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

<b>Sponsor/company:</b> sanofi-aventis		<b>ClinicalTrials.gov Identifier:</b> NCT00668486	
<b>Generic drug name:</b> Lactic Acid		<b>Study Code:</b> LACAC_L_03748	
		<b>Date:</b> 06/Feb/2009	
<b>Title of the study:</b>	Dermatological evaluation of the photo irritation and potential photo sensitivity - Dermacyd Breeze (LACAC_L_03748)		
<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> Date first subject enrolled: 21-Jan-2008 Date last subject completed: 21-Feb-2008	<b>Phase of development:</b> III		
<b>Objectives:</b>	To prove the absence of photo irritation and potential photo sensitivity of the product Dermacyd Breeze.		
<b>Methodology:</b>	Single-center, open label, non-comparative study.		
<b>Number of subjects:</b>	Planned: 25-30	Randomized: NA	Treated: 28
<b>Evaluated:</b>		Safety: 28	
<b>Diagnosis and criteria for inclusion:</b>	Female volunteers, 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 Informed Consent Form (ICF) signature.		
<b>Investigational product:</b> Dose: Administration:	Lactic acid Patients are going to receive some applications and irradiation in the skin. Topical usage.		
<b>Duration of treatment:</b> 5 weeks		<b>Duration of observation:</b> 5 weeks	

<b>Reference therapy:</b>	NA
<b>Criteria for evaluation:</b>	
<b>Safety:</b>	<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: 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: Causality: not related, possible related, probably related or definitely related.</p> <p>-Intensity: Mild, Moderate or Severe.</p>
<b>Statistical methods:</b>	<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 shown with standard deviation, mode and median.</p> <p>-Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.</p>
<b>Summary:</b>	A total of 28 female volunteers were enrolled to the study. All of them finished the study. Any patient had cutaneous reaction.
<b>Safety results:</b>	No volunteer presented skin reaction.
<b>Date of report:</b>	29-jan-2009