NOVARTIS

VIGAMOX (moxifloxacin hydrochloride 0.5%)

Ophthalmic solution

Basic Succinct Statement

CODE: BSS SN00081-1016; APPR 25 JUL 16

This material is only meant for Healthcare Professionals

VIGAMOX*

Important note: Before prescribing, consult full prescribing information.

Presentation: 5ml DROP-TAINER*. Each mL of solution contains 5.45 mg moxifloxacin hydrochloride equivalent to 5 mg moxifloxacin base. May also contain hydrochloric acid/sodium hydroxide to adjust pH.

Indications: For the treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of the following organisms : ♦**Gram-positive bacteria:** *Corynebacterium* species†, *Microbacterium* species, *Micrococcus luteus*† [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains], *Staphylococcus aureus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains], *Staphylococcus epidermidis* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains], *Staphylococcus haemolyticus* [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains], *Staphylococcus hominis*† [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains], *Staphylococcus warneri*† [including erythromycin resistant strains], *Streptococcus mitis*† [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains] Streptococcus pneumoniae [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains], *Streptococcus viridans* [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]; ♦**Gram-negative bacteria:** *Acinetobacter* species, *Haemophilus "alconae"* [including ampicillin resistant strains] Haemophilus influenzae [including ampicillin resistant strains], *Klebsiella pneumoniae*†, *Moraxella catarrhalis*†, *Pseudomonas aeruginosa**; ♦**Other microorganisms:** *Chlamydia trachomatis* *(†Efficacy for this organism was studied in fewer than 10 infections. Preoperative and postoperative sterilization (when prophylactic antibiotic treatment is required).*

Dosage and administration: ♦Instill one drop in the affected eye 3 times a day for 7 days. ♦**For preoperative and postoperative sterilization:** Usually, instill one drop in the affected eye(s) 5 times per day before operation and 3 times per day after operation.

Contraindications: Hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

Warnings and Precautions: ♦For ocular use only. Not for injection. VIGAMOX Solution should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye. In patients receiving systemically administered quinolones, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated. As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein

staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis. Tendon inflammation and rupture may occur with systemic fluoroquinolone therapy including moxifloxacin, particularly in elderly patients and in those treated concurrently with corticosteroids. Therefore, treatment with VIGAMOX Solution should be discontinued at the first sign of tendon inflammation. ♦Avoid contaminating the applicator tip with material from the eye, fingers or other source. Systemically administered quinolones have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction. ♦**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: ♦**Common (1 to 10%):** eye pain, eye irritation ♦**Uncommon (0.1 to 1%):** headache, punctate keratitis, dry eye, conjunctival haemorrhage, ocular hyperaemia, eye pruritus, eyelid oedema, ocular discomfort (burning/stinging), dysgeusia. ♦**Rare (0.01 to 0.1%):** haemoglobin decreased, paresthesia, corneal epithelium defect, corneal disorder, conjunctivitis, blepharitis, eye swelling, conjunctival oedema, vision blurred, visual acuity reduced, asthenopia, erythema of eyelid, nasal discomfort, pharyngolaryngeal pain, sensation of foreign body (throat), vomiting, alanine aminotransferase increased, gamma- glutamyltransferase increased ♦**Not known:** ulcerative keratitis, keratitis, lacrimation increased, photophobia, eye discharge, erythema, pruritus, rash, urticaria, dizziness**,** hypersensitivity, palpitations**,** dyspnoea, nausea.

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