin, streptomycin and gentamicin.

Precautions

If sensitisation or irritation occurs, discontinue use.
If extensive attributed to the antibiotic component, neomycin containing the patient should avoid preparations in the future.

When using neomycin-containing preparations to control secondary infection in chronic dermatoses, such as chronic otitis externa or stasis dermatitis, it should be bome in mind that the skin is more liable to become sensitive to other substances, including neomycin.

If local infection should continue or become severe, or in the presence of systemic infection, appropriate antimicrobial therapy should be instituted. If a favourable response is not obtained, the use of this preparation should be temporarily discontinued, until the infection has been controlled.

If extensive areas are treated or if the occlusive technique is used, the possibility exists of increased systemic absorption and suitable precautions will be required in patients with electrolyte imbalance, gastrointestinal disturbances, diabetes, myopathy, cataract, renal or hepatic impairment, osteoporosis, and hemorrhage.
As with other antibiotic-containing topical preparations, prolonged use may result in an overgrowth of non-susceptible fungi. Appropriate measures should be taken if this occurs.

Dosage and Administration

The patient should lie with the affected ear upward and in such a position as to be able to retain the drops in the ear. Following instillation of the drops, the patient should maintain this redlining position for 5 minutes, to facilitate penetration of the drops into the ear canal.

Repeat the procedure for the other ear, if necessary.
If preferred, a cotton wick may be inserted into the ear canal, and then saturated with the solution. This wick should be kept moist by adding further solution every 4 hours. The wick should be replaced at least once every 24 hours.

Adults: 2-3 drops into the affected ear, 3-4 times daily.

Children: 1-2 drops into the affected ear, 3-4 times daily.

Presentation

Dropper bottle of 5 ml.