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:	NCT00783861
		Study Code:	LACAC_L_04370
Generic drug name:	Lactic Acid	Date:	26/Oct/2009

Title of the study:	Dermatological evaluation of topic compatibility (primary and accumulated dermical irritability, dermical sensibility)– Dermacyd Femina Pocket BR (LACAC_L_04370)		
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: 06-Oct-2008 Date last subject completed: 14-Nov-2008		Phase of development: III	
Objectives:	To demonstrate the absence of irritation potential (primary dermic irritability and cumulated dermic irritability) and allergy (sensibilization) of the product Dermacyd Femina Pocket BR.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 50-60	Randomized: NA	Treated: 54
Evaluated:		Safety: 54	
Diagnosis and criteria for inclusion:	Female healthy volunteers; aged among 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 ICF signature.		
Investigational product: Dose: Administration:	Lactic acid Intimate wipes were applied over the skin. Topical usage.		
Duration of treatment: 06 weeks		Duration of observation: 06 weeks	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	- Compatibility evaluated by the occurrence of adverse events reported by the subject or noted by the investigator 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: Mild, Moderate or Severe.
Statistical methods:	In case of occurrence of adverse reaction, it was used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group). -The sum of the occurrences was divided by the number of volunteers that presented reaction, representing the mean of positive cutaneous answer to the product. The value was shown with standard deviation, mode and median. -Percentage of volunteers with adverse reaction, taking into consideration the number and intensity.
Summary:	A total of 54 female volunteers were enrolled in the study. No patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	14-Oct-2009