NOVARTIS

MAXITROL

(Neomycin Sulfate 3,500IU, Polymyxin B sulphate 6,000 IU, Dexamethasone 1mg)

Sterile ophthalmic suspension and ointment

Basic Succinct Statement

CODE: BSS RD SEP 18 - APPRV 20 SEP 18

This material is only meant for Healthcare Professionals

MAXITROL

Important note: Before prescribing, consult full prescribing information.

Presentation: ♦**MAXITROL suspension:** DROP-TAINER* dispenser. 1 ml of suspension contains 1 mg dexamethasone, 3,500 (International Units) IU of neomycin sulfate and 6,000 IU polymyxin B sulfate, and 0.04 mg Benzalkonium Chloride as preservative. ♦**MAXITROL ointment:** Tube. 1 g of ointment contains 1 mg dexamethasone, 3,500 IU neomycin sulfate and 6,000 IU polymyxin B sulfate, and 0.5 mg methylparaben as well as 0.1 mg propylparaben as a preservative.

Indications: Ocular inflammation when concurrent use of an antimicrobial is judged necessary.

Dosage and administration: ♦**Suspension:** 1 to 2 drops topically in the conjunctival sac(s). In severe disease, drops may be used hourly, being tapered to discontinuation as the inflammation subsides. ♦**Ointment:** Apply a small amount into the conjunctival sac(s) up to 3 or 4 times daily or, may be used adjunctively with drops at bedtime. ♦If more than one topical ophthalmic product is being used, the products must be administered at least 5 minutes apart. Eye ointments should be administered last.

Contraindications: ♦Hypersensitivity to the active substance or to any of the excipients. ♦Herpes simplex keratitis. ♦Vaccinia, varicella, and other viral infections of cornea or conjunctiva. ♦ Fungal diseases of ocular structures or untreated parasitic eye infections. ♦Mycobacterial ocular infections.

Warnings and Precautions: ♦ Sensitivity to topically administered aminoglycosides, such as neomycin, may occur in some patients. Severity of hypersensitivity reactions may vary from local effects to generalized reactions such as erythema, itching, urticarial, skin rash, anaphylaxis, anaphylactoid reactions, or bullous reactions. If hypersensitivity develops during use of this medicine, treatment should be discontinued. ♦ Additionally, topical use of neomycin may lead to a skin sensitization. ♦ Cross-hypersensitivity to other aminoglycosides can occur, and the possibility that patients who become sensitized to topical neomycin may also be sensitive to other topical and / or systemic aminoglycosides should be considered. ♦ Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic neomycin or when applied topically to open wounds or damaged skin. Nephrotoxic and neurotoxic reactions have also occurred with systemic polymyxin B. Although these effects have not been reported following topical ocular use of this product, caution is advised when used concomitantly with systemic aminoglycoside or polymyxin B therapy. ♦Prolonged use of ophthalmic corticosteroids may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, reduced visual acuity and visual field defects, and posterior subcapsular cataract formation. In patients receiving prolonged ophthalmic corticosteroid therapy, intraocular pressure should be checked routinely and frequently. This is especially important in pediatric patients, as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults. MAXITROL is not approved for use in pediatric patients. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes). ♦Cushing's syndrome and/or adrenal suppression associated with systemic absorption of

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ophthalmic dexamethasone may occur after intensive or long-term continuous therapy in predisposed patients, including children and patients treated with CYP3A4 inhibitors (including ritonavir and cobicistat). In these cases, treatment should not be discontinued abruptly, but progressively tapered. ♦ Corticosteroids may reduce resistance to and aid in the establishment of non-susceptible bacterial, fungal, parasitic or viral infections and mask the clinical signs of infection. ♦ Fungal infection should be suspected in patients with persistent corneal ulceration. If fungal infection occurs, corticosteroids therapy should be discontinued. ♦ As with other anti-infectives, prolonged use of antibiotics such as neomycin and polymyxin B may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. ♦ Topical ophthalmic corticosteroids may slow corneal wound healing. Topical non-steroidal anti-inflammatory drugs (NSAIDs) are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems. ♦In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. ♦Contact lens wear is discouraged during treatment of an ocular inflammation or infection. ♦MAXITROL suspension contains benzalkonium chloride which may cause eye irritation and is known to discolor soft contact lenses. Avoid contact with soft contact lenses. However, if the healthcare provider considers contact lenses use appropriate, patients must be instructed to remove contact lenses prior to application of MAXITROL suspension and wait at least 15 minutes before reinsertion. ♦MAXITROL sterile ophthalmic ointment contains methylparahydroxybenzoate and propylparahydroxybenzoate which may cause allergic reactions (possibly delayed). ♦MAXITROL sterile ophthalmic ointment contains wool fat which may cause local skin reactions (e.g. contact dermatitis). ♦**Pregnancy:** There are no or limited amount of data from the use of dexamethasone, neomycin or polymyxin B in pregnant women. Aminoglycoside antibiotics, such as neomycin, do cross the placenta after intravenous dosing in pregnant women. Non-clinical and clinical systemic exposure to aminoglycosides has been shown to induce ototoxicity and nephrotoxicity. At the low dose administered via this topical product, neomycin is not expected to cause ototoxicity or nephrotoxicity from in utero exposure. In a rat study where animals were orally administered neomycin at up to 25 mg/kg bw/day, no evidence of maternal toxicity, fetotoxicity or teratogenicity was observed. Prolonged or repeated corticoid use during pregnancy has been associated with an increased risk of intra-uterine growth retardation. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism. Studies in animals have shown reproductive toxicity after systemic and ocular administration of dexamethasone. There is no data available regarding the safety of polymyxin B in pregnant animals. MAXITROL is not recommended during pregnancy.♦**Breast-feeding:** It is unknown whether topical ophthalmic dexamethasone, neomycin or polymyxin B are excreted in human milk. Aminoglycosides are excreted in human milk after systemic administration. No data is available on the passage of dexamethasone and polymyxin B into human breast milk. However, it is likely that the amount of dexamethasone, neomycin and polymyxin B would not be detectable in human milk and would not be capable of producing clinical effects in the infant following appropriate maternal use of this topical product. A risk to the breastfed child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue or abstain from therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. ♦**Fertility:** There are no available data on the use of

neomycin or polymyxin B affecting male or female fertility. There is limited clinical data to evaluate the effect of dexamethasone on male or female fertility. Dexamethasone was free of adverse effects on fertility in a chorionic gonadotropin primed rat model. ♦**Ability to drive and use machines**: Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient must wait until the vision clears before driving or using machinery.

Adverse drug reactions: The following adverse reactions have been reported during clinical studies with MAXITROL and are classified according to the following convention: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥1/1,000 to < 1 / 100), rare (≥ 1/10,000 to < 1/1,000), and very rare (< 1 / 10,000). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. ♦**Uncommon:** keratitis, intraocular pressure increased, eye pruritus, ocular discomfort, eye irritation. ♦**Post-Marketing Surveillance [frequency cannot be estimated from the available data]:** hypersensitivity, headache, Stevens-Johnson syndrome, *[in order of decreasing seriousness]:* ulcerative keratitis, vision blurred, photophobia, mydriasis, eyelid ptosis, eye pain, eye swelling, foreign body sensation in eyes, ocular hyperaemia, lacrimation increased.

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