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:	NCT00663390
		Study Code:	LACAC_L_03743
Generic drug name:	Lactic Acid	Date:	27/Jan/2009

Title of the study:	Monocentric Study, Phase III, for Safety Dermatological Evaluation: acceptability with gynaecological follow up – Dermacyd Delicata Pocket BR (LACAC_L_03743)		
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: 17-Dec-2007 Date last subject completed: 14-Jan-2008		Phase of development: III	
Objectives:	To prove the safety of the gynecological formulation in normal and usual use conditions.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 30-35	Randomized: NA	Treated: 31
Evaluated:		Safety: 30	
Diagnosis and criteria for inclusion:	Female, Healthy volunteers, aged between 18 and 60 years old; integral skin in the region tested; willingness in following the study procedures, to be present in the clinic at the days and scheduled time and ICF signature;		
Investigational product: Dose: Administration:	Lactic acid Wipes to be used in the external genital area, 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 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 datas are going to be filled out in patient CRF and Adverse Reactions Form.
Statistical methods:	In case of occurrence of adverse reaction, it will be used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group). -The sum of the occurrences will be divided by the number of volunteers that present reaction, representing the mean of positive cutaneous answer to the product. The value will be show with standard deviation, mode and median. -Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.
Summary:	A total of 31 female volunteers were enrolled to the study. One patient did not return to the final evaluation. None of them presented skin reaction in the tested region concerning dermatological and gynecological monitoring.
Safety results:	No volunteer presented skin reaction
Date of report:	07-jan-09