

## NEW ZEALAND DATA SHEET

### 1. PRODUCT NAME

Maxidex™ dexamethasone 0.1% sterile ophthalmic suspension

Maxidex™ dexamethasone 0.1% sterile ophthalmic ointment.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of Maxidex Ophthalmic Suspension contains Dexamethasone 1 mg.

Each g of Maxidex Ophthalmic Ointment contains Dexamethasone 1 mg.

#### Excipient with known effect

Eye Drops: Benzalkonium chloride 0.1 mg in 1.0 mL (0.01%) as a preservative.

Eye Ointment: Methyl hydroxybenzoate 0.5 mg in 1 g (0.05%) as a preservative

Propyl hydroxybenzoate 0.1 mg in 1 g (0.01%) as a preservative.

For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Eye drops, suspension.

Eye ointment.

### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic indications

Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe. These include allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivides when the inherent hazard of steroid use is accepted to obtain an advisable diminution in oedema and inflammation, corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies. May be used to suppress graft reaction after keratoplasty.

#### 4.2. Dose and method of administration

##### Maxidex Ophthalmic Suspension

Shake well before using.

Topical application: One or two drops in the conjunctival sac.

##### *Severe or Acute Inflammation*

Every 30 to 60 minutes as initial therapy, reducing the dosage when favorable response is observed to every two to four hours. Further reduction may be made to one drop three or four times daily if sufficient to control inflammation. If favorable response is not obtained in three to four days, additional systemic or conjunctival therapy may be indicated.

##### *Chronic Inflammation*

Every three to six hours, or as frequently as necessary.

##### *Allergies or Minor Inflammation*

Every three to four hours until the desired response is obtained.

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.

If more than 1 topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Ointments should be administered last.

#### Maxidex Eye Ointment

Apply ribbon of ointment into the conjunctival sac(s) up to four times daily. When a favorable response is observed, dosage may be reduced gradually to once a day application for several days.

#### **4.3. Contraindications**

Contraindicated in epithelial herpes simplex (dendritic keratitis), vaccinia, varicella, and most other viral diseases of the cornea and conjunctiva; tuberculosis of the eye; fungal disease of ocular structures or untreated parasitic eye infections; mycobacterial ocular infections; acute purulent untreated infections which like other diseases caused by microorganisms, may be masked or enhanced by the presence of the steroid.

Hypersensitivity to dexamethasone, the active substance, or to any of the excipients listed under Section 6.1. List of excipients.

#### **4.4. Special warnings and precautions for use**

For topical use only.

Prolonged use may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. In acute purulent conditions of the eye, corticosteroids may mask infection or enhance existing bacterial, viral or fungal infection. If these products are used for 10 days or longer, intraocular pressure should be routinely and frequently monitored even though it may be difficult in children and uncooperative patients. This is especially important in paediatric patients, as the risk of corticosteroid-induced ocular hypertension may be greater in children and may occur earlier than in adults. Maxidex Eye Drops and Ointment are not approved for use in paediatric 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 infections.

Employment of corticosteroid medication in the treatment of herpes simplex other than epithelial herpes simplex keratitis in which it is contraindicated requires great caution and only in conjunction with antiviral therapy; periodic slit-lamp microscopy is essential. The extensive use of steroids may cause systemic side effects and ocular herpes simplex has occurred in patients under systemic or local corticosteroid therapy for other conditions.

The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid dosing and 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.

During the course of therapy, if the inflammatory reaction does not respond within a reasonable period, other forms of therapy should be instituted.

Individuals may be sensitive to one or more of the components of this product. If any reaction indicating sensitivity is observed, discontinue use.

Maxidex Eye Drops 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 Maxidex Eye Drops and wait at least 15 minutes before reinsertion.

Maxidex Eye Ointment contains methyl parahydroxybenzoate (methyl paraben) and propyl parahydroxybenzoate (propyl paraben) which may cause allergic reactions (possibly delayed).

### **Visual Disturbance**

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

### **Patient Warning**

No contact lenses should be worn under Maxidex treatment.

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

### **Paediatric use**

Safety and effectiveness in paediatric patients have not been established.

### **Use in the elderly**

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

### **Renal and hepatic impairment**

The safety and efficacy of Maxidex in patients with hepatic or renal impairment have not been established.

## **4.5 Interactions with other medicinal products and other forms of interactions**

Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems.

CYP3A4 inhibitors including ritonavir and cobicistat may increase systemic exposure resulting in increased risk of adrenal suppression/Cushing's syndrome. (See Section 4.4). The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid effects.

#### **4.6 Fertility, pregnancy and lactation**

##### **Pregnancy**

Pregnancy Category B3.

