Dexamethasone 0.1% eye drops

Newborn use only

2022

Alert	There is a lack of data on the safety and efficacy of dexamethasone drops in neonates for ocular conditions. They are extrapolated from paediatric and adult population. Dexamethasone can delay epithelial healing and may even worsen infection.
Indication	1. Post-operative therapy following ocular surgeries including laser photocoagulation. 2. Steroid amenable inflammatory conditions of the conjunctiva, cornea and anterior segment of the eye. 3. Corneal injury from chemical, thermal burns or penetration of foreign bodies.
Action	Dexamethasone is a synthetic analog of naturally occurring glucocorticoids. It reduces inflammation, thereby reducing scarring, neovascularization and corneal stromal melt.
Drug type	Glucocorticoid
Trade name	Maxidex, Dexamethasone sodium phosphate Minims
Presentation	Maxidex 0.1% (containing 1mg/mL dexamethasone) eye drops (suspension) Dexamethasone sodium phosphate 0.1% Minims (preservative free) – available under SAS scheme.
Dose	Prescribe only in consultation with treating ophthalmologist. Dose depends on the indication and severity of the condition. **Post laser photo-coagulation:** 1 drop 8 hourly.[1,2] **Post cataract surgery:** 1 drop 6 hourly.[3] **Herpetic stromal keratitis:** 1 drop 6 hourly.[4-6] **Non-infectious inflammatory eye conditions and corneal injury:** 1-2 drops every 1-2 hours. Reduce dosage when a favourable response is observed.[7-10]
Dose adjustment	Not applicable
Maximum dose	
Total cumulative dose	
Route	Topical
Preparation	Not applicable
Administration	Shake the bottle well before use. Do not let the tip of the dropper touch the eye. Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart.
Monitoring	Eye check as per the ophthalmologist advice
Contraindications	Hypersensitivity to dexamethasone or to any of the excipients. Acute and untreated viral, bacterial, fungal or mycobacterial diseases of cornea and conjunctiva except herpes zoster keratitis.
Precautions	Prolonged use may result in cataract and ocular hypertension/glaucoma with damage to the optic nerve. Cushing's syndrome and/or adrenal suppression associated with systemic absorption may occur after intensive or long-term continuous therapy in predisposed patients, including treatment with CYP3A4 inhibitors (ritonavir and cobicistat). Corneal wounds – Healing may be delayed.
Drug interactions	Concomitant use of topical steroids and topical NSAIDs may cause additive delay in corneal healing.
Adverse reactions	Local: Ocular discomfort, keratitis, conjunctivitis, photophobia, ocular hyperaemia, ocular hypertension/glaucoma and posterior subcapsular cataract. Systemic: hypertension, irritability, adrenal suppression, Cushing's syndrome.
Compatibility	Not applicable
Incompatibility	Not applicable
Stability	Maxidex: Discard 4 weeks after opening. Minims: Single use - discard after opening.
Storage	Do not store above 25°C. Do not refrigerate or freeze. Keep container tightly closed. Store in original container to protect from light (Minims)
Excipients	Maxidex: Dibasic anhydrous sodium phosphate, polysorbate 80, disodium edetate, sodium chloride, hypromellose, purified water, benzalkonium chloride (0.1 mg/mL), citric acid monohydrate and/or sodium hydroxide. Minims: Purified water, anhydrous disodium hydrogen phosphate, sodium dihydrogen phosphate dehydrate, disodium edetate.
Special comments	

Evidence	**Efficacy** **<u>Retinopathy of Prematurity (ROP)</u>** Topical steroids are commonly administered after laser for ROP to reduce inflammation and to decrease the risk of post-laser posterior synechiae. [1] However, there is very little data from controlled studies. In a cohort of 48 infants, Öhnell et al. reported significantly lower need for laser surgery (26%) in infants with Type 2 ROP without plus disease if dexamethasone eye drops were used for a mean duration of 28 days compared to 76% in the placebo group.[2] **<u>Post-cataract surgery</u>** Self et al. reviewed the practice of postoperative management following surgery for cataract in 388 eyes across five large UK centres. Topical corticosteroids were routinely used in a tapering dose regimen, usually over 4–6 weeks. The age of patients in the review ranged from 2 months to 16 months.[3] **<u>Herpes simplex keratitis</u>** In a placebo-controlled trial, topical corticosteroid therapy reduced the risk of persistent or progressive stromal keratouveitis by 68%. The time to resolution of stromal keratitis and uveitis was significantly shorter in the steroid group (26 vs 72 days; p <0.001). However, no differences in visual outcome or recurrent herpetic eye disease were identified between the groups.[4] **<u>Varicella keratitis</u>** In a retrospective review of 8 eyes (7 children) Denier et al. used topical dexamethasone eye drops with oral acyclovir to treat stromal keratitis after varicella infection. The median duration of tapering topical steroid eye drop regimen was 26 months. At the end of follow-up (median 31 months) all patients regained a best-corrected visual acuity of 20/20.[5] **<u>Bacterial keratitis and corneal ulcer</u>** In a systematic review of four RCTs to evaluate the benefits of topical corticosteroids as adjunctive therapy for bacterial keratitis in adults, Herretes et al. noted no difference in time to re-epithelialization or visual outcomes in the steroid arm. There was not enough evidence in this review to support the use of adjuvant steroids in bacterial keratitis and corneal ulcer.[11] However, a separate publication of the post-hoc analysis of an RCT stratified early (< 4 days) and late (> 4 days) commencement of steroids and severity of condition and found significant improvements in visual acuity in participants with severe but not in moderate and mild keratitis.[6] **<u>Non-infectious inflammatory conditions and corneal injury</u>** A dose tapering schedule starting at 1-2 hourly dexamethasone drops and weaning over one month was used for non-inflammatory conditions of the anterior segment of eye.[7-10] **Safety** Aly et al. studied 20 infants with bilateral congenital cataract who received topical dexamethasone eye drops for 6 weeks in addition to single subconjunctival injection at the end of surgery. There was a statistically significant increase in the weight, systolic and diastolic blood pressure and a statistically significant reduction in both the morning and afternoon serum ACTH levels.[12] Similarly, in another retrospective study of 26 children by Bangsgaard et al., 10 developed adrenal suppression, 2 developed Cushing's syndrome and 1 developed Addisonian crisis during general anaesthesia.[13] **Pharmacokinetics** The bioavailability of a topical medicine depends on the drug formulation, drop size, and the patient. At the most 5% of a drug applied topically enters the ocular structures.[14] In one study, the mean dexamethasone concentrations in the aqueous humour, vitreous, and serum were 30.5 ng/mL, 1.1 ng/mL and 0.7 ng/mL respectively following topical application of 0.1% dexamethasone disodium phosphate.[15] Higher steroid concentration in topical preparations, increasing ocular contact time, inflammation and injury to corneal epithelium increase corneal and aqueous humour concentrations of steroid.[16] The membranes in the eyes of newborns and infants are thin and corneal permeation may be more rapid compared to older age groups. The age-related lower tear volume in neonates can lead to topical medications becoming concentrated in the eye.[17] It is estimated that a newborn requires only one-half of the adult dosage of eye drops to obtain an equivalent ocular concentration.[18] Consequently, neonates are subject to much higher risks of systemic side effects compared to older age groups.
Practice points	
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