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

Sponsor/company:	sanofi-aventis	ClincialTrials.gov Identifier:	NCT00881374
		Study Code:	LACAC_L_04679
Generic drug name:	Lactic Acid	Date:	05/Feb/2010

Title of the study:	Dermatological evaluation of topic compatibility, primary dermic irritability, accumulated and dermic sensitivity)– Dermacyd Infantile (LACAC_L_04679)		
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: 02-Feb-2009 Date last subject completed: 12-Mar-2009		Phase of development: III	
Objectives:	To confirm the absence of irritation potential (primary dermic irritability and cumulated dermic irritability) or allergy (sensibilization) of the product Dermacyd Infantile.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 50-60	Randomized: NA	Treated: 55
Evaluated:		Safety: 54	
Diagnosis and criteria for inclusion:	Aged among 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 ICF signature.		
Investigational product: Dose: Administration:	Lactic acid Patients received some sample applications in the skin, like a curative. Topical usage.		
Duration of treatment: 06 weeks		Duration of observation: 06 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. All adverse reactions were noted in the appropriate form, independent of being associated or not with the sample (causality). -Level of skin irritation in the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, burning and itching and their intensity and causality: - Intensity: Mild, Moderate or Severe.
Statistical methods:	In case of adverse reaction's occurrence, it would be 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 in consideration the number, intensity and causality.
Summary:	A total of 55 volunteers were enrolled in the study. One volunteer gave up the study due to particular reasons. No volunteer had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	03-Feb-2010