NOVARTIS

MAXIDEX (dexamethasone 0.1%)

1mg/mL sterile ophthalmic suspension

Basic Succinct Statement

CODE: BSS RD 21 JAN 18; APPR 08 FEB 19

This material is only meant for Healthcare Professionals

MAXIDEX

Important note: Before prescribing, consult full prescribing information.

Presentation: DROP-TAINER* dispenser. Each ml of suspension contains 1 mg dexamethasone and 0.1 mg Benzalkonium Chloride as a preservative.

Indications: Management of conditions generally responsive to corticosteroids such as: ♦**Certain inflammatory eye conditions of the anterior segment:** acute and chronic anterior uveitis, iridocyclitis, iritis and cyclitis, herpes zoster ophthalmicus. ♦**Certain external diseases:** phlyctenular kerato-conjunctivitis, non-purulent conjunctivitis, including vernal, allergic, catarrhal. It is very effective where allergy is a main factor. ♦Recurrent marginal ulceration of toxic or allergic etiology. ♦Thermal and chemical burns. ♦Post-operatively to reduce inflammatory reactions.

Dosage and administration: Topical application (1 or 2 drops in the conjunctival sac). ♦**Use in severe or acute inflammation:** Every 30 to 60 minutes as initial therapy, reducing the dosage when favourable response is observed to every 2 to 4 hours. Further reduction may be made to 1 drop 3 or 4 times daily if sufficient to control inflammation. If favourable response is not obtained in 3 to 4 days, additional systemic or conjunctival therapy may be indicated. ♦**Use in chronic inflammation:** Every 3 to 6 hours, or as frequently as necessary. Being tapered to discontinuation as inflammation subsides. ♦**Use in allergies or minor inflammation**: Every 3 to 4 hours until the desired response is obtained. Being tapered to discontinuation as inflammation subsides.

Contraindications: ♦Hypersensitivity to the active substance or to any of the excipients.♦Acute, untreated bacterial infections. ♦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: ♦Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions. ♦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. MAXIDEX 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, fungal or parasitic infections and mask the clinical signs of infection.

♦Fungal infection should be suspected in patients with persistent corneal ulceration. Corticosteroids therapy should be discontinued if fungal infection occurs. ♦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. The wearing of contact lenses is discouraged during treatment of an ocular inflammation. MAXIDEX ophthalmic suspension contains benzalkonium chloride which may cause eye irritation and is known to discolour 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 MAXIDEX ophthalmic suspension 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 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 trials with MAXIDEX ophthalmic suspension 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), very rare (<1/10,000). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. ♦**Common:** ocular discomfort. ♦**Uncommon**: dysgeusia, keratitis, conjunctivitis, dry eye, vital dye staining cornea present, photophobia, vision blurred, eye pruritus, foreign body sensation in eyes, lacrimation increased, abnormal sensation in eye, eyelid margin crusting, eye irritation, ocular hyperaemia. • Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data. Within each System Organ Class adverse reactions are presented in order of decreasing seriousness. ♦**Not known:** hypersensitivity, Cushing's syndrome, adrenal insufficiency, dizziness, headache, glaucoma, ulcerative keratitis, intraocular pressure increased, visual acuity reduced, corneal erosion, eyelid ptosis, eye pain, mydriasis.