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:	NCT00783939
		Study Code:	LACAC_L_04307
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 Tangerine Mix LACAC_L_04307		
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: 02-Sep-2008 Date last subject completed: 26-Sep-2008		Phase of development: III	
Objectives:	To prove the safety of the gynecological liquid soap formulation in normal and usual conditions.		
Methodology:	Single-center, open label, comparative study.		
Number of subjects:	Planned: 30-35	Randomized: NA	Treated: 31
Evaluated:		Safety: 31	
Diagnosis and criteria for inclusion:	Age between 10 and 20 years old; integral skin in the analyze region; use the same category 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 Tangerine Mix 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. All of them were analyzed and no one cutaneous reaction was detected
Safety results:	None of the volunteers analyzed had a cutaneous reaction
Date of report:	05-Feb-09