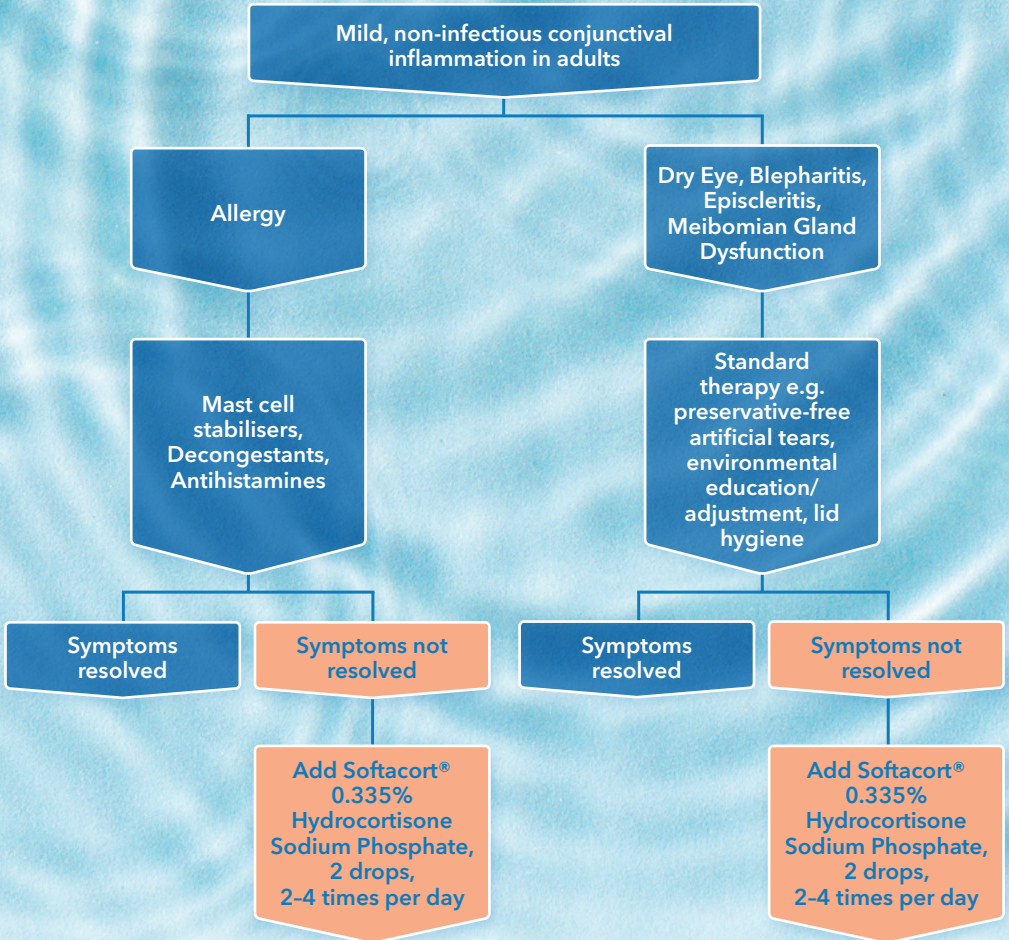


Treatment algorithm

Topical steroids are recommended at step 2 and step 4 in TFOS DEWS II guidelines¹





Softacort[®]

0.335% Hydrocortisone
Sodium Phosphate

Summary

- Effective reduction of mild non-infectious conjunctival inflammation²
- No significant effect on intraocular pressure²
- Preservative-free, cost-effective treatment²

Prescribing information

Softacort[®] 3.35mg/ml eye drops, solution in single-dose container. Abbreviated Prescribing.

Contains: Hydrocortisone sodium phosphate.

Information: Please refer to Summary of Product Characteristics before prescribing.

Presentation: 3 sachets each containing 10 single-dose units of 0.4ml. A single-dose container contains enough to treat both eyes.

Indications(s): Treatment of mild non-infectious allergic or inflammatory conjunctival disease.

Posology and method of administration: Adults & the Elderly: 2 drops 2-4 times per day in the affected eye. Treatment will generally vary from a few days up to a maximum of 14 days. Consider gradual tapering off down to one drop every other day to avoid relapse. Children: safety and efficacy is not established.

