**Study Summary: Clinical evaluation of an HP-Guar gellable lubricant eye drop for the relief of dryness of the eye**

**Key Points**
- SYSTANE® Lubricant Eye Drops contains two demulcents, polyethylene glycol 400 (0.4%) and propylene glycol (0.3%) and the polymer HP-Guar as a gelling agent. Once exposed to the pH of the ocular tears and surface, the HP-Guar in SYSTANE® Lubricant Eye Drops forms a “soft” gel with increased viscosity and bioadhesive properties that promote retention of the two demulcents in order to protect the ocular surface.
- SYSTANE® Lubricant Eye Drops significantly reduced symptoms of dryness in the morning and evening, compared to REFRESH TEARS* with one demulcent (carboxymethylcellulose sodium 0.5%) ($P = 0.015$ and $P = 0.023$, respectively).
- In the cohort of subjects with baseline corneal staining scores greater than or equal to 4.9, treatment with SYSTANE® Lubricant Eye Drops resulted in the largest differences in efficacy (significantly less conjunctival and corneal staining, $P<.001$), compared REFRESH TEARS*.

**Purpose**
To evaluate the efficacy and safety of a lubricant eye drop (SYSTANE® Lubricant Eye Drops) containing polyethylene glycol 400 and propylene glycol demulcents with HP-Guar (hydroxypropyl-guar) as a gelling agent to REFRESH TEARS* containing carboxymethylcellulose sodium 0.5% for reducing dry eye signs and symptoms.

**Design**
The design was intended to help mitigate some of the problematic environmental and experimental design factors inherent in many dry eye disease studies. Average age of the study population for the total sample was 59 years, and 71.3% of the subjects were females. Prior to enrolling in the study, 78% of the subjects reported using lubricating eye drops.

**Method**
A six-week, concurrently controlled, randomized, double-masked, multi-site study was conducted. Eighty-seven (87) adult volunteer with a diagnosis of dry eye were enrolled at seven clinical sites. Subjects qualifying at the screening visit (day -7) were dispensed relabeled Sensitive Eyes Rewetting Drops, for both eyes 4 times a day for 1 week.

On Day 0 (baseline), if they were still eligible (corneal staining score >3 in same eye), subjects were randomized (1:1) to use either Test (SYSTANE® Lubricant Eye Drops) or Control (REFRESH TEARS*) in both eyes, 4 times per day for the duration of the study. Follow-up visits occurred at Days 7, 14, 28 and 42.
Summary: Clinical evaluation of an HP-guar gellable lubricant eye drop for the relief of dryness of the eye

All subjects were evaluated for safety and intent to treat analyses. Conjunctival staining and corneal staining were measured at each visit. The worst eye, which was defined as the eye with the higher composite corneal staining score at Day 0, was followed for changes in corneal staining and total conjunctival staining throughout the study.

At each visit, subjects also rated the frequency of ocular comfort during the previous 3 days by completing seven anchored visual analog scales. These scales measured burning, stinging, blurry, gritty, dry, scratchy and foreign body sensation. At Day 7 and upon exit, all subjects rated 6 statements using a 5-point Likert-scale (1: strongly disagree to 5: strongly agree). Likert statements included, “My eyes feel refreshed longer than expected when I used the drops,” “My eyes feel dry in the morning,” and “My eyes feel dry at the end of the day.”

Results

Symptoms: SYSTANE® Lubricant Eye Drops significantly reduced symptoms of dryness in the morning and evening, compared to REFRESH TEARS* (P = 0.015 and P = 0.023, respectively) (Figure 2).

Subjects in the SYSTANE® Lubricant Eye Drops group also reported lower frequencies of foreign body sensation (Figure 3) and felt their eyes were “refreshed longer” compared to those in the REFRESH TEARS* group (P = 0.033 and P = 0.037 respectively).
**Summary:** Clinical evaluation of an HP-guar gellable lubricant eye drop for the relief of dryness of the eye

**Signs:** In the cohort of subjects with baseline corneal staining scores greater than or equal to 4.9, treatment with SYSTANE® Lubricant Eye Drops resulted in the largest differences in efficacy (significantly less conjunctival and corneal staining, $P < 0.001$), compared to REFRESH TEARS*. Subjects using SYSTANE® Lubricant Eye Drops in the higher corneal staining cohort (> 4.9) showed significantly less overall corneal staining than those in the REFRESH TEARS* group ($P < 0.001$).

**Conclusion**
SYSTANE® Lubricant Eye Drops is more effective than REFRESH TEARS* at reducing the signs and symptoms associated with dry eye problems.

The observed efficacy differences could be attributed to the differences in formulations with respect to preservatives, demulcients, viscosity, active ingredients and excipients. SYSTANE® Lubricant Eye Drops is preserved with POLYQUAD®, while REFRESH TEARS* is preserved with Purite*. Both preservatives have shown to be safe and have been used in numerous ophthalmic formulations for several years.

The difference in viscosity between the two products may account for some of the observed effects. The viscosities of the solutions are approximately 10 cps and 3 cps for SYSTANE® Lubricant Eye Drops and REFRESH TEARS* respectively. A unique attribute of SYSTANE® Lubricant Eye Drops is the addition of HP-Guar as a gelling agent, which is pH sensitive. When exposed to the ocular pH viscosity increases significantly.

* Trademarks are the properties of their respective owner.

**Citation**