Safety of Overnight Whitening with a Brush-Applied Peroxide Gel

R.W. Gerlach¹, M.L. Barker¹, A.A. Desai²*, C. Mahony², M.J. Prendergast², R.F. Date²
¹P&G, Mason, OH, USA, ²P&G, Egham, Surrey, UK

ABSTRACT

Objectives: Clinical research was conducted to evaluate safety of a brush-applied peroxide-based whitening gel across a diverse population.

Methods: After informed consent, 560 healthy adult subjects were screened to ascertain whitening history and current tooth sensitivity. Of these, 544 were assigned to treatment with a 19% sodium percarbonate brush-applied whitening gel (Crest® Night Effects™) that dries to form a film. Treatment was unsupervised QD for 14 nights. Safety and tolerability were assessed from clinical examination (baseline and end-of-treatment) and interview. Adverse events were collected irrespective of causality.

Results: 511 subjects completed the 14 night regimen. The study population exhibited considerable diversity. Mean (SD) age was 41.3 (13.4), ranging from 18-98. Most (74%) participants were female, and 12% of the sample reported daily tobacco usage. A total of 63 subjects (12%) had a possibly or probably-related adverse event during treatment. These were predominantly symptomatic events, particularly oral irritation (6.1% of subjects) and tooth sensitivity (5.5%). 95% confidence intervals for percent occurrence were (4.16%, 8.50%) for oral irritation and (3.67%, 7.82%) for tooth sensitivity. Only two subjects (0.4%) had both oral irritation and tooth sensitivity during treatment. Clinical examination findings were unremarkable. Adverse events were overwhelmingly (99%) mild in severity, though 1 subject reported moderate pharyngitis during the treatment. No subjects discontinued use early due to treatment-related adverse events.

Conclusion: Use of a 19% sodium percarbonate brush-applied film over 14-days was well tolerated, with mild and transient oral irritation or tooth sensitivity representing the most common adverse events associated with treatment.