NOVARTIS

TOBREX® (tobramycin 0.3%)

3mg/mL sterile ophthalmic solution

Basic Succinct Statement

CODE : BSS RD 22 MAR 19; APPR 03 DEC 19

This material is only meant for Healthcare Professionals

TOBREX®

Important note: Before prescribing, consult full prescribing information.

Presentation: DROP-TAINER Dispenser. Each ml of suspension contains Tobramycin 0.3% and 0.01% Benzalkonium Chloride as a preservative.

Indications: Treatment of external infections of the eye and its adnexa caused by susceptible bacteria.

Dosage and administration: ♦**Use in mild to moderate disease:** instill one or two drops into the affected eye(s) every four hours. ♦**Use in severe infections:** instill two drops into the eye(s) hourly until improvement, following which treatment should be reduced prior to discontinuation.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: ♦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 ocular 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 tobramycin therapy. Caution is advised when used concomitantly. ♦Caution should be exercised when prescribing Tobrex Eye Drops to patients with known or suspected neuromuscular disorders such as myasthenia gravis or Parkinson's disease. Aminoglycosides may aggravate muscle weakness because of their potential effect on neuromuscular function. ♦As with other antibiotic preparations, prolonged use of TOBREX Ophthalmic Solution may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated. ♦**Contact lenses:** Contact lens wear is not recommended during treatment of an ocular infection. TOBREX Ophthalmic Solution contains benzalkonium chloride which may cause eye irritation and is known to discolour 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 this product and wait at least 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 at application, 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 trials TOBREX Ophthalmic Solution and are classified according to the subsequent 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. ♦**Common:** ocular discomfort, ocular hyperaemia ♦**Uncommon:** hypersensitivity, headache, keratitis, corneal abrasion, visual impairment, vision blurred, erythema of eyelid, conjunctival oedema,

eyelid oedema, eye pain, dry eye, eye discharge, eye pruritus, lacrimation increased, urticaria, dermatitis, madarosis, leukoderma, pruritus, dry skin ♦**Post-marketing surveillance:** anaphylactic reaction, eye allergy, eye irritation, eyelids pruritus, Stevens-Johnson syndrome, erythema multiforme, rash