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Sponsor/company:	sanofi-aventis		ClinialTrials.gov Identifier:	NCT00371852	
Generic drug name:	LACTIC ACID		Study Code:	LACTO_L_01811	
			Date:	15-May-2008	
Title of the study:	Dermatological evaluation of topic compatibility (primary and accumulated dermal irritability, dermal sensibility)– Dermacyd Feminine Wipes (LACTO_L_01811)				
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:				Phase of development: III	
Date first subject enrolled:	22-May-2006				
Date last subject completed:	30-Jun-2006				
Objectives:	To demonstrate the absence of irritation potential (primary dermic irritability and cumulated dermic irritability) and allergy (sensibilization) of the product Dermacyd Feminine Wipes.				
Methodology:	Single-center, open label, non-comparative study.				
Number of subjects:	Planned: 50		Randomized: NA	Treated: 53	
Evaluated:			Safety: 53		
Diagnosis and criteria for inclusion:	Female volunteers, aged between 18 and 60 years old, Phototypes: I, II, III and IV, with integral skin in the region tested, willingness in following the study procedures and signature of ICF.				
Investigational product:	Lactic acid				
Dose:	Wipes to be used at least during 48 hours.				
Administration:	Topical usage.				
Duration of treatment: 06 weeks			Duration of observation: 06 weeks		

Reference therapy:	NA
Criteria for evaluation:	
Safety:	<p>- Compatibility 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 53 female volunteers were enrolled to the study. All of them completed the treatment period of 06 weeks without cutaneous reaction.
Safety results:	No volunteer presented skin reaction in the tested region.
Date of report:	23-Apr-2008