Softacort®

0.335% hydrocortisone sodium phosphate

Real-world case studies of the use of Softacort® in the treatment of mild non-infectious conjunctival inflammation

Prescribing information can be found on the back page

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1 CLINICAL CASE 1

CASE REPORT OF THE MANAGEMENT OF INFLAMMATION IN DRY EYE DISEASE (KERATOCONJUNCTIVITIS SICCA) WITH A COMBINATION THERAPY

Dr Martin Emesz
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RELEVANT HISTORY

The case concerns 15 patients (average age 64 +/- 15 years old) suffering from mild to moderate keratoconjunctivitis sicca (KCS). Depending on the severity of their KCS, the most common patient symptoms are: foreign-body and grittiness sensation, hyperaemia, mucoid discharge, ocular irritation, ocular dryness, excessive tearing, photophobia, itching, fluctuation or blurry vision.

None of them used contact lenses and two were smokers. It must be said that, despite treatment with a lacrimal substitute, the symptomatology did not disappear, which justified the change to Softacort® *(Hydrocortisone sodium phosphate 3.35mg/ml – preservative-free – solution in single dose container – Treatment of mild non-infectious allergic or inflammatory conjunctival diseases)* combined with 3.0g/ml trehalose and 0.15g/ml hyaluronic acid.

CLINICAL FINDINGS

The mean duration of the symptoms was 6.3 +/- 3.4 years. Patients were evaluated before start of treatment then 2 and 6 weeks after beginning treatment. Symptoms were assessed using the Ocular Surface Disease Index (OSDI) questionnaire (12 symptoms graded each from 0-4). Clinical examination was performed with Keratograph 5M® (Oculus, Germany) to assess the non-invasive keratograph break-up time (NIK-BUT), the nasal and temporal conjunctival injection, the Meibomian glands and the tear meniscus height.

Lissamine green (Optitech, India) was used to evaluate the conjunctiva and to stain devitalized epithelial cells as well as cells that lack adequate mucin coverage. The evaluation of lissamine green was performed with the Oxford grading scale.

Safety was assessed by visual acuity, non-contact tonometry, biomicroscopy, funduscopy, lens examination and by monitoring adverse events and changes in symptoms.

Statistics were analysed by Excel 2016® and PSPP 0.10.2.®

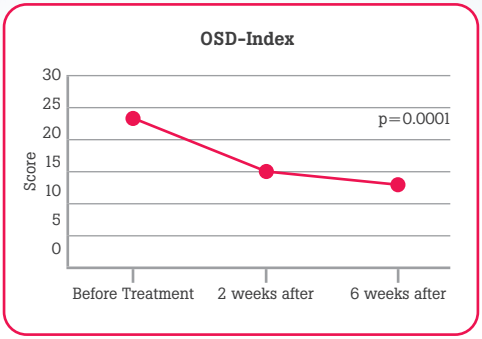
MANAGEMENT

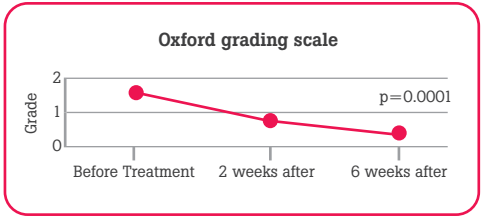
Lubricating supplements are the medications most commonly used to treat Dry Eye Disease. The patients discontinued their previous lacrimal substitutes and were treated with Softacort® 3.35mg/ml eye drops, associated with the combination of 3.0g/ml trehalose and 0.15g/ml hyaluronic acid eye drops, 3 times a day each for a two-week period, followed by the combination of 3.0g/ml trehalose and 0.15g/ml hyaluronic acid eye drops 6 times a day for a four-week period.

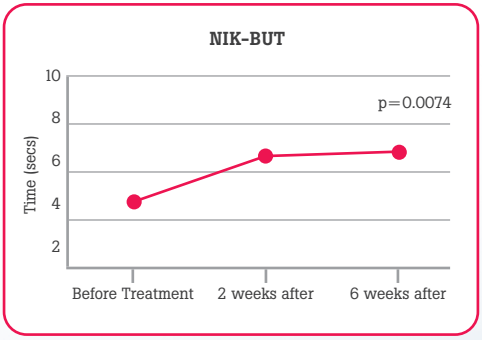
EVALUATION

After the six weeks treatment, compared to the evaluation at the baseline visit, all the patients showed:

- A significant improvement of symptoms
- Statistically significant improvements of OSDI, NIK-BUT, temporal conjunctival injection and the lissamine green staining.







However, there was no statistical significance concerning the nasal conjunctival injection and the tear meniscus height.

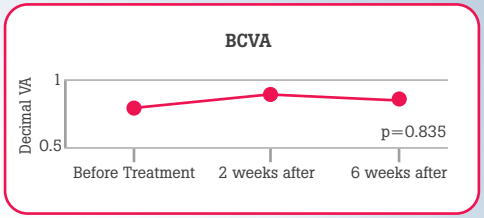
The tolerance was good with no relevant adverse effects, in particular no increase of the IOP.

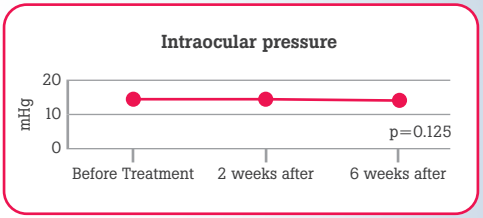
CONCLUSION

Topical Softacort® 3.35mg/ml eye drops, in association with a combination of 3.0g/ml trehalose and 0.15g/ml hyaluronic acid topical eye drops, seems to be a benefical way for the treatment of Dry Eye patients whose symptoms were not relieved by lacrimal substitutes, without any increase in their IOP.

KEY POINTS

- Dry Eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles[1]
- For the treatment of Dry Eye Disease the inflammatory components affecting the ocular surface as well as the Meibomian glands have to be sufficiently medicated
- These patient cases demonstrate the added value of a combined therapy in healing inflammatory components of keratoconjunctivitis sicca





1. Craig JP, TFOS DEWS II Report Executive Summary, Ocul Surf. 2017 Oct;15(4):802–812.

2 CLINICAL CASE 2

THE MANAGEMENT OF EVAPORATIVE DRY EYE DISEASE ASSOCIATED WITH MEIBOMIAN GLAND DYSFUNCTION

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RELEVANT HISTORY

This case concerns a 28-year-old woman suffering from posterior blepharitis related to Meibomian gland dysfunction (MGD) associated with moderate evaporative Dry Eye.

