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 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 cortisone. 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.

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; 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 monitored even though it may be difficult in children and uncooperative patients.

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 silt-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.

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.

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.

Pregnancy
Pregnancy Category B3.
There are no adequate or well-controlled studies in pregnant women. Studies in animals have shown reproductive toxicity. 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.

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

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: 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

Interactions
No interactions studies have been performed

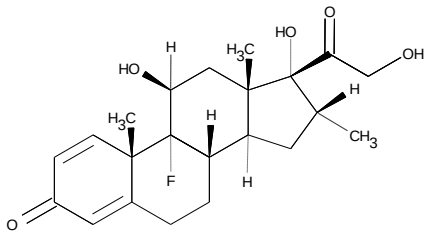
Overdosage
An ocular overdose of MAXIDEX can be flushed from the eye(s) with lukewarm water. Treatment of any overdose is symptomatic and supportive.

Pharmaceutical Precautions
Keep out of reach of children.
Store at or below 25°C.
Discard 4 weeks after opening.

Medicine Classification
Prescription Medicine.

Package Quantities
MAXIDEX Suspension in 5 mL and 15 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 name: Pregna-1,4-diene-3, 20-dione,9-fluoro-11, 17, 21-trihydroxy-16-methyl-,(11 ß, 16α)-.

Name and Address
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Date of Preparation
23 August 2011

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