

<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>			
Sponsor/company:	sanofi-aventis	ClinialTrials.gov Identifier:	NCT00933699
Generic drug name:	Lactic acid	Study Code:	LACAC_L_04803
		Date:	13 September 2010

Title of the study:	Monocentric Study, Phase III, for Safety Dermatological Evaluation: acceptability with gynaecological follow up – Dermacyd PH_DESILSTY_FL (Dermacyd Stay on Floral) LACAC_L_04803		
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:			Phase of development: III
Date first subject enrolled:	24-Jun-2009		
Date last subject completed:	21-Jul-2009		
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 in the clinic at the days and scheduled time and Informed Consent Form signature;		
Investigational product:	Lactic acid		
Dose:	Investigational product was applied in the external genital area, in small quantity, without rinsing 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:	<p>- Acceptability evaluated by the occurrence of adverse events reported by the subject or noted by the investigator according the evaluation scale reaction:</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>In case of Adverse Event, these data were filled out in patient CRF and Adverse Reactions Form.</p>
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. Thirty of them were older than 45 years old and nineteen were postmenopause ones. 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:	23-Aug-2010