The diagnosis was made two years ago and she has been given several different treatments since then.

The patient has no past history of allergic diseases or smoking and has been wearing contact lenses for two years.

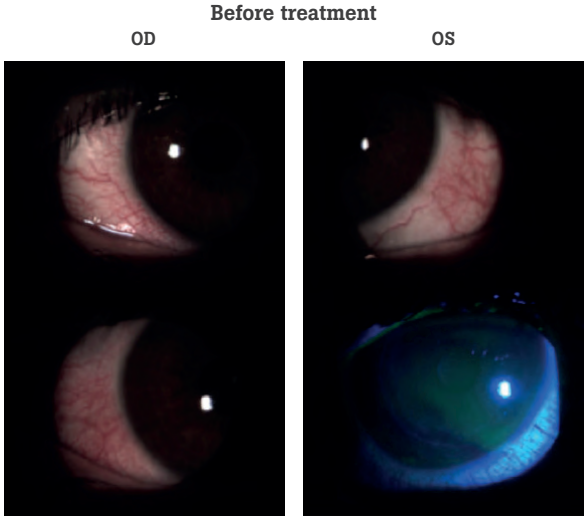
CLINICAL FINDINGS

The patient was evaluated at baseline and follow-up visits.

At baseline visit, her score, using the Ocular Surface Disease Index (OSDI), was 55.6.

Clinical examination was also performed to assess best corrected visual acuity (BCVA), the Fluorescein break-up time (FBUT), the intraocular pressure (IOP), the Schirmmer test and ocular disorders:

- BCVA OD: 6/10
- BCVA OS: 7/10
- FBUT OD: 5s
- FBUT OS: 7s
- IOP: 15mmHg OD/14mmHg OS
- Schirmer I test without anesthesia: >15mm OU
- Biomicroscope examination of both eyes: severe conjunctival hyperaemia, moderate superficial punctate keratitis (SPK) (Oxford Grade: II OD/III OS), plugging of Meibomian Gland orifices, hyperaemia and telangiectasis of posterior lid margin.



TREATMENT

We decided to maintain the ongoing treatment and to add 1 instillation of Softacort® *(Hydrocortisone sodium phosphate 3.35mg/ml – preservative-free – solution in single dose container – Treatment of mild non-infectious allergic or inflammatory conjunctival diseases)*, every 12 hours for 2 weeks.

EVALUATION

After the two weeks of treatment the patient reported a decrease in symptoms. The treatment made her more comfortable and she reported fewer dry and burning sensations.

We noticed some remarkable symptom scores:

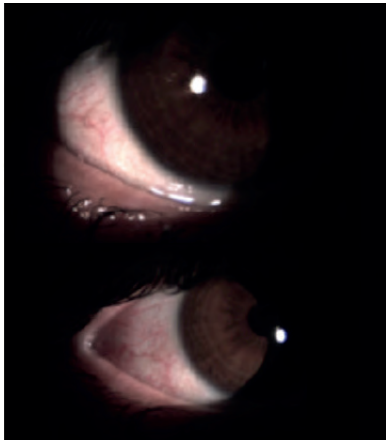
- BCVA OD: 9/10
- BCVA OS: 9/10
- FBUT OU: 8s
- IOP: 16mmHg OD/14mmHg OS
- Ocular disorders: discrete conjunctival hyperaemia, better SPK (Oxford grade: I OD/I OS), less hyperaemia of the lid margin.

Confirming the decrease of complaints, the OSDI significantly decreased to 22.7.

The tolerance was good with no relevant adverse effects, in particular no increase of the IOP. Furthermore, upon instillation of Softacort® 3.35mg/ml eye drops the patient did not report any transient discomfort.

2 weeks after treatment

OD



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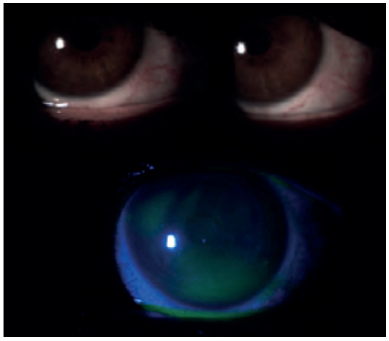

CONCLUSION

In evaporative Dry Eye associated with MGD, when the inflammatory component of the disease is more active, Softacort® 3.35mg/ml eye drops may help to control the signs and symptoms of the disease with a good tolerance. No significant difference in intraocular pressure was noted.

KEY POINTS

- Signs, symptoms and patient satisfaction are the corner stones of Dry Eye treatment
- Effective and convenient treatment is required to remove or treat the triggers, to treat MGD and to target pathophysiological mechanisms that underlie the vicious cycle of Dry Eye Disease[1]
- Softacort® 3.35mg/ml eye drops, is an anti-inflammatory adjuvant to control severe discomfort in evaporative Dry Eye associated with MGD
- These results need to be confirmed by a large-scale, clinical trial

1, Jones L. TFOS DEWS II Management and Therapy Report. Ocul Surf. 2017 Jul;15(3):575-628.

CHRONIC DRY EYE IN PATIENTS WITH CHRONIC GRAFT VERSUS HOST DISEASE: A CASE SERIES

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CASE REPORT

Management of severe Dry Eye Disease (DED) associated with chronic graft-versus-host disease (cGvHD) after allogeneic bone marrow or hematopoietic stem cell transplantation can be challenging to patients and their physicians. The Ocular Surface Disease of these patients is characterised by severe Dry Eye with kerato-conjunctival inflammation which can be very difficult to control. Ocular therapy is multimodal, involving topical lubricants, punctal occlusion, topical steroids, and topical immunomodulators, as well as adjustment of systemic steroids and immunomodulators. Clearly there remains an urgent clinical need to optimize current therapies and to develop novel treatments for cGvHD-related DED.

