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	ClincialTrials.gov Identifier:	NCT00784069
		Study Code:	LACAC_L_04367
Generic drug name:	Lactic Acid	Date:	26/Oct/2009

Title of the study:	Dermatological evaluation of the photo irritation and photo sensitivity potential - Dermacyd Breeze Pocket BR (LACAC_L_04367)		
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: 13-Oct-2008 Date last subject completed: 14-Nov-2008		Phase of development: III	
Objectives:	To prove the absence of photo irritation and photo sensitivity potential of the product Dermacyd Breeze Pocket BR.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 25-30	Randomized: NA	Treated: 27
Evaluated:		Safety: 27	
Diagnosis and criteria for inclusion:	Female healthy volunteers, aged among 18 and 60 years old; phototypes: I, II, III and IV; with intact skin over the region tested; willingness in following the study procedures and ICF signature.		
Investigational product: Dose: Administration:	Lactic acid Intimate wipes were applied over the skin and patients received irradiation at this region Topical usage.		
Duration of treatment: 05 weeks		Duration of observation: 05 weeks	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	- Photo irritation and photo sensitive potential evaluated by the occurrence of adverse events reported by the subject or noted by the investigator as follows: - Level of skin irritation over the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, ardor and itching and their intensity: Mild, Moderate or Severe.
Statistical methods:	In case of occurrence of adverse reaction, it was used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group). -The sum of the occurrences was divided by the number of volunteers that presented reaction, representing the mean of positive cutaneous answer to the product. The value was shown with standard deviation, mode and median. -Percentage of volunteers with adverse reaction, taking into consideration the number and intensity.
Summary:	A total of 27 female volunteers were enrolled in the study. All of them finished the study. No patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	14-Oct-2009