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:	NCT00664391
		Study Code:	LACAC_L_03746
Generic drug name:	Lactic Acid	Date:	06/Feb/2009

Title of the study:	Monocentric Study, Phase III, for Safety Dermatological Evaluation: acceptability with gynaecological follow up – Dermacyd Breeze LACAC_L_03746		
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-Jan-2008 Date last subject completed: 12-Feb-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: 32
Evaluated:		Safety: 32	
Diagnosis and criteria for inclusion:	Age between 18 and 60 years old, integral skin test in the region, willingness in following the study procedures and to be present in the clinic at the days and scheduled time and Informed Consent Form (ICF) signature;		
Investigational product: Dose: Administration:	Lactic acid Liquid soup to be applied in the external genital area, in small quantity, with abundantly rinse after use, 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 data are going to be filled out in patient CRF and Adverse Reactions Form.
Statistical methods:	Will be evaluated the total number of the subjects that have adverse events during the study.
Summary:	A total of 32 female volunteers were enrolled to the study. All of them finished the study. Any patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	29-jan-2009