RELEVANT HISTORY

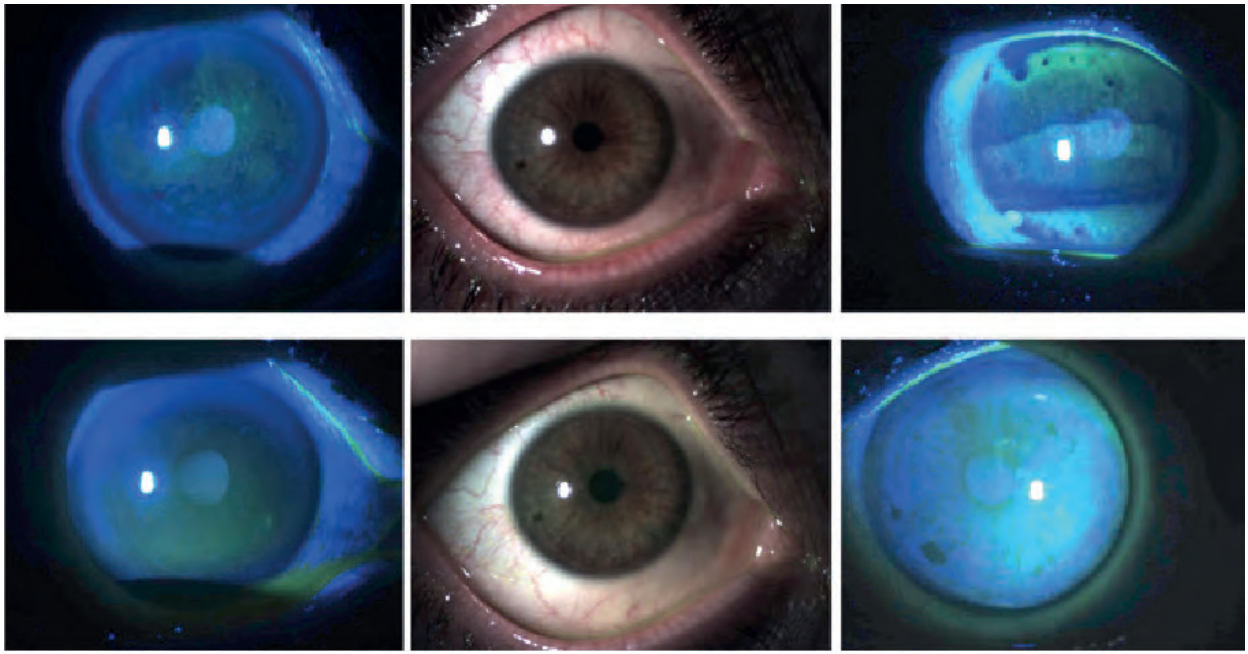
The case series concerns 5 patients (mean age: 50 years old) suffering from chronic DED with underlying cGvHD. All patients had been diagnosed with DED for more than 6 months, had been treated with at least topical lubricants for more than 3 months and had a symptomatic scale – Ocular Surface Disease Index (OSDI) – over 30.

CLINICAL FINDINGS

At inclusion, all patients underwent ophthalmologic examination including best corrected visual acuity (BCVA), OSDI, corneal staining (measured with the Oxford scale), tear break-up time (TBUT), conjunctival hyperaemia and intraocular pressure.

Clinical investigation revealed a previous history of allogenic bone marrow transplantation with subsequent cGvHD affecting the skin and eyes in all patients.

Clinical Examinations



TREATMENT AND MANAGEMENT

This case series was conducted to evaluate the effects of Softacort® *(Hydrocortisone sodium phosphate 3.35mg/ml – preservative-free – solution in single dose container – Treatment of mild non-infectious allergic or inflammatory conjunctival diseases)* every 12 hours for 14 days in cGvHD patients with severe Dry Eye.

EVALUATION

This case series demonstrated results that are clinically significant:

- The mean OSDI was 52 before starting the treatment and it changed to a mean value of 31 after the treatment, with all patients except one having improved symptoms;
- Visual acuity was maintained in every patient except in one for whom it improved;
- Corneal staining and/or conjunctival hyperaemia profiles improved in all patients except one.

Safety was demonstrated and no difference in intraocular pressure was noted.

All patients reported transient eye discomfort upon instillation. All the side effects were mild and well tolerated.

CONCLUSION

Topical preservative-free hydrocortisone 0.335% is an effective anti-inflammatory agent for controlling the inflammation in cGvHD related DED.

KEY POINTS

- The treatment and management of cGvHD related DED is continually changing as new therapies are proposed, trialled and validated
- This case series demonstrates the added value of lower potency steroids in cGvHD related DED

4 CLINICAL CASE 4

ANTI-INFLAMMATORY THERAPY IN THE MANAGEMENT OF EVAPORATIVE DRY EYE ASSOCIATED WITH MEIBOMIAN GLAND DYSFUNCTION

Dr Paulo Guerra
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RELEVANT HISTORY

This case concerns a 37-year-old woman suffering from posterior bepharitis related to Meibomian gland dysfunction (MGD) associated with moderate evaporative Dry Eye.

The diagnosis was made eight years ago and she was treated with different lubricants, several cycles of minocycline 100mg/day, 0.1% fluoro-metholone or 0.25% prednisolone and 0.1% chloramphenicol combination. She is currently treated with preservative-free 0.15% sodium hyaluronate, 2 drops every 2 hours and lid hygiene.

Her past medical history is unremarkable, with no history of allergic diseases or smoking. The patient is a contact lens wearer.

CLINICAL FINDINGS

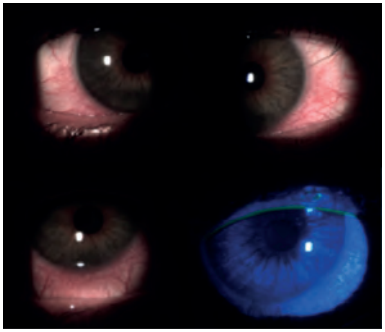
The patient was evaluated at baseline and follow-up visits.

At baseline visit her score, assessed using the Ocular Surface Disease Index (OSDI), was 43.7. Clinical examination was also performed to assess best corrected visual acuity (BCVA), the Fluorescein break-up time (FBUT), the intraocular pressure (IOP), the Schirmmer test and ocular disorders:

- BCVA OD: 9/10
- BCVA OS: 10/10
- FBUT OD: 7s
- FBUT OS: 8s
- IOP: 12mmHg OD/12mmHg OS
- Schirmer I test without anesthesia: >15mm OU
- Biomicroscope examination of both eyes: Severe conjunctival hyperaemia especially OD, staining of the exposed inter-palpebral conjunctiva and cornea (Oxford Grade: I OU), plugging of Meibomian Gland orifices, hyperaemia and telangiectasis of posterior lid margin.

