

A Clinical Study to Evaluate the Effects of Three Dry Mouth Products

GSK data on file. RH01986

Aim

To investigate the effects of three dry mouth relief products (Biotène® Oral Balance Gel, Biotène® Oral Rinse and Biotène® Moisturizing Mouth Spray) versus water after 28 days of use, in a population of self-reported dry mouth sufferers

Study products and usage

- Biotène® Oral Balance Gel
- Biotène® Oral Rinse
- Biotène® Moisturizing Mouth Spray

Table 1: Test Products & Administration

Test Products	Administration
Biotène® Oral Balance Gel	Half inch length of the gel onto the tongue and spread thoroughly using their tongue
Biotène® Oral Rinse	Rinsed their mouth with 15 ml of Biotène® Oral Rinse for 30 seconds and spat out
Biotène® Moisturizing Mouth Spray	Sprayed one jet directly into their mouth
Control product: Water	One measured sip of water (15 ml)

Subjects used their allocated product 2-5 times a day

Methods

- Subjects with self-reported dry mouth symptoms, determined by a modified dry mouth screening questionnaire score, participated in a 28-day randomized study
- The subjective efficacy of the study products vs water was assessed using a modified Product Performance and Attributes Questionnaire (PPAQ)
 - The PPAQ was conducted at certain time points (30 mins, 1 hr, 2 hrs, 4 hrs) after supervised product use following product use at home
 - The PPAQ was done on Day 1, Day 8 and Day 29
- The questionnaire assessed efficacy (moisturization, lubrication and dry mouth relief), duration and comfort after product use

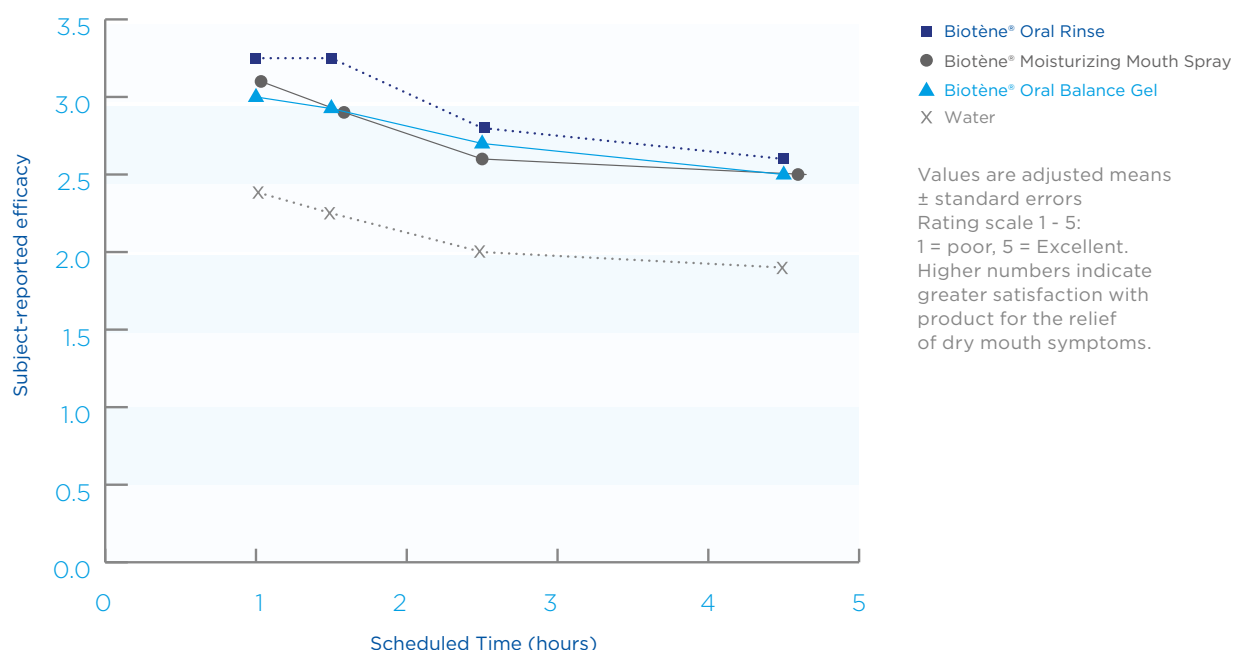
Results

- 467 subjects were screened and 396 were randomized into four treatment groups

Biotène® Oral Balance Gel	101
Biotène® Oral Rinse	98
Biotène® Moisturizing Mouth Spray	98
Water	99

- Results demonstrated a statistically significant difference in the subject-reported efficacy of all Biotène® products compared to the control product (water)
- The active treatments were found to be superior to water in relieving the discomfort of dry mouth at 2 hours after 28 days of treatment (Figure 1)
- Similar results were recorded for all other questions in the PPAQ questionnaires on Day 1, 8 and 29 assessments

Figure 1: PPAQ “Relieving the discomfort of dry mouth” at Day 29



Conclusion

Subjects using Biotène® Oral Balance Gel, Biotène® Oral Rinse and Biotène® Moisturizing Mouth Spray reported statistically significant improvement of relief from dry mouth symptoms compared to those using water