

Addendum May 2023

Hydrocortisone sodium phosphate (Softacort) eye drops for treatment of mild non-infectious allergic or inflammatory conjunctival diseases NMR – additional information

RAG Recommendation = RED

Following a request and further information received from Mr Ahmed Gomaa, Cornea consultant at Blackpool Victoria Hospital, MLCSU have reviewed the initial NMR presented to LSCMMG in October 2022 with a RED RAG recommendation.

The original MLCSU RED RAG recommendation continues and we ask LSCMMG to review the allocated BLACK RAG rating with respect to the new information provided.

Softacort are presented as a preservative free single use eyedrop at a cost of £10.99 for 30 unit doses¹. The recommended dosage is 2 drops, 2 to 4 times daily, in the affected eye. The duration of this dosing regimen will generally vary from a few days to a maximum of 14 days.

Assuming maximal use ie 4 x 14 =56, then 2 x 30 (60) will be prescribed and the cost per course will be **£21.98**.

Unit dose eyedrops (preservative free) are the preferred form of treatment for patients with allergic or inflammatory conjunctival disease, as preservatives can harm corneal and conjunctival epithelial cells. Solutions with preservatives also have greater penetration than those without, as the preservative disrupts tight junctions between corneal epithelial cells. Preservative-free eye drops cause the least disruption to the ocular surface at both clinical and cellular levels.²

Other unit dose, preservative free, steroid eyedrops are available and costs for the equivalent course are:

- Minims Prednisolone Sodium Phosphate 0.5% w/v, Eye drops solution - £13.50 for 20 unit doses - for 60 units ie 3 x 20 cost = **£40.50**
- Dexafree (Dexamethasone Phosphate 0.1% w/v Eye Drops, Solution) - £11.53 for 20 unit doses - for 60 units ie 3 x 20 cost = **£34.59**
- Dropodex (Dexamethasone Phosphate 0.1% w/v Eye Drops, Solution) - £11.53 for 20 unit doses - for 60 units ie 3 x 20 cost = **£34.59**
- Eythalm (Dexamethasone Phosphate 0.1% w/v Eye Drops, Solution) - £11.53 for 20 unit doses - for 60 units ie 3 x 20 cost = **£34.59**
- Minims Dexamethasone sodium phosphate 0.1% w/v, Eye drops solution - £11.46 for 20 unit doses - for 60 units ie 3 x 20 cost = **£34.38¹**

Softacort is therefore the least expensive of the preservative free unit dose steroid eyedrops available.

The use of steroids can lead to significant ocular side effects.

Intraocular pressure (IOP) elevation following steroid use is well- documented³. Steroids are known to induce ocular hypertension when administered with topical, periocular, and even systemic or inhalational routes. IOP rise after steroid therapy occurs more frequently with topical administration than systemic administration. The IOP rise may occur with drops or ointment applied directly to the eye or over the skin of the eyelids. Normal individuals

classified as high steroid responders are more likely to develop Primary Open Angle Glaucoma (POAG).

In general, the pressure-inducing effect of steroids is directly proportional to its anti-inflammatory potency.

Other available topical ocular steroids include:

- prednisolone acetate 1% (most potent)
- dexamethasone 0.1%
- betamethasone 0.1%
- prednisolone sodium phosphate 0.5%
- fluorometholone 0.1% (least potent)

Hydrocortisone is the least potent steroid available for ophthalmic use, dexamethasone is approximately 25 to 30 times intrinsically more potent than hydrocortisone.⁴

Clinical trials have shown Softacort to cause minimal IOP increase.

Pleyer et al (2013)⁵

Amongst other things this review looked at the effect of topical corticosteroids in patients deemed as steroid responders. These are patients who have a documented history of IOP increase in response to corticosteroid treatment, in which a small dose of corticosteroid or a short duration of treatment may result in a disproportionate increase in IOP. Steroid responders generally constitute 18-36% of the general population. The review found that when used in steroid responders, of the various commonly used corticosteroids, dexamethasone 0.1% caused the maximum increase in IOP and hydrocortisone 0.5% the least.

Kallab et al (2019)⁶

IOP did not change at the end of the treatment period in either the intense dose (baseline, 14.1 ± 1.8 ; day 14, 13.9 ± 2.0 mmHg) or in the standard dose group (baseline, 12.8 ± 1.9 ; day 14, 13.3 ± 2.1 mmHg). No difference between the two groups was observed ($p = 0.45$).

Shortt et al (2017)⁷

This study shows significant differences in the IOP rise and therefore greater safety of this new preservative-free hydrocortisone and other soft corticoids when compared to Maxidex (Dexamethasone 0.1% w/v).

Formulary inclusions:

Softacort appears and is approved for secondary care prescribing in:

- Northern Care Alliance NHS Group Formulary
- Pan Mersey APC Formulary
- Moorfields Eye Hospital Formulary
- Bristol Eye Hospital Formulary

References

¹ NHS Drug Tariff May 2023 <https://www.drugtariff.nhsbsa.nhs.uk/#/00837338-DC/DD00837078/Part%20VIII%20products%20H>

² K Walsh, L Jones, The use of preservatives in dry eye drops, *Clinical Ophthalmology*. 13, 1409 (2019) PMID: 31447543.

³ McLean JM. Use of ACTH and cortisone. *Trans Am Ophthalmol Soc*. 1950;48:293–296

⁴ van Rensburg E, Meyer D. Astute and safe use of topical ocular corticosteroids in general practice: practical guidelines. *Contin Med Educ*. 2013;31:127-129

⁵ Pleyer et al; “Intraocular pressure effects of common topical steroids for post-cataract inflammation: are they all the same?” *Ophthalmol Ther* (2013) 2:55 - 72

⁶ Kallab et al., “Topical Low Dose Preservative-Free Hydrocortisone Reduces Signs and Symptoms in Patients with Chronic Dry Eye: A Randomized Clinical Trial”, *Adv Ther*, vol 37, pp 329–341, 2019

⁷ Shortt et al, Softacort®, preservative-free hydrocortisone 0.335% drops: A new anti-inflammatory drop with minimal effects on intraocular pressure. *Acta Ophthalmologica*
<https://onlinelibrary.wiley.com/doi/10.1111/j.1755-3768.2017.0S030>