Before treatment

OD



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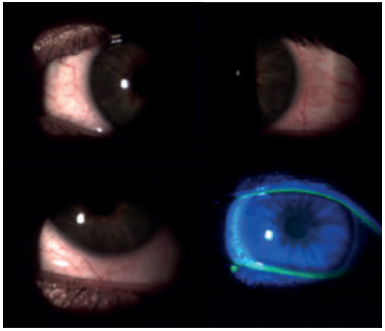


TREATMENT AND MANAGEMENT

We decided to treat this patient with the same ongoing treatment of preservative-free 0.15% sodium hyaluronate eye drops, two drops every two hours, and lid hygiene; but we added 1 instillation of Softacort® *(Hydrocortisone sodium phosphate 3.35mg/ml – preservative-free – solution in single dose container – Treatment of mild non-infectious allergic or inflammatory conjunctival diseases)*, every 12 hours for 2 weeks.

EVALUATION

After the two weeks of treatment the patient reported reduced redness and noticed that her eyes were more comfortable. The treatment made her more comfortable and she reported fewer dry and burning sensations.

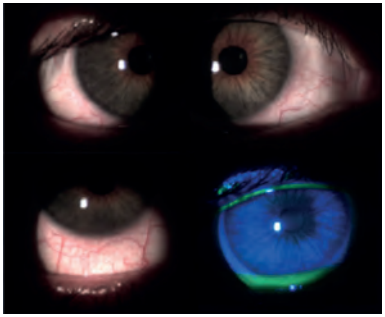
The symptom scores improved significantly:

- BCVA OD: 9/10
- BCVA OS: 10/10
- FBUT OU: 11s
- IOP: 13mmHg OD/11mmHg OS
- Ocular disorders: discrete conjunctival hyperaemia, no staining (Oxford grade: 0 OU), less lid margin hyperaemia

Confirming the decrease of complaints, the OSDI significantly decreased to 27.

After treatment

OD



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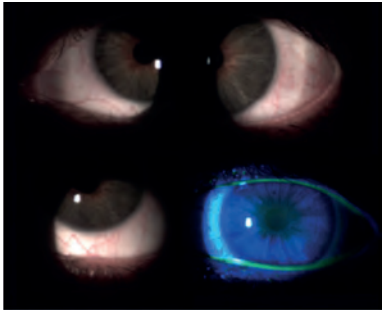

Treatment tolerance was good. No relevant adverse effect, especially no increase of IOP, was detected. Furthermore, upon instillation of Softacort® 3.35mg/ml eye drops, solution in single-dose container the patient did not report any transient discomfort.

CONCLUSION

In evaporative Dry Eye associated with MGD, when the inflammatory component of the disease is more active, Softacort® 3.35mg/ml eye drops, solution in single-dose container may help to control the signs and symptoms of the disease.

KEY POINTS

- In more severe cases of Dry Eye Disease, the use of soft corticosteroids to break the vicious cycle may be considered to control the disease, as recommended by TFOS DEWS II report[1]
- Softacort® 3.35mg/ml eye drops, thanks to its anti-inflammatory properties is efficient in controlling severe discomfort in evaporative Dry Eye associated with MGD

4 STEPS MANAGEMENT & THERAPY FOR DRY EYE[1]

STEP 1

- Education regarding Dry Eye, its management, treatment and prognosis
- Modification of local environment
- Education regarding potential dietary modifications (including oral essential fatty acid supplementation)
- Identification and potential modification/elimination of offending systemic and topical medications
- Ocular lubricants of various types (if MGD is present, then consider lipid containing supplements)
- Lid hygiene and warm compresses of various types

STEP 2

If step 1 options are inadequate consider:

- Change to Non-preserved ocular lubricants to minimize preservative-induced toxicity
- Use Tea tree oil treatment if Demodex
- Overnight treatments (such as ointment or moisture chamber devices)
- Tear conservation via Punctal occlusion
- Moisture chamber spectacles/goggles
- In-office, physical heating and expression of the Meibomian glands (including device-assisted therapies)
- In-office intense pulsed light therapy for MGD
- Prescription drugs to manage DED
  - Topical antibiotic, or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present)
  - Topical corticosteroid (limited-duration)
  - Topical secretagogues
  - Topical non-glucocorticoid immunomodulatory drugs (such as cyclosporine)
  - Topical LFA-1 antagonist drugs (such as lifitegrast)
  - Oral macrolide or tetracycline antibiotics

STEP 3

If step 1 & 2 are inadequate consider:

- Oral secretagogues
- Autologous/allogeneic serum eye drops
- Therapeutic contact lens options
  - Soft bandage lenses
  - Rigid scleral lenses

STEP 4

If step 1, 2 & 3 are inadequate consider:

- Topical corticosteroid for longer duration
- Amniotic membrane grafts
- Surgical punctal occlusion
- Other surgical approaches (e.g. tarsorrhaphy, salivary gland transplantation)

1. Jones L. TFOS DEWS II Management and Therapy Report. Ocul Surf. 2017 Jul;15(3):575-628.

5 CLINICAL CASE 5

THE MANAGEMENT OF INFLAMMATION IN CHRONIC EVAPORATIVE DRY EYE DISEASE RELATED TO MEIBOMIAN GLAND DYSFUNCTION, WITH TOPICAL HYDROCORTISONE THERAPY

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RELEVANT HISTORY

The case concerns a 79-year-old woman suffering from Dry Eye Disease for several years, with follow-up in our department since 1997. Bilateral cataract surgery and retinal detachment repairs have occurred during this time. Since her surgeries she has complained of dry eyes: current treatment consisted of 3.0g/ml trehalose and 0.15g/ml hyaluronic acid eye drops four to five times a day and 138 ug/g Retinol palmitate lubricating ointment once at night.

The patient attended our emergency department, complaining that the discomfort wasn't sufficiently relieved by this treatment regime.

CLINICAL FINDINGS

Symptoms included foreign body sensation, tearing, photophobia, pain and fluctuating vision. The symptom score obtained with Ocular Surface Disease Index (OSDI) was 70.5.

