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	ClincialTrials.gov Identifier:	NCT00793026
		Study Code:	LACAC_L_04365
Generic drug name:	Lactic Acid	Date:	26/Oct/2009

Title of the study:	Safety Dermatological Evaluation: genital mucous evaluation through clinical study with gynecological follow up – Dermacyd Breeze Pocket BR LACAC_L_04365		
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: 04-Nov-2008 Date last subject completed: 28-Nov-2008		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: NA	Treated: 32
Evaluated:		Safety: 30	
Diagnosis and criteria for inclusion:	Healthy volunteers, aged between 18 and 60 years old; intact skin test in the region to be tested; use the same category cosmetic product; willingness in following the study procedures and to be present at the clinic during the days scheduled and ICF signature;		
Investigational product: Dose: Administration:	Lactic acid Liquid soap to be applied over the external genital area, in small quantity, with abundantly rinse after use, during 21± 2 days. Topical usage.		
Duration of treatment: 21 ± 2 days		Duration of observation: 21 ± 2 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 as follows: -Level of skin irritation in the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, ardor and itching and their intensity: Mild, Moderate or Severe. In case of adverse event, these data were 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).
Summary:	A total of 32 female volunteers were enrolled in the study. Two of them did not return to the final visit and, for this reason, only 30 patients were evaluated. None of these evaluated patients had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	14-Oct-2009