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Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	ClinicalTrials.gov Identifier:	NCT00687037
		Study Code:	CPYRY_L_03930
Generic drug name:	Cetylpyridinium Chloride	Date:	12/Feb/2009

Title of the study:	Single site Study, Phase III, for Safety Dermatological Evaluation: Acceptability with odontologic follow-up – Cepacol Canela Power		
Investigator(s):	Sergio Schalka *MEDCIN – Instituto da Pele* Avenida Dr. Carlos de Moraes Barros, nº 304, Osasco, São Paulo		
Study center(s):	1 BR center		
Publications (reference):	None		
Study period: Date first subject enrolled: 17-Jan-2008 Date last subject completed: 12-Feb-2008		Phase of development: III	
Objectives:	To prove the formulation safety, in usual condition - odontologic use.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 30-35	Randomized: NA	Treated: 32
Evaluated:		Safety: 30	
Diagnosis and criteria for inclusion:	Both sexes volunteers, aged between 18 and 60 years old, Integral buccal mucous, normal odontologic exams, willingness in following the study procedures and ICF signature.		
Investigational product: Dose: Administration:	Cetylpyridinium Chloride (antiseptic mouthwash for oral hygiene) Rinse mouth with 20 mL twice a day. antiseptic mouthwash for oral hygiene		
Duration of treatment: 21 days		Duration of observation: 21 days	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	Dermatological Evaluation: Acceptability with odontologic follow-up are going to be evaluated by the occurrence of adverse events reported by the subject or noted by the investigator or dentistry with causality as follow: -No reaction; Reaction not related to the study product; Reaction remotely related to the study product; Reaction probably related to the study product or Reaction definitely related to the study product. Level of skin irritation in the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, ardor and itching and their intensity and causality: -Causality: not related, possible related, probably related or definitely related. -Intensity: Mild, Moderate or Severe.
Statistical methods:	In case of occurrence of adverse reaction, it will be used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group). The sum of the occurrences will be divided by the number of volunteers that present reaction, representing the mean of positive cutaneous answer to the product. The value will be shown with standard deviation, mode and median. Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.
Summary:	A total of 32 both sexes' volunteers were enrolled to the study, 30 volunteers completed the study. One volunteer did not return to final evaluation due to personals reasons and one volunteer was excluded due to presented exclusion criteria.
Safety results:	During the evaluation period , 04 volunteers reported mouth-burn during all study period, one volunteer reported mouth burn of mild intensity after the day 6 till the day 21 day, 01 volunteer reported mouth-burn related to product due to "strong flavor" and 01 volunteer reported burn-mouth of severe intensity. But in all cases during the clinical exam, it was not detected any active oral lesion. Another 26 volunteers completed the study and none presented any adverse event.
Date of report:	05- Feb-09