Clinical examination at baseline and after two weeks of treatment included best corrected visual acuity (BCVA), lid margin and Meibomian glands, tear meniscus, tear break-up time (TBUT) and corneal staining (NEI grading scale). Intraocular pressure (IOP) was also checked.

Baseline examination revealed:

- BCVA 8/10 R&L (Snellen)
- Moderate anterior blepharitis in both eyes
- Meibomian gland dysfunction in both eyes
- Telangiectasia of the lid margin in both eyes
- Moderate conjunctival injection in both eyes
- Normal tear meniscus in both eyes
- Tear break-up time: 5 seconds in both eyes
- Corneal staining score: RE-4, LE-5
- IOP: RE 21mmHg, LE 20mmHg
- Conjunctivitis
- No ocular mycosis and tuberculosis
- No sign of infection

Figure 1: Meibomian gland dysfunction and moderate conjunctival injection

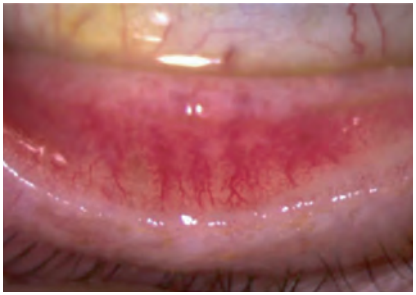


Figure 2: Anterior blepharitis and Meibomian gland dysfunction (right eye)

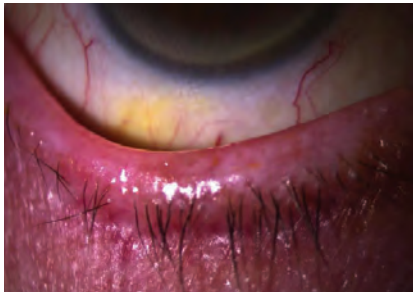
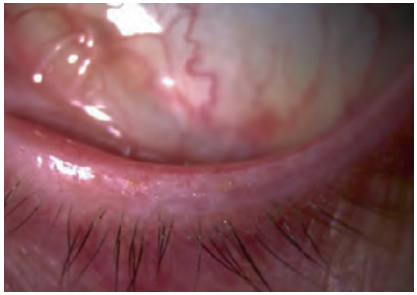


Figure 3: Moderate anterior blepharitis and Meibomian gland dysfunction (left eye)



MANAGEMENT/TREATMENT

Daily treatment with 3.0g/ml trehalose and 0.15g/ml hyaluronic acid eye drops as required and 138ug/g Retinol palmitate lubricating ointment was maintained, but adding two things: daily lid hygiene and warm compresses, plus Softacort® *(Hydrocortisone sodium phosphate 3.35mg/ml – preservative-free – solution in single dose container – Treatment of mild non-infectious allergic or inflammatory conjunctival diseases)*, three times a day, for two weeks.

Figure 4: Lid margin with less telangiectasias (right eye)

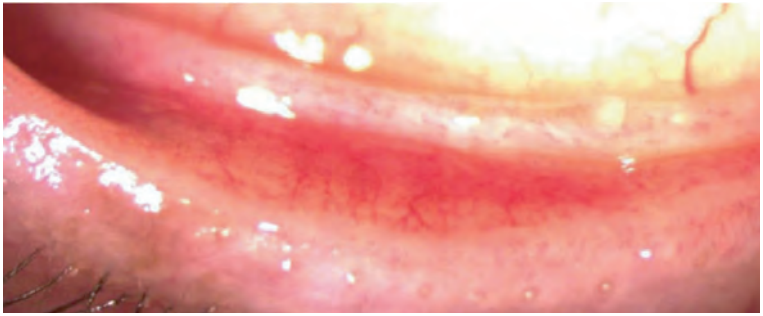
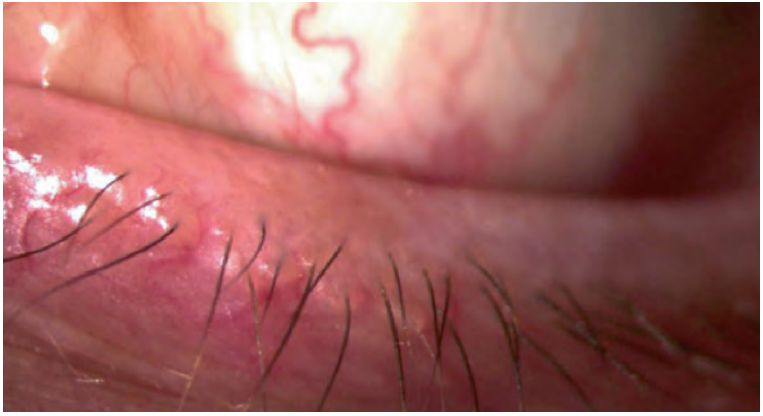


Figure 5: Lid margin (left eye)



EVALUATION

After two weeks of treatment, this patient described a two-fold reduction in her symptoms: OSDI decreased to 54.5. She was able to decrease 3.0g/ml trehalose and 0.15g/ml hyaluronic acid eye drops applications to just 2–3 times daily.

BCVA improved to 9.5/10 and 9/10 in the right and left eye, respectively. We also observed improvements in MGD, telangiectasia and corneal staining (NEI grading scale, 1 and 2 respectively). TBUT was unchanged, at 5 seconds in both eyes.

Tolerance to this treatment regime was good without noticeable side effects, and IOP was measured at 22mmHg in the right eye and 18.5 in the left eye.

CONCLUSION

These findings support the possible influence of inflammation induced by hyperosmolarity and tear film instability in the vicious cycle of Dry Eye Disease. Furthermore, inflammation has been thought to alter pain modulation and ocular surface homeostasis.[1,2] Regarding this, topical corticosteroids have been advised to treat conjunctival pathologies.[3,4] A combination treatment of Meibomian gland dysfunction and tear supplementation has also showed efficacy.[5]

Chronic evaporative Dry Eye Disease associated with Meibomian gland dysfunction can be symptomatically improved by Softacort® 3.35mg/ml eye drops after 14 days of treatment.

Long-term relief of symptoms needs to be confirmed by a long-lasting, randomized, controlled trial.

