

**Tobramycin 0.3%**

**Dexamethasone 0.1%**

**STERILE OPHTHALMIC SUSPENSION**

Made in Argentina - Rx ONLY

Quality quantitative formula:
Each set of suspension contains:
- Dexamethasone 0.10 mg
- Tobramycin 0.30 mg

Additional excipients:
- Benzalkonium chloride 0.01 mg, Disodium edetate dihydrate 0.10 mg, Sodium chloride 1.2 mg, Sodium hydroxide 0.15 mg, Hydroxypropylmethylcellulose 0.25 mg, Tophamine 0.00 mg, Sucrose and 25% q.s., pH 0.10 mg, Hydroxypropylated water, q.s. 1.00 mg.

Therapeutic action:
Combination of topical ophthalmic use of a steroid anti-inflammatory agent (Dexamethasone) and an antimicrobial agent (Tobramycin).

ATC Classification: S01FC01

Indications:
External infections, treatment of the eye and its appendages caused by germs sensitive to Tobramycin, and characterized by tissue inflammation.

Pharmacological characteristics/Properties:
Pharmacological action
Dexamethasone is a potent steroid anti-inflammatory agent, which suppresses the inflammatory response to a broad variety of agents. Tobramycin is an aminoglycoside antibiotic, which is soluble in water, bactericidal, active against a broad variety of gram-positive and gram-negative pathogenic agents.

In vitro studies demonstrate that Tobramycin is effective against the following microorganisms: Staphylococci, including Staphylococcus aureus and Staphylococcus epidermidis (coagulase-positive and coagulase-negative) and Pseudomonas aeruginosa. Enterobacter, including Escherichia coli, Proteus vulgaris, Morganella morgani, and Klebsiella pneumoniae, Strepococcus, including some Group A-beta-hemolytic strains, some nonhemolytic species and some Streptococcus pneumoniae. Haemophilus influenzae, Moraxella catarrhalis, Neisseria, and other aerobic and anaerobic pathogens associated with these disease processes.

Dosage and Administration:
According to medical judgment. It is recommended, as guiding dosage, to use it for 2 or 3 drops into the affected eye(s) every 2 or 3 hours.

Contraindications:
Known hypersensitivity to any components of the formula. Narrow angle glaucoma, epiphora, Sjogren’s syndrome, and other diseases of the tear film or the eye.

Warnings:
Prolonged use of corticoids may result in intraocular hypertension and/or glaucoma with damage to the optic nerve, deficits in visual acuity and fields of vision and posterior subcapsular cataract formation. Prolonged use of corticoids may also suppress the host immune response and increase the possibility of secondary ocular infections. In those diseases, causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticoids. If this product is used during 10 or more days, intraocular pressure should be controlled daily. Some patients may develop hypersensitivity to the aminoglycoside topical application. If an hypersensitivity reaction to Tobramycin occurs, its use should be discontinued. It is recommended to remove contact lenses before applying the product.

GOTABIOTIC F® is packaged under sterile conditions. Avoid allowing the dropper tip to touch the eyelids, eyelashes, surrounding areas or any other surface in order to prevent contamination. Keep the dropper bottle carefully closed and do not use within 4 weeks of opening it.

Precautions:
The possibility of persistent fungal infections of the cornea should be considered, after a long-term corticoid dosing. Bacterial ketotin associated with the systemic use of multiple dose topical aminoglycoside products use have been reported. These can be maintained without contamination by patients who, in most cases, had suffered from coexistent bacterial diseases or an ocular epithelial surface injury. Patients should be instructed to handle the dropper tip correctly, avoiding the contact with the eye and surrounding structures or any other surface. Patients should be informed that the improper handling of the container may contain it, resulting in ocular infections. Using contaminated solutions may cause severe ocular damage with subsequent reduced vision. If during the treatment any other disease develops (e.g. trauma, surgical surgery or infection), the patient should report it immediately to the doctor, in order to evaluate the benefit of continue using the product. The preservative (benzalkonium chloride) may be absorbed by soft contact lenses, three patients will wait, at least, 15 minutes after every instillation to remove them.

As with other antibiotics, prolonged use may result in overgrowth of non-susceptible microorganisms, including fungi. If superinfection occurs, appropriate therapy should be initiated.

Cross-hypersensitivity to other aminoglycosides antibiotics may occur. If hypersensitivity develops with this product, should be discontinued and an appropriate therapy should be initiated. If topical ophthalmic Tobramycin is administered concomitantly with other systemic aminoglycoside antibiotics, their total serum concentration should be monitored.

GOTABIOTIC F® is highly concentrated and should be used with caution in isolated cases.

The most frequent adverse reactions to topical aminoglycoside antibiotics, including eye irritation and hypersensitivity, including eye edema, redness and pruritus with conjunctival hyperemia. These reactions occur in less than 3% of patients treated with Tobramycin. Similar reactions may occur with other aminoglycoside antibiotics topical use.

**Overdosage:**
If an overdosage occurs, go to the nearest hospital or toxicology centers.

**How supplied:**
Dropper bottle, containing 5-ml ophthalmic suspension.

Storage conditions:
Store below 30°C. Protect from light. Shake well before use.

Keep drugs out of reach of children.
Delicate use product. To be administered under prescription and medical surveillance.

Manufactured by:
LABORATORIOS POEN S.A.C.E.I.
Bermúdez 1004 - C1407BDR Buenos Aires, Argentina
www.poen.net.ar

Technical Director:
Víctor D. Cobalman, Pharmacist.

Delicate use product. To be administered under prescription and medical surveillance.

This product contains benzalkonium chloride (0.00025%) and a preservative that may cause sensitization (0.00003% sodium edetate). Topically administered corticosteroids are absorbed from the eye. In rabbits, corticosteroids cause fetal reabsorptions and specific disturbances, such as palatine fissure. In rabbits, corticosteroids cause fetal reabsorptions and specific disturbances involving head, ears, palate, limbs, etc.

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