EvoTears®

Summary of Clinical Studies

EvoTears® is 100% Perfluorohexyloctane. Clinical data on > 2000 subjects supports the safety and efficacy of Perfluorohexyloctane (BID-QID; 4 weeks - 1 year) in Evaporative Dry Eye Disease

YEAR	FULL REFERENCE	TITLE	STUDY SIZE(N)	INTERVENTION	RESULTS
2015	Steven, P., Scherer, D., Krösser, S., Beckert, M., Cursiefen, C. and Kaercher, T., 2015. Journal of Ocular Pharmacology and Therapeutics, 31(8), pp.498-503.	Semifluorinated alkane eye drops for treatment of dry eye disease—a prospective, multicenter noninterventional study.	30	4 times daily (QID) for 6 weeks	Significant reduction of corneal staining and significant increase of Schirmer I and TFBUT. OSDI score dropped significantly from a mean of 55 (–23.0) to 34 (–22.4). Safe and effective in treating mild to moderate hyperevaporative DED
2017	Steven, P., Augustin, A.J., Geerling, G., Kaercher, T., Kretz, F., Kunert, K., Menzel-Severing, J., Schrage, N., Schrems, W., Krösser, S. and Beckert, M., 2017. Journal of Ocular Pharmacology and Therapeutics, 33(9), pp.678-685.	Semifluorinated alkane eye drops for treatment of dry eye disease due to meibomian gland disease.	72	4 times daily (QID) for 6-8 weeks	Tear film breakup time, corneal and conjunctival fluorescein staining, number of expressible Meibomian glands, and severity of anterior and posterior blepharitis significantly improved after 6–8 weeks. Significant decrease of OSDI-values from 37 (–13) to 26 (–16). Significantly improves clinical signs of Meibomian gland disease and associated mild to moderate DE
2020	Schmidl, D., Bata, A.M., Szegedi, S., Aranha Dos Santos, V., Stegmann, H., Fondi, K., Krösser, S., Werkmeister, R.M., Schmetterer, L. and Garhöfer, G., 2020. Journal of Ocular Pharmacology and Therapeutics, 36(3), pp.154-161.	Influence of perfluorohexyloctane eye drops on tear film thickness in patients with mild to moderate dry eye disease: a randomized controlled clinical trial.	48	4 times daily (QID) for 4 weeks	Increased TFT and LLT values measured. These tear film reestablishing attributes are in line with the mode of action of perfluorohexyloctane eye drops to avoid evaporation through stabilization of the lipid layer
2020	Son, H.S., Yildirim, T.M., Khoramnia, R., Poompokawat, P., Knorz, M.C. and Auffarth, G.U., 2020. Journal of Refractive Surgery, 36(7), pp.474-480.	Semi-fluorinated alkane eye drops reduce signs and symptoms of evaporative dry eye disease after cataract surgery	40	4 times daily (QID) for 5 weeks	Median TBUT increased from 6.8 (preoperative) to 14 seconds (P < .001); total corneal staining score decreased from 3.53 (preoperative) to 2.36 (P < .001). The mean CDVA improved from 0.41 (preoperative) to 0.14 logMAR (P < .001) and there was a statistically significant decrease in all scores from the VAS questionnaire. Good efficacy and high tolerability
2020	Eberwein, P., Krösser, S. and Steven, P., 2020. Ophthalmic research, 63(1), pp.50-58.	Semifluorinated Alkane Eye Drops in Chronic Ocular Graft-versus-Host Disease: A Prospective, Multicenter, Noninterventional Study	25	4 times daily (QID) for 12 weeks	No changes in clinical or safety parameters but fast relief in symptoms in 57% of the patients. One adverse reaction occurred. This study showed no change in clinical signs in severe DED due to oGvHD, which was not unexpected due to the underlying pathomechanisms. Showed improvement of symptoms in individual patients allowing application of perfluorohexyloctane as an additional symptomatic therapy in oGvHD.
2021	Dorothea Groß and Thomas Kaercher. EC Ophthalmology 12.6 (2021): 32-44	Comparison of the Clinical Efficacy of Three Different Eye Drops for the Treatment of Dry Eye	30	4 times daily (QID) for 28 days	Statistically significant improvements in NIBUT were found in all groups (p < 0.001), with a larger percentual increase with EvoTears® at day 28 vs baseline (+121.3%). Patients treated with EvoTears® had less corneal staining than patients with Systane® Balance treatment (p = 0.007) at day 28. In all groups, significant changes in the expression of Meibomian glands, quality score of Meibomian secretion, level of conjunctival hyperemia and corneal staining , ocular surface disease index (OSDI). The patients and the investigator scored efficacy and tolerability as acceptable or very good in all groups.
2021	Tauber, J., Wirta, D.L., Sall, K., Majmudar, P.A., Willen, D. and Krösser, S., 2021. Cornea, 40(9), p.1132.	Randomized Clinical Study (SEECASE) to Assess Efficacy, Safety, and Tolerability of NOV03 for Treatment of Dry Eye Disease	336	2 times (BID) / 4 times daily (QID) for 8 weeks	The SEECASE study demonstrated that Perfluorohexyloctane improves signs and symptoms in patients with highly symptomatic evaporative dry eye disease.
2021	ClinicalTrials.gov.Identifier NCT00287391 Available at: https://ClinicalTrials.gov/show/NCT04139798	Perfluorohexyloctane for the treatment of signs and Symptoms of Dry Eye Disease Associated With Meibomian Gland Dysfunction (GOBI Study)	597	4 times daily (QID) for 57 days	Significant improvement in total corneal fluorescein staining (tCFS) and dryness score from day 15, with continued results through day 57.
2021	ClinicalTrials.gov Identifier: NCT04567329. -Available at: https://clinicaltrials.gov/ct2/show/NCT04567329?term=MOJAVE&draw=2&rank=1	Effect of NOV03 (Perfluorohexyloctane)on Signs and Symptoms of Dry Eye Disease Associated With Meibomian Gland Dysfunction (Mojave Study)	622	4 times daily (QID) for 57 days	Significant improvement in total Corneal Fluorescein Staining (tCFS), and dryness score and in each of the signs and symptoms of DED associated with MGD that were evaluated.
Ongoing	ClinicalTrials.gov Identifier NCT04140227, Available at: https://clinicaltrials.gov/ct2/show/NCT04140227?term=KALAHARI-&draw=2&rank=2	Long-Term Safety and Tolerability of NOV03 (Perfluorohexyloctane) in Subjects Who Completed Trial NVU-003 (Kalahari Study).	209	4 times daily (QID) for 12 months	No results available yet

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