NOVARTIS

TOBRADEX® (tobramycin 0.3% and dexamethasone 0.1%)

3mg/mL and 1mg/mL sterile ophthalmic suspension and ointment

Basic Succinct Statement

CODE: BSS PI RD 22 MAR 19; APPR 12 DEC 19

This material is only meant for Healthcare Professionals

TOBRADEX®

Important note: Before prescribing, consult full prescribing information.

Presentation: ♦**Suspension:** DROP-TAINER dispenser. Each ml of suspension contains 3 mg tobramycin, 1 mg dexamethasone and 0.1 mg Benzalkonium Chloride as a preservative. ♦**Ointment:** 3.5g ophthalmic tube. Each gram of ointment contains 3 mg tobramycin, 1 mg dexamethasone and 5 mg chlorobutanol as a preservative.

Indications: Steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.

Dosage and administration: ♦**Suspension:** One or two drops instilled into the conjunctival sac(s) every four to six hours. During the initial 24 to 48 hours, the dosage may be increased to one or two drops every 2 hours. Frequency should be decreased gradually as warranted by improvement in clinical signs. Care should be taken not to discontinue therapy prematurely. ♦**Ointment:** Apply a small amount (approximately 1/2 inch ribbon) into the conjunctival sac(s) up to three or four times daily. ♦TOBRADEX Ophthalmic Ointment may be used adjunctively with drops at bedtime.

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

Warnings and Precautions: ♦Gently closing the eyelid and nasolacrimal occlusion after instillation is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic side effects. ♦Sensitivity to topically administered aminoglycosides 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. ♦Cross-hypersensitivity to other aminoglycosides can occur, and the possibility that patients who become sensitized to topical tobramycin 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 aminoglycoside therapy. Caution is advised when used concomitantly. ♦ Use caution in patients with known or suspected neuromuscular disorders such as myasthenia gravis or Parkinson disease; aminoglycosides may aggravate muscle weakness. ♦Prolonged use of topical 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. TOBRADEX® Ophthalmic Suspension and Ointment 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 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 bacterial, viral or fungal or parasitic 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. ♦Prolonged use of antibiotics such as tobramycin may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated. ♦Topical ophthalmic corticosteroids may slow corneal wound healing. Topical 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 not recommended during treatment of an ocular inflammation or infection. TOBRADEX® Ophthalmic Suspension contains benzalkonium chloride which may cause eye irritation and is known to discolor soft contact lenses. Avoid contact with soft contact lenses. In case patients are allowed to wear contact lenses, they must be instructed to remove contact lenses prior to application of TOBRADEX® Ophthalmic Suspension and wait at least the 15 minutes before reinsertion. ♦**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: ♦**Uncommon (≥0.1 to <1%):** intraocular pressure increased, eye pain, eye pruritus, ocular discomfort, eye irritation ♦**Rare (≥0.01 to <0.1%):** keratitis, eye allergy, vision blurred, dry eye, ocular hyperaemia, dysgeusia ♦**Unknown:** anaphylactic reaction, hypersensitivity, dizziness, headache, eyelid oedema, erythema of eyelid, mydriasis, lacrimation increased, nausea, abdominal discomfort, erythema multiforme, rash, swelling face, pruritus