Interventional Results Summary

Study Number: 300026

Title: A Clinical Study to Evaluate the Efficacy of a Stannous Fluoride Toothpaste for the Relief of Dentine Hypersensitivity in a Chinese Population

Sponsor: Haleon

Study Center: This study was conducted at a single center in China.

Actual First Subject First Visit: 08 May 2023

Actual Last Subject Last Visit: 19 Sep 2023

Product / Medicine: Stannous fluoride (SnF2)

Brief Summary: The purpose of this study was to evaluate the efficacy of a 0.454 percentage (%) weight/weight (w/w) SnF2 toothpaste for the relief of dentine hypersensitivity (DH) in China.

Phase: Not applicable

Study Design: This study was a single center, randomized, controlled, examiner-blind, 3 treatment arm, parallel group design study, stratified by maximum baseline Schiff sensitivity score (of the 2 selected 'test teeth'), with a treatment period of 12 weeks, to investigate the clinical efficacy of a SnF2 toothpaste for the relief of DH in a Chinese population. The SnF2 test dentifrice was compared to commercialized negative and positive control toothpastes.

Actual Enrolment: 416

Study Population:

- Ages Eligible for Study: 18 Years to 70 Years
- Sexes Eligible for Study: All
- Gender Based: No
- Accepts Healthy Volunteers: Yes
- Participant provision of a signed and dated informed consent document indicating that the participant was informed of all pertinent aspects of the study before any study procedures were performed.
- Participant who was willing and able to understand and comply with scheduled visits, product usage requirements and other study procedures.
- A participant in good general, oral and mental health with, in the opinion of the investigator or medically qualified designee, no clinically significant or relevant abnormalities in medical history or upon oral examination, or condition, that impacted the participant's safety, wellbeing or the outcome of the study, if they participated in the study, or affected the individual's ability to understand and follow study procedures and requirements.
- Participant who owned a smartphone with the WeChat application installed.
- A participant who presented the following oral and dental inclusions applied at Screening (Visit 1):

a) Self-reported history of tooth sensitivity lasting more than six months but not more than 10 years and experience DH symptoms at least 'once a week' or more frequently (as mentioned in Screening questionnaire).
b) Good general oral health, with a minimum of 20 natural teeth.
c) Minimum of 2 accessible non-adjacent teeth (incisors, canines, pre-molars), preferably in different quadrants, with clinically confirmed DH.

- Each eligible tooth met of the following criteria:

a) Exposed dentine due to facial/cervical erosion, abrasion or gingival recession (EAR).
b) Modified Gingival Index (MGI) = 0 directly adjacent to the exposed dentine (i.e., the test area) only.

c) Clinical mobility = 0.
d) DH as evidenced by qualifying levels of tactile and evaporative (air) sensitivity (tactile threshold less than or equal to [≤] 20 gram (g) and Schiff sensitivity score more than or equal to [≥] 2).

- A participant who presented the following oral and dental inclusions applied at Baseline (Visit 2):

a) All teeth identified at Screening (Visit 1) as eligible for Baseline assessments were reassessed for tactile sensitivity first; eligible teeth with Baseline tactile threshold ≤ 20 g were then re-assessed for evaporative (air) sensitivity.
b) Participants had a minimum of two non-adjacent, accessible teeth (incisors, canines, pre-molars), preferably in different quadrants, with clinically confirmed DH as evidenced by qualifying levels of tactile and evaporative (air) sensitivity:
   i) Tactile threshold ≤ 20 g at Screening and Baseline.
   ii) Schiff sensitivity score ≥ 2 at Screening and Baseline.
   iii) VAS ≥ 40 millimeters (mm) at Baseline.

- The clinical examiner selected two 'test teeth' from those eligible teeth which met the tactile threshold and Schiff sensitivity score criteria at both Screening and Baseline, and the VAS criterion at Baseline.
- Each test tooth demonstrated a consistent DH response to the evaporative (air) stimulus at both Screening and Baseline:
   i) Screening Schiff sensitivity score = 2 and Baseline Schiff sensitivity score = 2 or Screening Schiff sensitivity score = 3 and Baseline Schiff sensitivity score = 3.

