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:	NCT00668460
		Study Code:	LACAC_L_03744
Generic drug name:	Lactic Acid	Date:	28/Jan/2009

Title of the study:	Monocentric Study, Phase III for Dermatological evaluation of topic compatibility (primary and accumulated dermical irritability, dermical sensibility)– Dermacyd Delicata Pocket BR (LACAC_L_03744)		
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: 03-Dec-2007 Date last subject completed: 10-Jan-2008		Phase of development: III	
Objectives:	To prove the absence of irritation potential (primary dermatological irritability and cumulated dermatological irritability) and allergy (sensibilization) of the product.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 50-60	Randomized: NA	Treated: 52
Evaluated:		Safety: 52	
Diagnosis and criteria for inclusion:	Healthy volunteers, female, aged between 18 and 60 years old; Phototypes: I, II, III and IV, with integral skin in the region tested, willingness in following the study procedures and to be present in the clinic at the days and schedule time and ICF signature.		
Investigational product: Dose: Administration:	Lactic acid Patients received some applications in the skin (external area). Topical usage.		
Duration of treatment: 6 weeks		Duration of observation: 6 weeks	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	-Compatibility evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follow: -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. These data are going to be filled out in patient CRF and Adverse Reactions Form.
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 show with standard deviation, mode and median. -Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.
Summary:	A total of 54 female volunteers were enrolled to the study. Two of them were discontinued: one due to exposure to the sun and for this reason had an itching; the other one took forbidden medication which could modify the study result. Any patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction in the tested region.
Date of report:	09- Jan-09