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:**	NCT00932945
		Study Code:	LACAC_L_04806
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 PH_DESILSTY_FR (Dermacyd Stay on Frutal) LACAC_L_04806		
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: 24-Jun-2009 Date last subject completed: 21-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: 31
Evaluated:		Safety: 30	
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 at the days and scheduled time and ICF signed;		
Investigational product: Dose: Administration:	Lactic acid Investigational product was applied over the external genital area, in small quantity, without rinsing after use, during 21 days. 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, possible related, probably related or definitely related. - Intensity: Mild, Moderate or Severe. In case of Adverse Event, these data were filled out in patient CRF and Adverse Reactions Form.
Statistical methods:	Subject's total number with adverse events was evaluated 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 four were post menopause ones. One volunteer gave up as soon as she was selected to participate. 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:	30-Aug-2010