Study Investigators/Centers: Shanghai Ninth People's Hospital, Shanghai Jiaotong University School of Medicine, Shanghai, China

Indication(s): Dentine hypersensitivity

Study Outcomes:

Primary Outcome Measures:

1. Adjusted Mean Change From Baseline in Schiff Sensitivity Score (Average of the Two Selected Test Teeth) at Week 12 (Test Dentifrice Versus [vs.] Negative Control) (Time Frame: Baseline and Week 12)

Secondary Outcome Measures:

2. Adjusted Mean Change From Baseline in Tactile Threshold (g) (Average of the Two Selected Test Teeth) at Week 12 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 12)
3. Adjusted Mean Change From Baseline in Visual Analog Scale (VAS) Score (mm) (Average of the Two Selected Test Teeth) at Week 12 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 12)
4. Adjusted Mean Change From Baseline in Schiff Sensitivity Score (Average of the Two Selected Test Teeth) at Week 6 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 6)
5. Adjusted Mean Change From Baseline in Tactile Threshold (g) (Average of the Two Selected Test Teeth) at Week 6 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 6)
6. Adjusted Mean Change From Baseline in VAS Score (mm) (Average of the Two Selected Test Teeth) at Week 6 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 6)

7. Adjusted Mean Change From Baseline in Schiff Sensitivity Score (Average of the Two Selected Test Teeth) at Week 6 and Week 12 (Positive Control vs. Negative Control) (Time Frame: Baseline, Week 6 and Week 12)
8. Adjusted Mean Change From Baseline in Tactile Threshold (g) (Average of the Two Selected Test Teeth) at Week 6 and Week 12 (Positive Control vs. Negative Control) (Time Frame: Baseline, Week 6 and Week 12)
9. Adjusted Mean Change From Baseline in VAS Score (mm) (Average of the Two Selected Test Teeth) at Week 6 and Week 12 (Positive Control vs. Negative Control) Time Frame: Baseline, Week 6 and Week 12)

Study Results:

Period Title: Overall Study	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Positive Control (Sensodyne Repair and Protect)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Started	97	50	96
Completed	95	49	96
Not Completed	2	1	0
Reason Not Completed			
Adverse Event	1	0	0
Protocol Violation	1	0	0
Withdrawal by Subject	0	1	0

Baseline Characteristics:

Arm/Group Title		**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Positive Control (Sensodyne Repair and Protect)**	**Negative Control (Crest Cavity Protection Fresh Lime)**	**Total**
Overall Number of Baseline Participants		95	49	96	240
Baseline Analysis Population Description:		Modified Intent-To-Treat (mITT) population included all randomized participants who completed at least one use of study product and had at least one post-Baseline efficacy assessment.			
Age, Continuous Mean (Standard Deviation) Unit of measure: years		42.4 (7.64)	43.7 (7.55)	43.2 (7.57)	43.0 (7.58)
Sex: Female, Male	Female	89 (93.68%)	47 (95.92%)	88 (91.67%)	224 (93.33%)
Measure Type: Count of Participants Unit of measure: participants	Male	6 (6.32%)	2 (4.08%)	8 (8.33%)	16 (6.67%)

Race/Ethnicity, Customized Measure Type: Count of Participants Unit of measure: participants	Asian – East Asian Heritage	95 (100%)	49 (100%)	96 (100%)	240 (100%)

Primary Outcome Results:

1. **Adjusted Mean Change From Baseline in Schiff Sensitivity Score (Average of the Two Selected Test Teeth) at Week 12 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 12)**

Analysis Population Description: mITT population.

Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	95	96
Mean (Standard Error) Unit of Measure: score on a scale	-0.90 (0.068)	-0.74 (0.068)
Statistical Analysis:		
Statistical Analysis Overview	Comparison Group Selection	Test Dentifrice (Sensodyne Sensitivity and Gum), Negative Control (Crest Cavity Protection Fresh Lime)
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.0871
	Method	Other [Mixed Model with Repeated Measure (MMRM)]
Method of Estimation	Estimation Parameter	Other [Adjusted Mean Difference]
	Estimated Value	-0.17
	95% Confidence Interval	-0.36 to 0.02
	Parameter Dispersion	Type: Standard Error of the Mean Value: 0.096
	Estimation Comments	Adjusted mean difference was calculated as test minus negative control.

