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	**ClinialTrials.gov Identifier:**	NCT00933569
		Study Code:	LACAC_L_04838
Generic drug name:	Lactic acid	**Date:**	13 September 2010

Title of the study:	Unicentric Study, Phase III, for Safety Dermatological Evaluation: acceptability with gynaecological follow up – Dermacyd Silver Floral LACAC_L_04838		
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: 16-Jun-2009 Date last subject completed: 08-Jul-2009		**Phase of development:** III	
Objectives:	To prove the safety of the gynecological formulation in normal and usual conditions.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 30-35	Randomized: 32	Treated: 32
Evaluated:		Safety: 31	
Diagnosis and criteria for inclusion:	Age between 18 and 65 years old, integral mucosa in the region tested, use the same category cosmetics products, willingness in following the study procedures and to be present at the clinic during the days and time scheduled and Informed Consent Form signed;		
Investigational product:	Lactic acid		
Dose:	Liquid soap applied over the external genital area, in small quantity, with abundantly rinse after use, during 21 days.		
Administration:	Topical usage.		

Duration of treatment: 21 days	**Duration of observation:** 21 days
Reference therapy:	NA
Criteria for evaluation:	
Safety:	- Acceptability evaluated by the occurrence of adverse events reported by the subject or noted by the investigator according to the evaluation scale reaction: -Level of skin irritation at the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, ardor and itching and their intensity and causality: - Causality: not related, possibly related, probably related or definitely related. - Intensity: Mild, Moderate or Severe. These data were filled out in patient CRF and Adverse Reactions Form.
Statistical methods:	It was evaluated the total number of the subjects that had adverse events during the study.
Summary:	A total of 32 female volunteers were enrolled to the study. Eleven of them were older than 45 years old and eight were menopause. One volunteer did not return to the final visit due to personal reasons. Any patient had cutaneous or mucosa reaction.
Safety results:	No volunteer presented reaction.
Date of report:	27-Aug-2010