These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company:	sanofi-aventis	ClinicalTrials.gov Identifier:	NCT00729599
		Study Code:	CPYRY_L_04020
Generic drug name:	Cetylpyridinium Chloride	Date:	04/Mar/2009

Title of the study:	Single site Study, Phase III, for Safety Dermatological Evaluation: basic acceptability with odontological follow-up – Cepacol Teen		
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: 28-Jul-2008 Date last subject completed: 25-Aug-2008		Phase of development: III	
Objectives:	To prove the formulation safety, in usual condition - odontological use.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 30-35	Randomized: NA	Treated: 30
Evaluated:		Safety: 30	
Diagnosis and criteria for inclusion:	Both sexes volunteers, aged between 10 and 20 years old, Integral buccal mucous, normal odontological exams, willingness in following the study procedures and Informed Consent Form (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 odontological follow-up are going to be evaluated by the occurrence of adverse events reported by the subject or noted by the investigator or dentist with causality as follows: 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, possibly 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 into consideration the number, intensity and causality.
Summary:	A total of 30 both sexes' volunteers were enrolled to the study. All of them finished the study. Two volunteers had mucosal Lesion during the study.
Safety results:	One volunteer reported the occurrence of a mucosal lesion (aphtha) after 3 days using the study product, however the lesion was not detected during the exam of the oral cavity. Another volunteer reported by phone contact, at day 16, the occurrence of a mucosal lesion (aphtha). During the clinical evaluation performed by the dentist, at day 21, it was detected an active mucosal lesion of moderate intensity. It was not prescribed any treatment. After one week, in a new clinical exam, it was not detected any active lesion.
Date of report:	02-Feb-09