Secondary Outcome Results:

2. Adjusted Mean Change From Baseline in Tactile Threshold (g) (Average of the Two Selected Test Teeth) at Week 12 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 12)		
Analysis Population Description : mITT population.		
Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	95	96
Mean (Standard Error) Unit of Measure: grams	25.86 (3.008)	19.65 (2.977)
Statistical Analysis:		
Statistical Analysis Overview	Comparison Group Selection	Test Dentifrice (Sensodyne Sensitivity and Gum), Negative Control (Crest Cavity Protection Fresh Lime)
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.0972
	Method	Other [van Elteren Test]
	Comments	P-value was from the van Elteren test adjusted for Baseline Schiff sensitivity stratification factor.
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	6.21
	Confidence Interval	-0.78 to 13.20
	Parameter Dispersion	Type: Standard Error of the Mean Value: 3.548
	Estimation Comments	Adjusted mean difference was calculated as test minus negative control.

3. Adjusted Mean Change From Baseline in Visual Analog Scale (VAS) Score (mm) (Average of the Two Selected Test Teeth) at Week 12 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 12)		
Analysis Population Description : mITT population.		
Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	95	96
Mean (Standard Error) Unit of Measure: score on a scale	-38.84 (2.872)	-33.02 (2.830)

Statistical Analysis:		
Statistical Analysis Overview	Comparison Group Selection	Test Dentifrice (Sensodyne Sensitivity and Gum), Negative Control (Crest Cavity Protection Fresh Lime)
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.0671
	Method	Other [MMRM]
	Comments	
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	-5.81
	Confidence Interval	-12.04 to 0.41
	Parameter Dispersion	Type: Standard Error of the Mean Value: 3.160
	Estimation Comments	Adjusted mean difference was calculated as test minus negative control.
4. Adjusted Mean Change From Baseline in Schiff Sensitivity Score (Average of the Two Selected Test Teeth) at Week 6 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 6)		
Analysis Population Description : mITT population. Only those participants with data available at the indicated timepoint were analyzed.		
Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	93	95
Mean (Standard Error) Unit of Measure: score on a scale	-0.51 (0.049)	-0.38 (0.049)
Statistical Analysis:		
Statistical Analysis Overview	Comparison Group Selection	Test Dentifrice (Sensodyne Sensitivity and Gum), Negative Control (Crest Cavity Protection Fresh Lime)
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.0673
	Method	Other [MMRM]
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	-0.13

	95% Confidence Interval	-0.27 to 0.01
	Parameter Dispersion	Type: Standard Error of the Mean Value: 0.070
	Estimation Comments	Adjusted mean difference was calculated as test minus negative control.
5. Adjusted Mean Change From Baseline in Tactile Threshold (g) (Average of the Two Selected Test Teeth) at Week 6 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 6)		
Analysis Population Description : mITT population. Only those participants with data available at the indicated timepoint were analyzed.		
Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	93	95
Mean (Standard Error) Unit of Measure: grams	11.74 (2.393)	9.36 (2.357)
Statistical Analysis		
Statistical Analysis Overview	Comparison Group Selection	Test Dentifrice (Sensodyne Sensitivity and Gum), Negative Control (Crest Cavity Protection Fresh Lime)
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.4050
	Method	Other [van Elteren Test]
	Comments	P-value was from the van Elteren test adjusted for Baseline Schiff sensitivity stratification factor.
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	2.38
	95% Confidence Interval	-2.44 to 7.20
	Parameter Dispersion	Type: Standard Error of the Mean Value: 2.446
	Estimation Comments	Adjusted mean difference was calculated as test minus negative control.
6. Adjusted Mean Change From Baseline in VAS Score (mm) (Average of the Two Selected Test Teeth) at Week 6 (Test Dentifrice vs. Negative Control) (Time Frame: Baseline and Week 6)		
Analysis Population Description: mITT population. Only those participants with data available at the indicated timepoint were analyzed.		

Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	93	95
Mean (Standard Error) Unit of Measure: score on a scale	-21.92 (2.603)	-16.28 (2.556)
Statistical Analysis		
Statistical Analysis Overview	Comparison Group Selection	Test Dentifrice (Sensodyne Sensitivity and Gum), Negative Control (Crest Cavity Protection Fresh Lime)
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.0346
	Method	Other [MMRM]
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	-5.64
	95% Confidence Interval	-10.88 to -0.41
	Parameter Dispersion	Type: Standard Error of the Mean Value: 2.656
	Estimation Comments	Adjusted mean difference was calculated as test minus negative control.
7. Adjusted Mean Change From Baseline in Schiff Sensitivity Score (Average of the Two Selected Test Teeth) at Week 6 and Week 12 (Positive Control vs. Negative Control) (Time Frame: Baseline, Week 6 and Week 12)		
Analysis Population Description: mITT population. Only those participants with data available at the indicated timepoints were analyzed.		
Arm/Group Title	**Positive Control (Sensodyne Repair and Protect)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	49	96
Mean (Standard Error) Unit of Measure: score on a scale		
Number Analyzed	47	95
Change from Baseline at Week 6	-0.36 (0.069)	-0.38 (0.049)
Number Analyzed	49	96

