

<p><i>These results are supplied for informational purposes only.</i></p> <p><i>Prescribing decisions should be made based on the approved package insert in the country of prescription</i></p>			
Sponsor/company:	sanofi-aventis	ClinialTrials.gov Identifier:	NCT00933075
Generic drug name:	Lactic acid	Study Code:	LACAC_L_04843
		Date:	13 September 2010

Title of the study:	Dermatological topic evaluation of the photo irritation and photo sensitivity potential – Dermacyd Silver Frutal (LACAC_L_04843)		
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:	Phase of development: III		
Date first subject enrolled:	22-Jun-2009		
Date last subject completed:	23-Jul-2009		
Objectives:	To prove that the product tested (Dermacyd Silver Frutal) does not cause photo irritation and photo sensitivity when exposure to the light.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 25-30	Randomized: 27	Treated: 27
Evaluated:		Safety: 27	
Diagnosis and criteria for inclusion:	Volunteers aged among 18 and 60 years old; phototypes: II and III, with integral skin in the region tested; willingness in following the study procedures and to be present at the clinic during the days and timing scheduled and Informed Consent Form signed.		
Investigational product:	Lactic acid		
Dose:	Patients received small quantity applications and irradiation over the skin.		
Administration:	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 were evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follow:</p> <p>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.</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>It is important to point out that the prototype Fitzpatrick scale was used to classify the skin colour and the sensibilization according to the skin colour.</p>
Statistical methods:	In case of adverse reaction occurrence , it would be used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group). However, it is important to point out that it was not observed skin reaction.
Summary:	A total of 27 volunteers were enrolled in the study. All of them finished the study. Any patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	30-Aug-2010