ISRCTN40779210 Basic Results

ANSM registration #:	2018-A01711-54
Clinical investigation plan #:	17E4554
Study Title:	Evaluation of the efficacy and safety of Vis med® Gel Multi 0.3% versus Vlsmed® Multi 0.18% on the treatment of moderate to severe ocular dryness.
Study Population:	81 patients were randomised in the study (ITT population): 41 patients in Vismed® Gel Multi 0.3% group and 40 patients in Vismed® Multi 0.18%. 70 patients were included in the PP population (35 patients per group).

Results:

Analysis on PP population showed a non-inferiority of Vismed® Gel Multi 0.3% compared to Vismed® Multi 0.18%. Both products induced a significant improvement in cornea and conjunctiva staining by fluorescein (Oxford score change on D35: -32.8% with Vismed® Gel Multi 0.3%, p<0.001 and -23.4% with Vismed® Multi 0.18%, p<0.001) without significant difference between the products.

After 84 days of treatment, the Oxford score still significantly improved, without significant difference between the products (-41.9% with Vismed® Gel Multi 0.3%, p<0.001 and -34.8% with Vismed® Multi 0.18%, p<0.001). Conjunctival staining by lissamine green and evaluation with Van Bijsterveld score showed a significant improvement of Van Bijsterveld score with Vismed® Gel Multi 0.3% at both D35 and 084 compared to DO (-0.69 ± 1.11 at D35 and -0.97 ± 1. 73 at D84, p<0.001) and a significant improvement with Vismed® Multi 0.18% at D84 only (-0.68 ± 1.32, p=0.010). The Tear Break-Up Time (TBUT) was slightly but significantly improved with Vismed® Multi 0.18% at D84 (+2.5 ± 6.2 s for the sum of three measurements), however no significant change was observed with Vismed® Gel Multi 0.3% (at the limit of significance at D84). Nevertheless, the difference between both products was not statistically significant. The Schirmer test increase was only significant for Vismed® Gel Multi 0.3% at D35 (+2.17 ± 7.77 mm/5 min, p=0.040). No significant differences between the products was observed at any timepoint.

The patient evaluation of ocular dryness symptoms and 5-Item Dry Eye Questionnaire (DEQ-5) showed a significant improvement, at all timepoints for both products (at D84: -5.8 ± 4.1, p<0.001 with Vismed® Gel Multi 0.3%, -4.8 ± 5.3, p<0.001 for Vismed® Multi 0.18%). No significant difference was observed between the products. On D35, most of the investigators and the patients were satisfied or very satisfied with the global performance of the treatments: 65. 7% of the investigators and 77.2 % of the patients for Vismed® Gel Multi 0.3% versus 82.9% of the Investigators and 68.6% of the patients for Vis med® Multi 0.18%. After 84 days, a greater satisfaction was observed in 76.4% of the investigators and 82.4 % of the patients for Vismed® Gel Multi 0.3% and respectively 82.4% and 76.5 % in the Vismed® Multi 0.18% group.

Both products were globally well tolerated. All adverse events were mild or moderate, and no patient reported severe adverse event. Three patients in each group had at least one adverse device effect, possibly related to study product, without significant difference between both groups.

Conclusion:

The non-inferiority of Vismed Gel Multi 0.3% in comparison with Vismed Multi 0.18% was demonstrated.

No significant difference was observed between products. Both products produced a significant improvement of eye dryness signs and symptoms, with a significant improvement of Oxford and Van Bijsterveld scores, ocular dryness symptoms (discomfort, burning, stinging, eye dryness sensation, itching, sandy feeling/ foreign body sensation, photophobia and blurred vision) and DEQ-5 questionnaire. Most of the patients and the investigators were satisfied with both treatment performances. Both products were well tolerated.