bitop
The Ectoin® Company

medEctoin®

The Next Generation of Ophthalmic Solutions
Ectoin® + Hyaluronic Acid Eye Drops: Powerful combination for modern eye care

Abstract
The global ophthalmic market is witnessing a shift towards natural, preservative-free eye care solutions that provide efficacy comparable to pharmaceuticals, but without their side effects. Ectoin®, a naturally occurring extremolyte, has demonstrated anti-inflammatory, cell-protective, and tear film-stabilizing properties. Combined with Hyaluronic Acid (HA), this innovative formulation addresses both dry eye disease (DED) and ocular inflammation.

Introduction: The Unmet Need in Ocular Surface Disease

Dry eye disease (DED) and ocular inflammation affect millions worldwide, with up to 33% of the population experiencing dry eye symptoms. Conventional treatments include artificial tears, corticosteroids, and vasoconstrictors, which offer short-term relief but come with risks such as increased intraocular pressure, rebound effects, and preservative-related toxicity.

The Science Behind Ectoin® and Hyaluronic Acid in Eye Care

Ectoin®: A Natural Cellular Protector

Ectoin® is a small organic molecule known as an extremolyte, which forms a Hydro Complex around ocular cells, stabilizing cell membranes and reducing inflammation. Clinical studies show that Ectoin® reduces inflammation of the conjunctiva, protects against allergen ingression and supports wound healing post-surgery.

Hyaluronic Acid (HA): The Gold Standard for Hydration

Hyaluronic Acid (HA) is an established viscoelastic polymer that enhances ocular surface lubrication and promotes epithelial regeneration. Studies show that when combined with Ectoin®, HA further extends tear film stability, improving hydration and reducing symptoms of dryness and irritation.

Regulatory & Market Positioning

- Class IIa Medical Devices with a strong clinical evidence base.
- Preservative-free, phosphate-free, and steroid-free, addressing growing market demand for natural ophthalmic solutions.
- Proven commercial feasibility: Well-established actives in shelf-stable formulation for up to 36 months. Two options for primary packaging: Multi-Dose Aptar OSD System or Single-Dose Ampoules.

Figure 4: medEctoin® + HA Eye Drops in Ophthalmic Squeeze Dispenser (OSD)

Clinical Evidence: Efficacy of bitop's medEctoin® eye drops

Dry Eye Disease (DED) Improvement:
A multicenter, non-interventional study assessed the effectiveness of Ectoin® eye drops compared to HA-based eye drops in 65 patients with mild to moderate DED. The results demonstrated:

- A 46% reduction in Ocular Surface Disease Index (OSDI) score over four weeks.
- Significant improvement in tear film break-up time (TBUT), confirming the protective and stabilizing effects on the ocular surface.

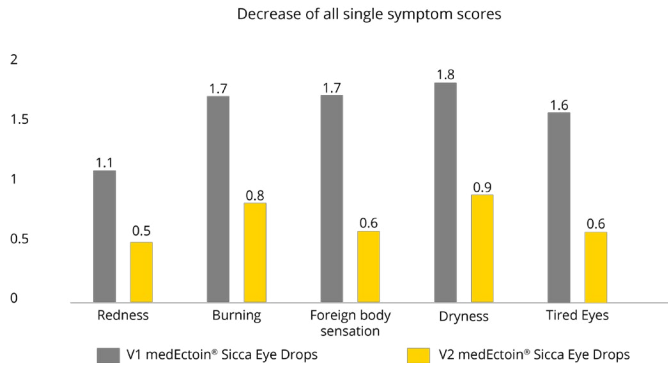

Figure 1: Clinical study report btph-032-2012-BAT04, unpublished: Ectoin containing ophthalmic solution in the treatment of dry eye disease.