KEY POINTS

- Dry Eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles. Cataract surgery has been shown to independently transiently induce or exacerbate Dry Eye[1]
- In more severe cases of Dry Eye Disease, the use of soft corticosteroids to break the vicious cycle may be considered to control the disease, as recommended by TFOS DEWS II report
- Softacort® 3.35mg/ml eye drops, treated this patient well

1. Belmonte C, Nichols JJ, Cox SM, *et al.* TFOS DEWS II pain and sensation report. Ocul Surf. 2017;15:404–437. doi:10.1016/j.jtos.2017.05.002.
2. Boboridis KG, Calonge M, Akova YA, *et al.* Role of corneal nerves in ocular surface homeostasis and disease. Acta Ophthalmol. 2018:137–145. doi:10.1111/aos.13844.
3. Cutolo CA, Barabino S, Bonzano C, *et al.* The Use of Topical Corticosteroids for Treatment of Dry Eye Syndrome The Use of Topical Corticoste-roids for Treatment of Dry Eye Syndrome. 2017;3948. doi:10.1080/09273948.2017.1341988.
4. Jones L, Downie LE, Korb D, *et al.* TFOS DEWS II Management and Therapy Report. Ocul Surf. 2017;15:575–628. doi:10.1016/j.os.2017.05.006.
5. Ngo W, Srinivasan S, Houtman D, *et al.* The relief of Dry Eye signs and symptoms using a combination of lubricants, lid hygiene and ocular nutraceuticals. J Optom. 2017;10:26–33.

ANTI-INFLAMMATORY THERAPY WITH TOPICAL HYDROCORTISONE IN THE MANAGEMENT OF EVAPORATIVE DRY EYE ASSOCIATED WITH MEIBOMIAN GLAND DYSFUNCTION

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RELEVANT HISTORY

This case concerns a 63-year-old woman suffering from Dry Eye Disease for three months. She attended our emergency department with burning, itching and foreign body sensations in both eyes for three days that she described as unbearable. Otherwise, her only relevant history was hyperopia and presbyopia. General medical history revealed a current non-steroidal anti-inflammatory therapy for knee surgery. Conjunctivitis was diagnosed related to a Dry Eye Disease.

CLINICAL FINDINGS

Symptoms included foreign body, burning and itching sensations, pain and fluctuating vision. Symptom score obtained with Ocular Surface Disease Index (OSDI) was 63.5.

Clinical examination was performed at baseline and after two weeks of treatment. We assessed best corrected visual acuity (BCVA), lid margin and Meibomian glands, tear meniscus, tear break-up time (TBUT) and corneal staining (NEI grading scale).

We also checked intraocular pressure (IOP). Baseline examination revealed:

- BCVA 9/10 R&L (Snellen chart)
- Meibomian gland dysfunction: gland orifices plugged in both eyes
- Telangiectasia of the lid margins in both eyes
- Normal tear meniscus in both eyes
- TBUT: 2 seconds in both eyes
- Corneal staining: 3 in the right eye and 6 in the left eye
- IOP: RE 12mmHg, LE 13mmHg
- Conjunctivitis
- No ocular mycosis and tuberculosis
- No sign of infection

Figure 1: Lid margin with telangiectasia and tear meniscus (right eye)

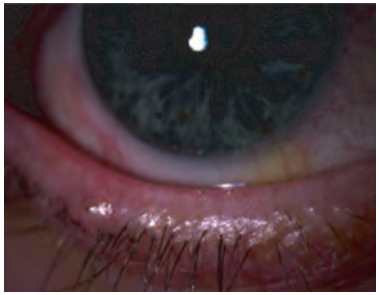


Figure 2: Lid margin with telangiectasia (right eye)

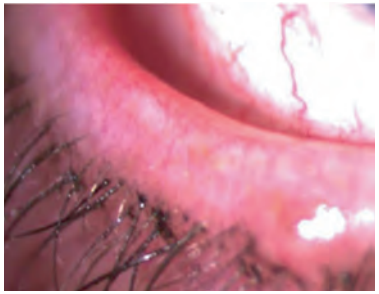


Figure 3: Superior lid margin (right eye)

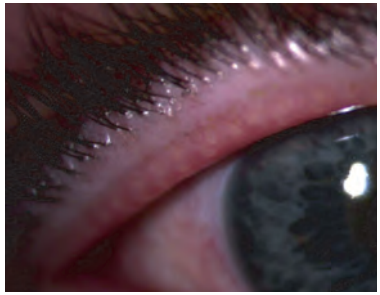


Figure 4: Lid margin (left eye)

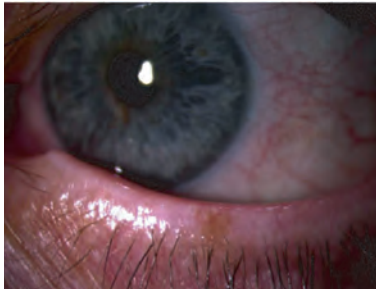
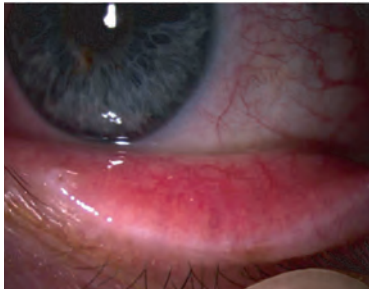


Figure 5: Moderate conjunctival injection (left eye)



MANAGEMENT/TREATMENT

We prescribed 3.0g/ml trehalose and 0.15g/ml hyaluronic acid eye drops three times daily, plus added lid hygiene with warm compresses and Softacort® *(Hydrocortisone sodium phosphate 3.35mg/ml – preservative-free – solution in single dose container – Treatment of mild non-infectious allergic or inflammatory conjunctival diseases)*, three times a day, for two weeks.

EVALUATION

After two weeks of treatment, the OSDI decreased to 36.4, and our patient described a subjective improvement but with persistent fluctuating vision.

The BCVA was improved to 10/10 with both eyes. We observed an improvement in tear film stability, TBUT was 5 seconds in both eyes. Meibomian gland dysfunction was unchanged with persistent telangiectasia. Corneal staining (NEI workshop grading scale) decreased to 2 and 0 in right and left eyes, respectively.

Tolerance was good with no noticeable side effects. Intraocular pressure was measured at 12mmHg in the right eye and 9 in the left eye.

