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:	NCT00785850
		Study Code:	LACAC_L_04301
Generic drug name:	Lactic acid	Date:	03/Mar/2009

Title of the study:	Safety Dermatological Evaluation: genital mucous evaluation with gynecological follow up – Dermacyd PH_DETINBACK Sweet Flower. LACAC_L_04301		
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: 21-Aug-2008 Date last subject completed: 17-Sep-2008		Phase of development: III	
Objectives:	To prove the safety of the Liquid soap formulation for gynecological use in usual conditions.		
Methodology:	Single-center, open label, comparative study.		
Number of subjects:	Planned: 30-35	Randomized: NA	Treated: 31
Evaluated:		Safety: 30	
Diagnosis and criteria for inclusion:	Age between 10 and 20 years old; integral skin in the analyzed region; use the same category of cosmetic product; willingness in following the study procedures and to be present in the clinic at the days and scheduled time and ICF signature.		
Investigational product: Dose: Administration:	Lactic acid Liquid soap to be applied in the external genital area, in small quantity, with abundant rinsing after use, during 21 days. Topical usage.		
Duration of treatment: 21 days		Duration of observation: 21 days	

Reference therapy: Dose: Administration:	Dermacyd PH_DETINLYN Sweet Flower To be used during 21 days, according sponsor instructions. Topical usage.
Criteria for evaluation:	
Safety:	Acceptability evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follow: -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. - Intensity: Mild, Moderate or Severe. These data are going to be filled out in patient CRF and Adverse Reactions Form.
Statistical methods:	Evaluation of the total number of the subjects that have adverse events during the study.
Summary:	A total of 31 female volunteers were enrolled to the study. One patient did not return to the final evaluation due to personal reasons, 30 volunteers were analyzed for safety and it was not detected any cutaneous reactions
Safety results:	None of the volunteers evaluated had cutaneousreaction.
Date of report:	05-Feb-09