GOTABiotic D®

TOBRAMYCIN 0.3%

Dexamethasone 0.1%

Naphazoline hydrochloride 0.02%

STEBILE ORTHOPHASIC SOLUTION

Made in Argentina - Rx ONLY

Qualitative-quantitative formula:
Each 100-ml solution contains:
- Tobramycin base 50 mg
- Dexamethasone 21-sodium phosphate 5 mg
- Naphazoline 21-sodium phosphate 5 mg

Benzalkonium chloride 10 mg, Disodium phosphate anhydrous; Monosodium phosphate (2D20), Sodium chloride; Purified water q.s.

Pharmacological action:
Combination of topical ophthalmic use of a steroidal anti-inflammation agent (Dexamethasone), an anti-microbial agent (Tobramycin) and a vasoconstrictor decongestive compound (Naphazline).

Product:
ATC Classification: S01C

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

Pharmacological characteristics/Properties:
Pharmacological active
Doorless ophthalmic solution is a potent steroidal anti-inflammatory agent, which suppresses the inflammatory response to a broad variety of agents. Tobramycin is an aminoglycosylic antibiotic, which is soluble in water, bactericidal, active against a broad variety of gram-positive and gram-negative ophthalmic pathogens agents.

In vitro studies demonstrate that Tobramycin is effective against the following microorganisms: Staphylococcus, including Staphylococcus aureus and Sphingobacterium epidermidis (coagulase-negative and coagula-negative) and Pseudomonas aeruginosa, Streptococcus, including some group A beta hemolytic strep; some non hemolytic species and some Strepisoplas pneumoae, Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoae, Enterobacter aerogenae, Proteus mirabilis, Morganella morgana, most Proteus vulgaris strains, Haemophilus influen- zae and H. anginosus, Moraxella lacunformae, Actinomycetes bacillus and some Neisseria species. Bacterial susceptibility studies demonstrate that, in some, microorganisms resistant to gentamycin are susceptible to Tobramycin.

Naphazoline is an eradication-type sympathetic drug with vasoconstric- tor action on the conjunctiva vascular system. It is assumed that this effect is caused by direct stimulation of the drug on alpha-adrenergic receptors in conjunctiva arterial, which causes a decreased conjunctival congestion.

Dosage and administration:
- According to medical judgment. As a guiding dosage, it is recommended to instill 1 or 2 drops into the affected eye(s) every 2 or 3 hours.

Contraindications:
- Known hypersensitivity to some components of the formula.
- Narrow angle glaucoma. Epithelial herpes simplex keratitis (dendritic keratitis).
- Valvella acute infections, Vancillia, and other cases of conjunctival viral diseases. Eye mycotic infections.

Warnings:
- Long contact use may result in intracocular hypertension and/or glaucoma with optic nerve damage, defects in visual acuity and visual field and posterior subcapsular cataact formation. Long contact use may also suppress the host immune response and increase the possibility of a secondary ocular infection. The topical use of corticoids has resulted in cornea or sclera perfora-
tions due to their increased thickness. If the product is used during ten or more days, intracocular pressure should be controlled daily. Some patients may develop hypersecretion to the aminoglycosides topical application. If a hypersensitivity reaction to Tobramycin occurs, it should be discontinued. It is recommended to remove contact lenses before applying GOTOBIOTIC D®.

- Patients under treatment with MAO inhibitors may undergo a severe hypertensive crisis if they receive a sympathomimetic agent. Naphazoline use in children, especially in the youngest ones, may cause CH de repressing causing coma and a marked reduction in body temperature. GOTOBIOTIC D® is packaged under sterile conditions. Avoid allowing the dropper tip to contact the eye, eyelids, surrounding areas or any other surface. Patients should be informed that the improper handling of the bottle may contaminate it, resulting in ocular infections. Using contaminated solu-
tions may cause severe ocular damage with subsequent vision reduction. If during the treatment any other disease develops (e.g. trauma, scalar surgery or infection), the patient should report it immediately to the doctor, in order to evaluate the benefit of continuing with the product use.

- The preservative - Benzalkonium chloride may be absorbed by soft contact lenses, these patients should wait, at least, 15 minutes after every instillation to put on the lenses.

- As with other antibiotics, long-term use may result in an excessive prolif-eration of non-susceptible microorganisms, including fungi. If superinfection occurs, appropriate therapy should be initiated. Cross-hypersensitivity development with this product, use should be discontinued and treatment must be changed. If ophthalmic topical Tobramycin is applied concomitantly with systemic antibiotics, their overall serum concentration should be controlled.

- Use the product cautiously in presence of hypertension, cardiovascular disor-
- disorders, hypoglycemia (diabetes) and hypothyroidism.

- Concomitant use of magnification or tricyclic antidepressants and Naphazoline may potentiate the Naphazoline procaine effect. Patients under treatment with MAO inhibitors may undergo a severe hypertensive crisis if receiving a sympathomimetic agent.

- Carcinogenesis - Mutagenesis - Impairment of fertility

- No long-term studies have been conducted in animals in order to evaluate the carcinogenic potential of the product.

- Pregnancy

- Dexamethasone shows teratogenic effects in female mice and rabbits after the topical ophthalmic application at high levels, therapeutic doses multiples. In mice, corticoids cause fetal reabsorptions and specific disturbances, such as palate fusion. In rabbits, corticoids cause fetal molar reabsorptions and multiple disturbances involving head, ears, limbs, etc.

- In pregnant women, well-controlled studies have not been performed. This ophthalmic product may be only used during pregnancy according to medi-
cal control and judgment, and if the potential benefit outweighs the poten-
tial risk to the fetus. Newborn infants from mothers treated with high doses of corticoids during pregnancy have suffered from hypoadrenalism signs.

- Nursing mother

- With topical application, corticosteroids are systemically absorbed. Therefore, due to the desmoxamethasone potential risk of adverse reactions on nursing infants, a decision should be made whether to discontinue nursing or to discontinue the treatment, taking into account the importance of the drug to the mother.

- Pediatric use

- Safety and effectiveness of this product have not been established in chil-
dren.

Adverse reactions:
- Intracocular hypertension. Posterior subcapsular cataact formation. Secondary eye infections due to Tobramycin-resistant pathogen agents, including herpes simplex. Final visual perforation.

- Filtering bubble may be seen rarely reported when using topical corticoids, after a cataact surgery.
- An itching or burning sensation may occur in isolated cases.

- The most frequent adverse reactions to topically applied Tobramycin are localized eye irritation and hypersensitivity, including eye-irrigating and swelling and conjunctival hyperemia. Their overall occurrence is less than 3% of patients treated with Tobramycin. Similar reactions may occur with other aminoglycoside antibiotics topical use.

- Other reported adverse reactions are:
- Ocular: myokines, discomfort, blurred vision, keratitis punctata, lacrimation.

- Systemic: dizziness, headache, nausea, sweating, nervousness, drowsiness, weakness, hyporeflexia, heart disturbances, hyperglycemia.

Overdosage:
- If an overdose occurs, go to the nearest hospital or toxicology center.

- How supplied

- Drogue bottle, containing 5 ml ophthalmic solution.

- Storage conditions

- Store below 30°C. Protect from light.

- Once the container is opened for the first time, it should be used within 4 weeks.

- Keep drugs out of reach of children.

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

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