

<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>			
<b>Sponsor/company:</b>	sanofi-aventis	<b>ClinialTrials.gov Identifier:</b>	NCT00933712
<b>Generic drug name:</b>	Lactic acid	<b>Study Code:</b>	LACAC_L_04839
		<b>Date:</b>	13 September 2010

<b>Title of the study:</b>	Dermatological evaluation of topic compatibility, primary dermic irritability, accumulated and dermic sensitivity– Dermacyd Silver Floral (LACAC_L_04839)		
<b>Investigator(s):</b>	Sergio Schalka MEDCIN – Instituto da Pele Avenida Dr. Carlos de Moraes Barros, nº 304, Osasco, São Paulo		
<b>Study center(s):</b>	1 BR center		
<b>Publications (reference):</b>	None		
<b>Study period:</b>	Phase of development: III		
Date first subject enrolled:	15-Jun-2009		
Date last subject completed:	23-Jul-2009		
<b>Objectives:</b>	To demonstrate the absence of potential irritability (primary dermic irritability and cumulated dermic irritability) and allergy (sensibilization) by the product Dermacyd Silver Floral.		
<b>Methodology:</b>	Single-center, open label, non-comparative study.		
<b>Number of subjects:</b>	Planned: 50-60	Randomized: 55	Treated: 55
<b>Evaluated:</b>		Safety: 55	
<b>Diagnosis and criteria for inclusion:</b>	Volunteers 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 to be present at the clinic during the days and timing scheduled and Informed Consent Form signed.		
<b>Investigational product:</b>	Lactic acid		
Dose:	Patients received small quantity applications over the skin.		
Administration:	Topical usage.		
<b>Duration of treatment:</b> 6 weeks	<b>Duration of observation:</b> 6 weeks		

<b>Reference therapy:</b>	NA
<b>Criteria for evaluation:</b>	
<b>Safety:</b>	<p>- Compatibility was 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 color and the sensibilization according to the skin color.</p>
<b>Statistical methods:</b>	In case of occurrence of adverse reaction, 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.
<b>Summary:</b>	A total of 55 female volunteers were enrolled in the study. All of them finished the study. Any patient enrolled had cutaneous reaction.
<b>Safety results:</b>	No volunteer presented skin reaction.
<b>Date of report:</b>	30-Aug-2010