Change from Baseline at Week 12	-0.67 (0.095)	-0.74 (0.068)
Statistical Analysis 1		
Statistical Analysis Overview	Comparison Group Selection	Positive Control (Sensodyne Repair and Protect), Negative Control (Crest Cavity Protection Fresh Lime)
	Comments	Change from Baseline at Week 6
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.8256
	Method	Other [MMRM]
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	0.02
	95% Confidence Interval	-0.15 to 0.19
	Parameter Dispersion	Type: Standard Error of the Mean Value: 0.085
	Estimation Comments	Adjusted mean difference was calculated as positive control minus negative control.
Statistical Analysis 2		
Statistical Analysis Overview	Comparison Group Selection	Positive Control (Sensodyne Repair and Protect), Negative Control (Crest Cavity Protection Fresh Lime)
	Comments	Change from Baseline at Week 12
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.5314
	Method	Other [MMRM]
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	0.07
	95% Confidence Interval	-0.16 to 0.30
	Parameter Dispersion	Type: Standard Error of the Mean Value: 0.117

	Estimation Comments	Adjusted mean difference was calculated as positive control minus negative control.
8. Adjusted Mean Change From Baseline in Tactile Threshold (g) (Average of the Two Selected Test Teeth) at Week 6 and Week 12 (Positive Control vs. Negative Control) [Time Frame: Baseline, Week 6 and Week 12]		
Analysis Population Description : mITT population. Only those participants with data available at the indicated timepoints were analyzed.		
Arm/Group Title	**Positive Control (Sensodyne Repair and Protect)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	49	96
Mean (Standard Error) Unit of Measure: grams		
Number Analyzed	47	95
Change from Baseline at Week 6	6.77 (2.883)	9.36 (2.357)
Number Analyzed	49	96
Change from Baseline at Week 12	18.53 (3.830)	19.65 (2.977)
Statistical Analysis 1		
Statistical Analysis Overview	Comparison Group Selection	Positive Control (Sensodyne Repair and Protect), Negative Control (Crest Cavity Protection Fresh Lime)
	Comments	Change from Baseline at Week 6
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.5575
	Method	Other [van Elteren Test]
	Comments	P-value was from the Van Elteren test adjusted for Baseline Schiff sensitivity stratification factor.
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	-2.59
	95% Confidence Interval	-8.48 to 3.30
	Parameter Dispersion	Type: Standard Error of the Mean Value: 2.990

	Estimation Comments	Adjusted mean difference was calculated as positive control minus negative control.
Statistical Analysis 2		
Statistical Analysis Overview	Comparison Group Selection	Positive Control (Sensodyne Repair and Protect), Negative Control (Crest Cavity Protection Fresh Lime)
	Comments	Change from Baseline at Week 12
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.7717
	Method	Other [van Elteren Test]
	Comments	P-value was from the van Elteren test adjusted for Baseline Schiff sensitivity stratification factor.
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	-1.12
	95% Confidence Interval	-9.60 to 7.37
	Parameter Dispersion	Type: Standard Error of the Mean Value: 4.308
	Estimation Comments	Adjusted mean difference was calculated as positive control minus negative control.

9. Adjusted Mean Change From Baseline in VAS Score (mm) (Average of the Two Selected Test Teeth) at Week 6 and Week 12 (Positive Control vs. Negative Control) [Time Frame: Baseline, Week 6 and Week 12]

Analysis Population Description : mITT population. Only those participants with data available at the indicated timepoints were analyzed.

