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Prescribing decisions should be made based on the approved package insert in the country of prescription*

Sponsor/company:	sanofi-aventis		ClinialTrials.gov Identifier:	NCT00497783	
Generic drug name:	Lactic Acid		Study Code:	LACTO_L_02949	
			Date:	19/May/2008	
Title of the study:	Safety Dermatological evaluation: acceptability with gynecological follow up – Dermacyd Femina Delicata (LACTO_L_02949)				
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-May-2007 Date last subject completed: 13-Jul-2007				Phase of development: III	
Objectives:	To evaluate in female volunteers, the safety of the formulation Dermacyd Femina Delicata in normal and usual usage conditions.				
Methodology:	Single-center, open label, non-comparative study.				
Number of subjects:	Planned: 30	Randomized: NA	Treated: 30		
Evaluated:		Safety: 30			
Diagnosis and criteria for inclusion:	Female volunteers, aged between 18 and 60 years old, with integral skin in the region tested, willingness in following the study procedures and signature of ICF.				
Investigational product: Dose: Administration:	Lactic acid Wipes to be used at least four times per day. Topical usage.				
Duration of treatment: 21 days	Duration of observation: 21 days				

Reference therapy:	NA
Dose:	NA
Administration:	NA
Criteria for evaluation:	
Safety:	<p>-Acceptability evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follow:</p> <p>No reaction, Reaction not related to the study product, Reaction remotely related to the study product, Reaction probably related to the study product or Reaction definitely related to the study product.</p> <p>-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:</p> <p>Causality: not related, possible related, probably related or definitely related.</p> <p>Intensity: Mild, Moderate or Severe.</p>
Statistical methods:	<p>In case of occurrence of adverse reaction, it will be used the “Evaluation scale of cutaneous answer”, by ICDRG (International contact Dermatitis Research Group).</p> <p>-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.</p> <p>-Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.</p>
Summary:	A total of 30 female volunteers were enrolled to the study. All of them completed the treatment period of 21 days. None of them present skin reaction in the tested region concerning dermatological and gynecological monitoring.
Safety results:	No volunteer presented skin reaction in the tested region concerning dermatological and gynecological monitoring.
Date of report:	23-Feb-2008