

*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: NCT00668226	
Generic drug name: Lactic Acid		Study Code: LACAC_L_03745	
		Date: 28/Jan/2009	
Title of the study:		Monocentric study, Phase III for Dermatological evaluation of the photo irritation and photo sensitivity potential - Dermacyd Delictata Pocket BR (LACAC_L_03745)	
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: 10-Dec-2007 Date last subject completed: 10-Jan-2008		Phase of development: III	
Objectives:		To prove the absence of photo irritation and photo sensitivity potential of the product .	
Methodology:		Single-center, open label, non-comparative study.	
Number of subjects:		Planned: 25-30	Randomized: NA Treated: 25
Evaluated:		Safety: 25	
Diagnosis and criteria for inclusion:		Healthy volunteers, Female , aged between 18 and 60 years old, Phototypes: II and III, 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 applications and irradiation in the skin. Topical usage.	
Duration of treatment: 5 weeks		Duration of observation: 5 weeks	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	<p>-Photo irritation and photo sensitive potential are going to be evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follow:</p> <p>-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:</p> <p>-Causality: not related, possible related, probably related or definitely related.</p> <p>-Intensity: Mild, Moderate or Severe.</p> <p>These data are going to be filled out in patient CRF and adverse reactions form.</p>
Statistical methods:	<p>In case of occurrence of adverse reaction, it will be used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group).</p> <p>-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.</p> <p>-Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.</p>
Summary:	A total of 25 female volunteers were enrolled to the study. All of them finished the study. None of them presented skin reaction in the tested region.
Safety results:	No volunteer presented skin reaction.
Date of report:	09- Jan-09