Arm/Group Title	**Positive Control (Sensodyne Repair and Protect)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
Overall Number of Participants Analyzed	49	96
Mean (Standard Error) Unit of Measure: score on a scale		
Number Analyzed	47	95

Change from Baseline at Week 6	-15.53 (3.123)	-16.28 (2.556)
Number Analyzed	49	96
Change from Baseline at Week 12	-29.30 (3.542)	-33.02 (2.830)
Statistical Analysis 1		
Statistical Analysis Overview	Comparison Group Selection	Positive Control (Sensodyne Repair and Protect), Negative Control (Crest Cavity Protection Fresh Lime)
	Comments	Change from Baseline at Week 6
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.8180
	Method	Other [MMRM]
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	0.75
	95% Confidence Interval	-5.63 to 7.12
	Parameter Dispersion	Type: Standard Error of the Mean Value: 3.235
	Estimation Comments	Adjusted mean difference was calculated as positive control minus negative control.
Statistical Analysis 2		
Statistical Analysis Overview	Comparison Group Selection	Positive Control (Sensodyne Repair and Protect), Negative Control (Crest Cavity Protection Fresh Lime)
	Comments	Change from Baseline at Week 12
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.3322
	Method	Other [MMRM]
Method of Estimation	Estimation Parameter	Other[Adjusted Mean Difference]
	Estimated Value	3.73
	95% Confidence Interval	-3.83 to 11.28

	Parameter Dispersion		Type: Standard Error of the Mean Value: 3.834
	Estimation Comments		Adjusted mean difference was calculated as positive control minus negative control.
Adverse Events			
Time Frame	From signing of the informed consent form until 5 days following the last administration of the study product or last study procedure (up to approximately 123 days).		
All-Cause Mortality			
Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Positive Control (Sensodyne Repair and Protect)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/97 (0%)	0/50 (0%)	0/96 (0%)
Serious Adverse Events			
Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Positive Control (Sensodyne Repair and Protect)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/97 (0%)	0/50 (0%)	0/96 (0%)
Other (Not Including Serious) Adverse Events			
Frequency Threshold for Reporting Other Adverse Events	0%		
Arm/Group Title	**Test Dentifrice (Sensodyne Sensitivity and Gum)**	**Positive Control (Sensodyne Repair and Protect)**	**Negative Control (Crest Cavity Protection Fresh Lime)**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	16/97 (16.49%)	9/50 (18%)	11/96 (11.46%)
Gastrointestinal disorders			
Angular Cheilitis	2/97 (2.06%)	0/50 (0%)	0/96 (0%)
Cheilitis	1/97 (1.03%)	0/50 (0%)	0/96 (0%)
Dental Caries	0/97 (0%)	0/50 (0%)	1/96 (1.04%)
Lip Ulceration	1/97 (1.03%)	0/50 (0%)	2/96 (2.08%)

Mouth Ulceration	3/97 (3.09%)	0/50 (0%)	0/96 (0%)
Oral Blood Blister	0/97 (0%)	0/50 (0%)	2/96 (2.08%)
Oral Cavity Fistula	0/97 (0%)	1/50 (2%)	0/96 (0%)
Oral Mucosal Blistering	0/97 (0%)	1/50 (2%)	0/96 (0%)
Tongue Ulceration	1/97 (1.03%)	0/50 (0%)	0/96 (0%)
General disorders			
Mucosal Inflammation	1/97 (1.03%)	0/50 (0%)	0/96 (0%)
Oedema Mucosal	0/97 (0%)	1/50 (2%)	0/96 (0%)
Infections and infestations			
Abscess Oral	0/97 (0%)	0/50 (0%)	1/96 (1.04%)
Gingival Abscess	0/97 (0%)	1/50 (2%)	1/96 (1.04%)
Gingivitis	2/97 (2.06%)	1/50 (2%)	0/96 (0%)
Herpes Simplex	0/97 (0%)	1/50 (2%)	0/96 (0%)
Nasopharyngitis	0/97 (0%)	0/50 (0%)	1/96 (1.04%)
Periodontitis	1/97 (1.03%)	0/50 (0%)	0/96 (0%)
Injury, poisoning and procedural complications			
Face Injury	0/97 (0%)	2/50 (4%)	1/96 (1.04%)
Lip Injury	1/97 (1.03%)	0/50 (0%)	0/96 (0%)
Mouth Injury	3/97 (3.09%)	2/50 (4%)	1/96 (1.04%)
Palate Injury	0/97 (0%)	0/50 (0%)	1/96 (1.04%)
Tooth Fracture	1/97 (1.03%)	0/50 (0%)	0/96 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Melanocytic Naevus	0/97 (0%)	1/50 (2%)	0/96 (0%)
Skin and subcutaneous tissue disorders			
Blood Blister	0/97 (0%)	0/50 (0%)	1/96 (1.04%)
Limitations and Caveats: Not Applicable			