Contraindications: Hypersensitivity to active substance or excipients. Ocular hypertension including that caused by known glucocorticosteroids. Herpes simplex and other corneal viral infections at acute stage of ulceration, unless combined with specific therapeutic agents. Conjunctivitis with ulcerative keratitis even at the initial stage. Ocular tuberculosis, ocular mycosis, acute ocular purulent infection, purulent conjunctivitis, and purulent blepharitis, stye and herpes infection that may be masked or aggravated by anti-inflammatory drugs.

Warnings and precautions: *Red eye:* Do not prescribe for undiagnosed red eye. *Ocular hypertension & cataracts:* Monitor patients at regular intervals during treatment – prolonged use of corticosteroids has been shown to cause ocular hypertensions especially for patients with previous IOP increase induced by steroids, and also cataract formation especially in children and the elderly. In children the ocular hypertensive response can happen more often, frequently and severely than in adults. *Immuno suppression:* Use of corticosteroids can result in opportunistic ocular infections due to delay or suppression or healing delay; and to the masking of symptoms. *Viral keratitis:* Not recommended but may be used if required only with a combined antiviral treatment and under close supervision.

Perforations and thinning of cornea / sclera: Thinning of cornea and sclera (caused by diseases) may increase risk of perforations with use of topical steroids. Suspect a fungal infection with corneal ulcerations where a steroid has been used for a long time. Remove contact lenses when using Softacort. With blurred vision or other visual disturbances, consider referring patients for evaluating possible causes which may include cataract, glaucoma or rare diseases like central serous chorioretinopathy (CSR). Softacort contains phosphates. *Children:* Long-term continuous corticosteroid therapy may produce adrenal suppression.

Pregnancy: Not recommended unless clearly necessary.

Lactation: Risk to newborns/infants cannot be excluded. It is unknown if Softacort is excreted in human milk.

Driving & using machines: Temporary blurred vision or other visual disturbances may affect ability to drive or use machines. Wait until vision clears before driving or operating machinery.

Undesirable effects:

Mild and transient burning and stinging immediately after instillation. Unseen with hydrocortisone, but have been observed with other topical corticosteroids: allergic and hypersensitivity reactions, delayed wound healing, posterior capsular cataract, opportunistic infections, herpes simplex infection, fungal infection, glaucoma, mydriasis, ptosis, corticosteroid induced uveitis, changes in corneal thickness, crystalline keratopathy, blurred vision. Very rarely, corneal calcification in patients with significantly damaged corneas.

Prolonged use of corticosteroids has been shown to cause ocular hypertension, especially with pre-existing or family history of increased IOP, and cataract formation. Children / elderly are more susceptible to IOP rise. Diabetics are more prone to sub capsular cataracts following topical steroids. In diseases causing thinning of the cornea, topical steroids could lead to perforation.

Overdose

Rinse with sterile water.

Discontinue treatment where prolonged overdose causes ocular hypertension.

Symptoms from accidental ingestion are unknown, however, consider gastric lavage or emesis.

Storage

Do not store above 25°C.

Keep the single-dose containers in the sachet, in order to protect from light. Discard any unused contents immediately after administration.

Legal category: Prescription Only Medicine (POM)

Basic NHS Price: £10.99 for a pack of 30 single-dose containers

PL No: 20162/0024

Sale and Supply: Théa Pharmaceuticals Ltd, IC5 Innovation Way, Keele University Science & Innovation Park, Keele, Newcastle Under Lyme, ST5 5NT

Date of preparation: 05/10/2018

Adverse events should be reported.
Reporting forms and information can be found
at <https://yellowcard.mhra.gov.uk/>.
Adverse events should also be reported to
Théa Pharmaceuticals: 0345 521 1290

References: 1. Jones, L. *et al.* Ocul Surf. 2017;15(3):575-628. 2. Kallab, M. *et al.* Adv Ther. 2020;37:329-341.

Théa Pharmaceuticals Limited, IC5 Innovation Way, Keele University Science and Business Park, Keele, Newcastle-under-Lyme, ST5 5NT **Office/Medical Information:** 0345 521 1290
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SC081JUN24

 **Théa**
let's open our eyes