Figure 6: Lid margin and improved conjunctival injection (right eye)

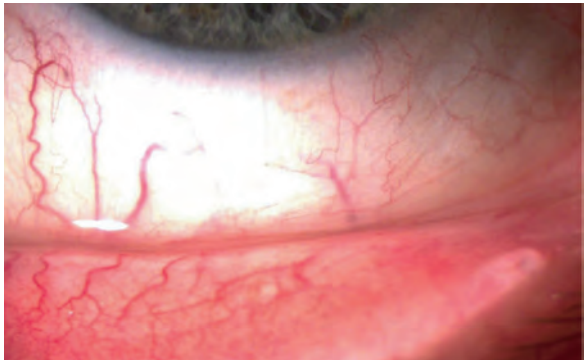
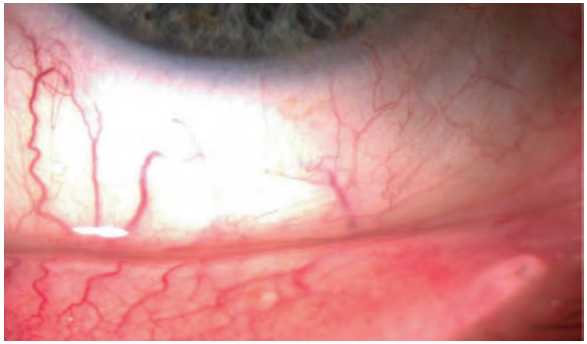


Figure 7: Lid margin (left eye)



CONCLUSION

These findings support the consideration of inflammation in breaking the vicious cycle of Dry Eye Disease. Indeed, topical corticosteroids have been advised to treat Dry Eye Diseases.[1,2] Our patient showed symptomatic improvement with topical steroid therapy even in the presence of concurrent, systemic non-steroidal anti-inflammatory treatment.

This case demonstrated that symptoms in Dry Eye Disease associated with Meibomian gland dysfunction can be improved by Softacort® 3.35mg/ml eye drops after 14 days of treatment. Long term relief of symptoms needs to be confirmed by further clinical trials.

KEY POINTS

- Dry Eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which tear film instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles[1]
- Effective and convenient treatment is required to remove or treat the triggers, and to target pathophysiological mechanisms that underlie the vicious cycle of Dry Eye Disease
- Softacort® 3.35mg/ml eye drops, is an anti-inflammatory adjuvant to control severe discomfort in evaporative Dry Eye associated with Meibomian gland dysfunction

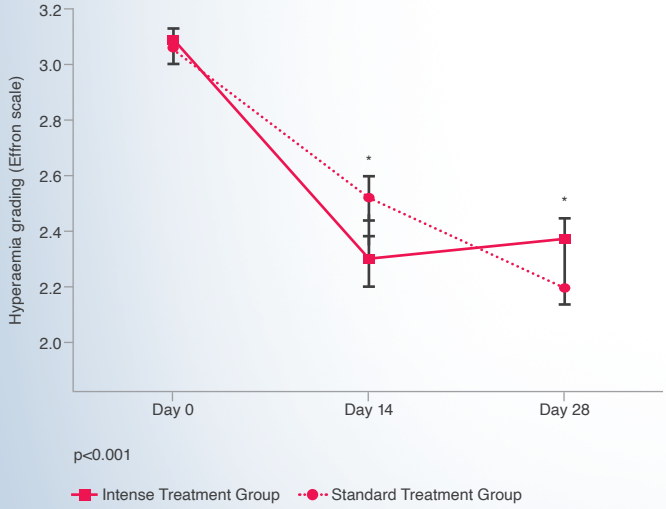
1. Cutolo CA, Barabino S, Bonzano C, *et al.* The Use of Topical Corticosteroids for Treatment of Dry Eye Syndrome The Use of Topical Corticoste-roids for Treatment of Dry Eye Syndrome. 2017;3948. doi:10.1080/09273948.2017.1341988.
2. Jones L, Downie LE, Korb D, *et al.* TFOS DEWS II Management and Therapy Report. Ocul Surf. 2017;15:575–628. doi:10.1016/j.os.2017.05.006.

SOFTACORT®: CONFIRMED EFFICACY WITH NO SIGNIFICANT EFFECT ON IOP[1]

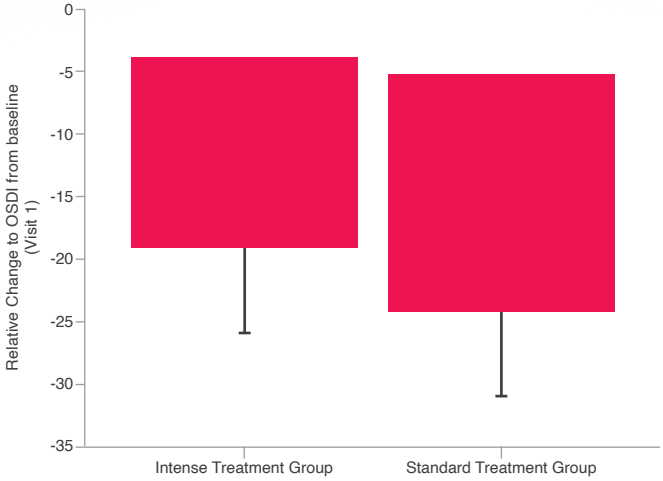
In a recent study,[1] efficacy of Softacort® was confirmed with no significant effect on IOP.

- 60 patients with moderate to severe DED and conjunctival hyperemia > Grade 2 on the Efron scale were randomised to receive Softacort® in one of two treatment groups:
  - Intense – qds x 12 days, followed by bd x 2 days
  - Standard – tds x 8 days, followed by bd x 3 days
- All patients continued use of artificial tears, as required

Conjunctival hyperaemia grading



Ocular Surface Disease Index



p<0.001

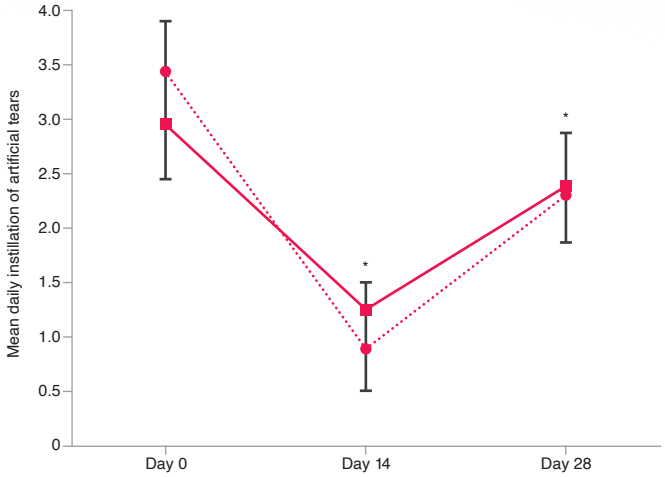
*Significant vs. basline for both groups

Adapted from Kallab 2020[1]

1. Kallab M *et al*, Adv Ther. 2020;37:329–341.

Softacort® had no effect on IOP, in either treatment group, and significantly reduced need for artificial tears.