Inflammation Reduction and Post-Operative Healing:
A controlled, prospective study comparing Ectoin® eye drops to corticosteroids (Fluorometholone) in 26 patients with functional epiphora found that Ectoin® achieved:

- Equivalent efficacy in reducing excessive tear flow without the side effects associated with corticosteroids, such as increased intraocular pressure.
- Faster corneal epithelialization (by 3-4 days) in post-surgical recovery, highlighting its regenerative properties.

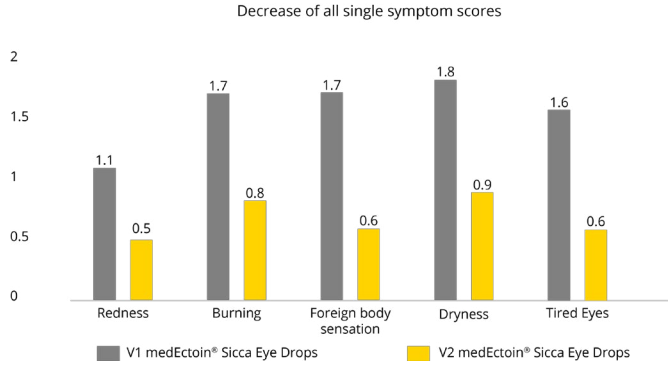

Figure 2: Martinez et al. 2018: Estudio comparativo de la eficacia del colirio de Ectoina (Ectodol®) en pacientes con epifora funcional. Congress poster presentation

Immediate Symptom Relief for Allergic Conjunctivitis:
A randomized controlled study in 50 patients suffering from allergen-induced conjunctivitis revealed that:

- Ectoin® eye drops reduced symptoms like itching and redness within 30 seconds.
- Long-term use provided comparable relief to standard antihistamines (Azelastine) but with superior tolerability.

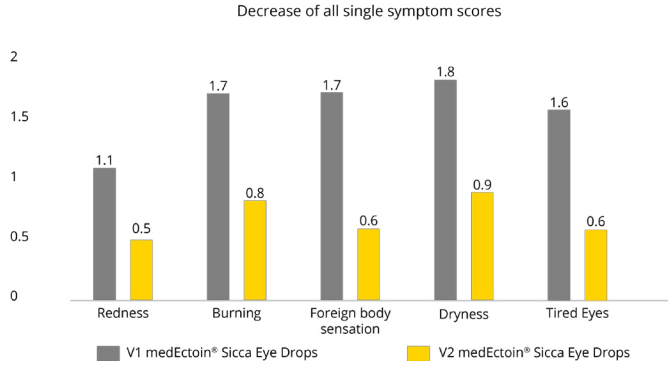

Figure 3: Clinical study on equivalent product: btph-015-2018-AAT04-EES09, unpublished: Comparison of Ectoin® Allergy Eye drops, Ectoin® Eye Spray Colloidal, and comparator for the treatment of environmental disorders of the eye of allergic patients

Licensing and Commercialization Opportunities

Pharmaceutical companies have two flexible options to integrate medEctoin® into their ophthalmic portfolios:

In-Licensing medEctoin® eye drops

Companies can directly in-license fully developed, clinically tested medEctoin® eye drops. These ready-to-market products provide a rapid entry into the growing ophthalmology segment, backed by strong clinical evidence and regulatory approvals.

Purchasing medEctoin® as a raw material for proprietary formulations

For companies looking to enhance their own eye drop formulations, medEctoin® can be sourced as a high-purity raw material. This enables the integration of a scientifically validated, natural ingredient into existing or new ophthalmic formulations, allowing brands to make evidence-based claims and strengthen product differentiation in the market.

Conclusion: A Licensing Opportunity for Next-Gen Ophthalmic Care

With the ophthalmology market shifting towards preservative-free, natural, and clinically effective treatments, medEctoin® + HA presents a strong commercial opportunity for pharmaceutical companies seeking to in-license differentiated, evidence-backed eye care solutions.

Next Steps

Pharmaceutical companies interested in licensing or co-development opportunities can contact our business development team for detailed discussions.

Contact: bd@bitop.de www.bitop.de

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