

A Clinical Study to Evaluate the Effects of Three Dry Mouth Products¹

Aim

To investigate the effects of three dry mouth symptom 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)

As well as supervised administration, subjects also used their allocated product at home 2-5 times a day, except for water which was sipped as often as required, as per specific directions applicable to each individual product

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 symptom relief), duration and comfort after product use

*Questionnaire was modified from the original Dry Mouth Inventory Quality of Life Questionnaire developed by GSK and the University of Sheffield

†Questionnaire was modified from a questionnaire in a previous study

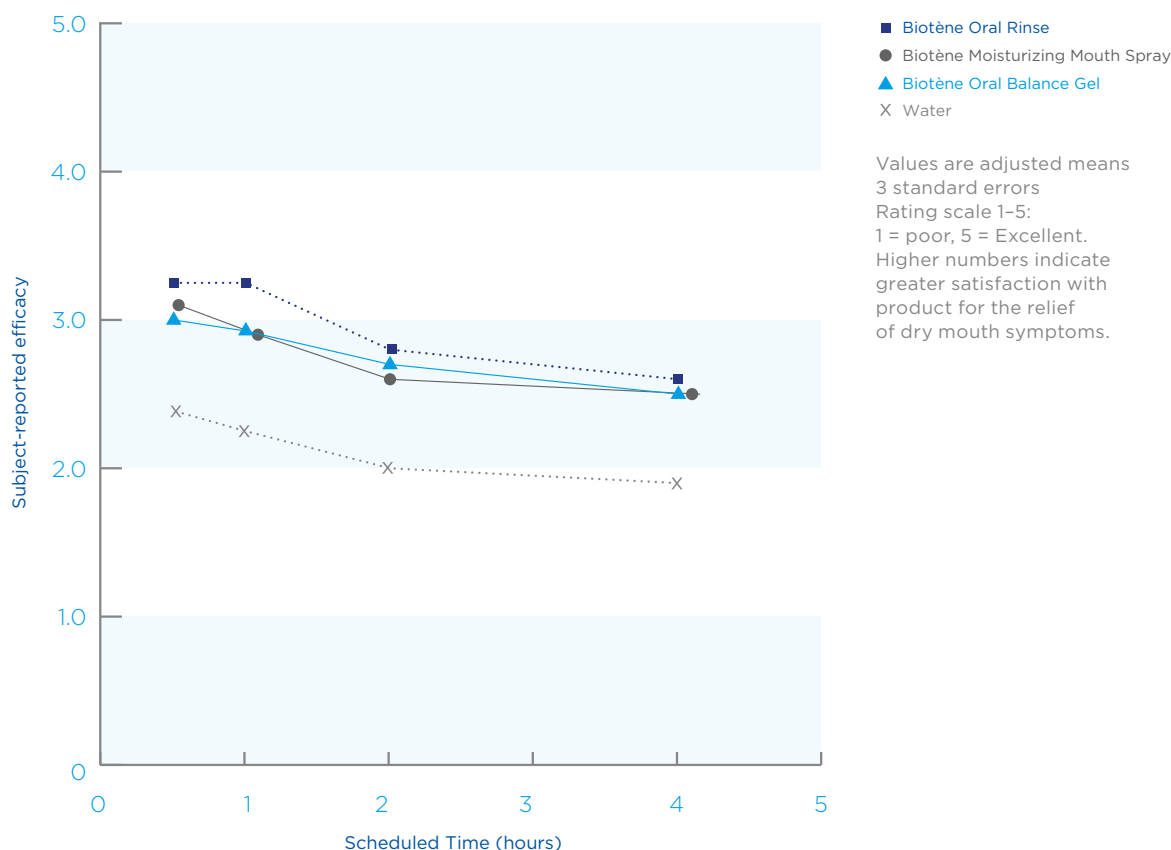
Results

- 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 up to 4 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

Reference

- Jose A, Siddiqi M, Cronin M, DiLauro TS, Bosma MK. A randomized clinical trial in subjects with dry mouth evaluating subjective perceptions of an experimental oral gel, an oral rinse and a mouth spray compared to water. *Am J Dent.* 2016;29(1):58-64.