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:	NCT00785720
		Study Code:	LACAC_L_04303
Generic drug name:	Lactic acid	Date:	21/Aug/2009

Title of the study:	Dermatological evaluation of the photo irritation and photo sensitivity potential - Dermacyd PH_DETINBACK Sweet Flower (LACAC_L_04303)		
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: 04-Aug-2008 Date last subject completed: 04-Sep-2008		Phase of development: III	
Objectives:	To prove the absence of photo irritation and photo sensitivity potential of the product Dermacyd PH_DETINBACK Sweet Flower.		
Methodology:	Single-center, open label, comparative study.		
Number of subjects:	Planned: 25-30	Randomized: NA	Treated: 26
Evaluated:		Safety: 26	
Diagnosis and criteria for inclusion:	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 to be present in the clinic at the days and scheduled time and Informed Consent Form (ICF) signature.		
Investigational product: Dose: Administration:	Lactic acid Patients received some applications and irradiation over the skin. Topical usage.		
Duration of treatment: 5 weeks		Duration of observation: 5 weeks	

Reference therapy: Dose: Administration:	Dermacyd PH_DETINLYN Sweet Flower Patients received some applications and irradiation over the skin. Topical usage.
Criteria for evaluation:	
Safety:	-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: 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. -Level of skin irritation in the tested region was 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. - Intensity: Mild, Moderate or Severe.
Statistical methods:	In case of occurrence of adverse reaction, it was 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 present 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 26 female volunteers were enrolled to the study. All of them finished the study. No patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	03-Aug-2009