MAXIDEX®
Dexamethasone 0.1% sterile ophthalmic suspension and ointment

Presentation
MAXIDEX® is an adrenocortical steroid prepared as a sterile, topical ophthalmic suspension and ointment.

Ophthalmic Suspension
Each mL contains:
Active: Dexamethasone 0.1%.
Preservative: Benzalkonium Chloride 0.01%. Vehicle: Hydroxypropyl Methylcellulose 0.5%.
Inactives: Sodium Chloride, Dibasic Anhydrous Sodium Phosphate, Polysorbate 80, Edetate Disodium, Citric Acid and/or Sodium Hydroxide (to adjust pH). Purified Water.

Ophthalmic Ointment.
Each gram contains:
Active: Dexamethasone 0.1%.
Preservatives: Methyl Paraben 0.05% and Propyl Paraben 0.01%. Inactive: Mineral Oil, White Petrolatum.

Uses

Actions
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 cortisol. The potency of this compound is accomplished by the addition of a methyl radical and a fluorine atom to the prednisolone radical.

Pharmacokinetics
Nil.

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 conjunctivitides 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.

Dosage and Administration
MAXIDEX 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 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.

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 micro-organisms, may be masked or enhanced by the presence of the steroid; hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions
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 ritonavir. 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).

**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.

**Carcinogenesis, Mutagenesis, Impairment of 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. Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of MAXIDEX*.

**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. Studies in animals have shown reproductive toxicity. The ocular administration of 0.1% dexamethasone also resulted in foetal anomalies in rabbits. MAXIDEX Eye Drops and Ointment is not recommended during pregnancy.

**Nursing Mothers**

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.

**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.

**Effects on Ability to Drive and 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.

**Adverse 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, 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

**Interactions**

Concomitant use of topical steroids and topical NSAIDs may increase the potential for corneal healing problems.
In patients treated with ritonavir, plasma concentrations of dexamethasone may be increased.

**Overdosage**

An ocular overdose of MAXIDEX® can be flushed from the eye(s) with lukewarm water. Treatment of any overdose is symptomatic and supportive. In New Zealand call 0800 POISON or 0800 764 766 for advice on management.

**Pharmaceutical Precautions**

Keep out of reach of children.
Store below 25°C.
Do not refrigerate Maxidex Eye Ointment.
Do not freeze Maxidex Eye Drops.
Discard 4 weeks after opening.

**Medicine Classification**

Prescription Medicine.

**Package Quantities**

MAXIDEX Suspension in 5 mL and 10 mL sterile DROP-TAINER® dispenser. MAXIDEX Ointment in 3.5 g ointment tube.

**Further Information**

The active ingredient is represented by the chemical structure:

![Chemical structure](image)

Chemical name: Pregna-1,4-diene-3, 20-dione, 9-fluoro-11, 17, 21-trihydroxy-16-methyl-(11β, 16α)-.
Name and Address
Pharmaco (NZ) Ltd
4 Fisher Crescent
Auckland 1060 New Zealand

Date of Preparation
February 2016

* a trademark of Novartis
(c) 2016 Novartis