There are no adequate or well-controlled studies in pregnant women. 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. Maxidex Eye Drops and Ointment are not recommended during pregnancy.

Animal reproductive studies are included in Section 5.3. Preclinical safety data.

##### **Breast-feeding**

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. A risk to the suckling child cannot be excluded.

Because many drugs are excreted in human milk, caution should be exercised when Maxidex is administered to a nursing woman. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Maxidex therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

##### **Fertility**

Studies have not been performed to evaluate the effect of topical ocular administration of dexamethasone on fertility. There is limited clinical data to evaluate the effect of dexamethasone on male or female fertility.

#### **4.7 Effects on ability to drive or use machines**

As with any topical ophthalmic medicinal product, 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.

#### **4.8 Undesirable effects**

Glaucoma with optic nerve damage, visual acuity and field defects, cataract formation, secondary ocular infection following suppression of host response; and perforation of the globe may occur.

##### **Post-marketing events**

The following adverse reactions are classified according to the following convention: very common, common, uncommon, rare, very rare, or not known (cannot be estimated from the available data), according to system organ classes. Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. The adverse

reactions have been observed during clinical trials and post-marketing experience with Maxidex Eye Drops and/or Eye Ointment.

#### *Eye disorders*

Common (> 1% to < 10%): ocular discomfort.

Uncommon (> 0.1% to ≤ 1%): keratitis, conjunctivitis, keratoconjunctivitis sicca, corneal staining, photophobia, vision blurred (see Section 4.4 Special Warnings and Precautions for Use), eye pruritus, foreign body sensation in eyes, lacrimation increased, abnormal sensation in eye, eyelid margin crusting, eye irritation, ocular hyperaemia.

Not Known: glaucoma, ulcerative keratitis, intraocular pressure increased, visual acuity reduced, corneal erosion, eyelid ptosis, eye pain, mydriasis.

#### *Immune system disorders*

Not Known: hypersensitivity.

#### *Nervous system disorders*

Uncommon (> 0.1% to ≤ 1%): dysgeusia.

Not Known: dizziness, headache.

#### *Endocrine disorders*

Not Known: Cushing's syndrome, adrenal insufficiency.

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting>.

### **4.9 Overdose**

An ocular overdose of Maxidex can be flushed from the eye(s) with lukewarm water. Treatment of any overdose is symptomatic and supportive.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic Group: Ophthalmologicals: Anti-inflammatory Agents, ATC Code S01B A01.

#### **Mechanism of action**

Dexamethasone is a potent synthetic corticosteroid. It has been demonstrated by animal and human studies based on an oral application to possess approximately six to seven times the potency of prednisolone and at least 30 times the potency of cortisone. The potency of this compound is accomplished by the addition of a methyl radical and a fluorine atom to the prednisolone radical.

#### **Pharmacodynamic effects**

No information available.

#### **Clinical efficacy and safety**

No information is available.

## **5.2 Pharmacokinetic properties**

No information is available.

## **5.3 Preclinical safety data**

### **Pregnancy**

Studies in animals have shown reproductive toxicity. The ocular administration of 0.1% dexamethasone also resulted in fetal anomalies in rabbits.

### **Carcinogenicity, fertility**

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of Maxidex.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

#### Eye drops, suspension

Benzalkonium chloride

Hypromellose

Sodium chloride

Dibasic anhydrous sodium phosphate

Polysorbate 80

Disodium edetate

Citric acid and/or sodium hydroxide (to adjust pH)

Purified water.

#### Eye ointment

Methyl hydroxybenzoate as a preservative

Propyl hydroxybenzoate as a preservative

Lanolin oil

White soft paraffin.

### **6.2 Incompatibilities**

Not known.

### **6.3 Shelf life**

#### Eye drops, suspension

18 months.

#### Eye ointment

36 months.

### **6.4 Special precautions for storage**

#### Eye drops, suspension

Store below 25° C.

Do not freeze.

Discard container 4 weeks after opening.

Eye Ointment

Store below 25° C.

Do not refrigerate.

Discard container 4 weeks after opening.

**6.5 Nature and contents of container**

Eye drops suspension

5 mL and 10 mL Drop-Tainer™ dispenser

Eye Ointment

3.5 g aluminium tube

**6.6 Special precautions for disposal**

No special requirements for disposal.

**7. MEDICINE SCHEDULE**

Prescription Only Medicine

**8. SPONSOR**

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335

**9. DATE OF FIRST APPROVAL**

Eye Drops: 31 December 1969

Eye Ointment: 4 February 1981

**10. DATE OF REVISION OF THE TEXT**

21 July 2020

**SUMMARY TABLE OF CHANGES**

Section	Summary of Changes
8 Sponsor	Update to Sponsor address