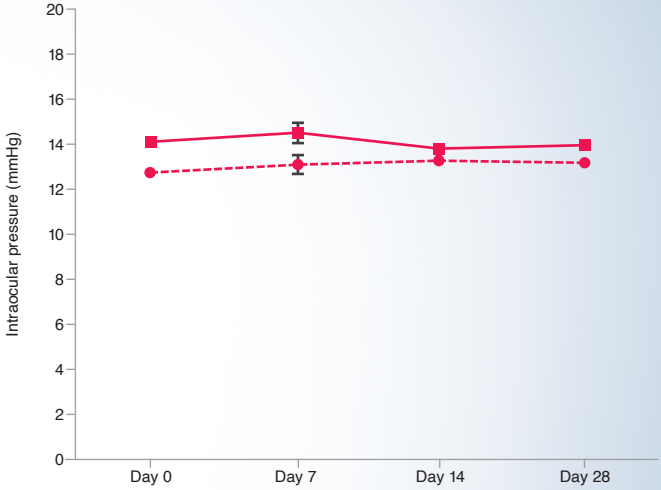
Mean daily use of artificial tears



p<0.001

Intense Treatment Group Standard Treatment Group

Intraocular pressure (IOP) over time



P=0.45

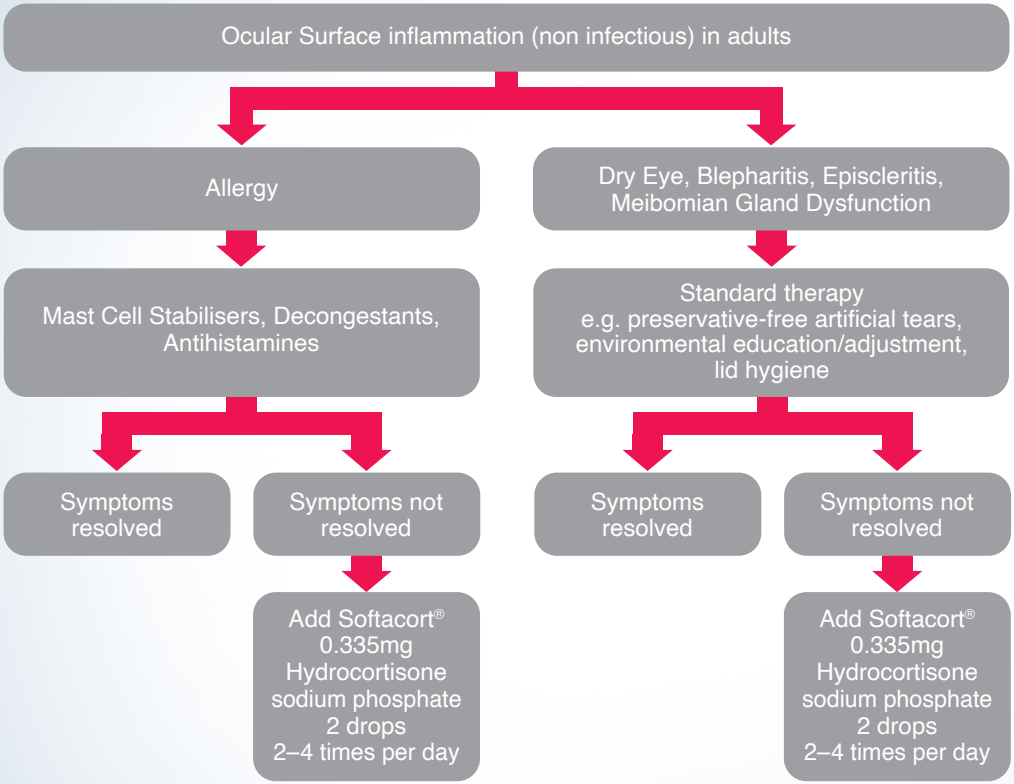
Intense Treatment Group Standard Treatment Group

*Significant vs. basline for both groups

1 . Kallab M *et al*, Adv Ther. 2020;37:329–341.

TREATMENT ALGORITHM

Topical steroids are recommended at step 2 and step 4 in TFOS DEWS II guidelines[1]



1. Jones L *et al.* TFOS DEWS II Management and Therapy Report. Ocul Surf 2017;15(3):575-628.

	Price per pack	Price per unit dose	Doses per pack	Preservative-free
Softacort® (Hydrocortisone Sodium Phosphate 0.335mg/ml)	£10.99	£0.36	30	√
Prednisolone Minims® 0.5% (Prednisolone Sodium Phosphate)	£12.25	£0.61	20	√

STANDARD PROTOCOL

2 drops, 3x a day, for 8 days followed by

2 drops, 2x a day, for 3 days

= 1 PACK

Softacort®

0.335% hydrocortisone sodium phosphate

SUMMARY

- **Effective reduction of mild non-infectious conjunctival inflammation**[1]
- **No significant effect on intraocular pressure**[1]
- **One-box preservative-free, cost-effective treatment**[1]

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 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 overdosage 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: Thea Pharmaceuticals Limited, IC5 Innovation Way, Keele University Science & Innovation Park, Keele, Newcastle-Under-Lyme, ST5 5NT
Date of preparation: March 2020

REPORT ADVERSE EVENTS TO THEA PHARMACEUTICALS LIMITED AND WWW.MHRA.GOV.UK/YELLOWCARD OR SEARCH FOR MHRA YELLOW CARD IN THE GOOGLE PLAY OR APPLE APP STORE.

Théa Pharmaceuticals Limited, IC5 Innovation Way, Keele University Science and Business Park, Keele, Newcastle-under-Lyme, ST5 5NT
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1. Kallab M *et al.* Adv Ther. 2020;37:329–341.

Théa
let's open our eyes

SC0043 April22