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

Sponsor/company: sanofi-aventis		ClinicalTrials.gov Identifier: NCT00785642	
Generic drug name: Lactic acid		Study Code: LACAC_L_04304	
		Date: 03/Mar/2009	
Title of the study:		Safety Dermatological Evaluation: genital mucous evaluation with gynecological follow up – Dermacyd PH_DETINLYN Tangerine Mix LACAC_L_04304	
Investigator(s):		Sergio Schalka <i>MEDCIN – Instituto da Pele</i> 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: 28-Aug-2008			
Date last subject completed: 22-Sep-2008			
Objectives:		To prove the safety of the gynecological formulation in normal and usual use conditions.	
Methodology:		Single-center, open label, comparative study.	
Number of subjects:		Planned: 30-35	Randomized: NA Treated: 31
Evaluated:		Safety: 30	
Diagnosis and criteria for inclusion:		Age between 10 and 20 years old; integral skin test in the analyze region; use the same category cosmetic product; willingness in following the study procedures and to be present in the clinic at the days and scheduled time and ICF signature.	
Investigational product:		Lactic acid	
Dose:		Liquid soap to be applied in the external genital area, in small quantity, with abundant rinsing after use, during 21 days.	
Administration:		Topical usage.	
Duration of treatment: 21 days		Duration of observation: 21 days	

Reference therapy:	Dermacyd PH_DETINBACK Tangerine Mix
Dose:	To be used during 21 days, according sponsor instructions.
Administration:	Topical usage.
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>-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> <ul style="list-style-type: none"> - Causality: not related, possible related, probably related or definitely related. - Intensity: Mild, Moderate or Severe. <p>These data are going to be filled out in patient CRF and Adverse Reactions Form.</p>
Statistical methods:	Evaluation of the total number of the subjects that have adverse events during the study.
Summary:	A total of 31 female volunteers were enrolled to the study. One patient did not return to the final evaluation due to personal reasons, 30 volunteers were analyzed and it was not detected any cutaneous reaction.
Safety results:	None of the volunteers analyzed had a cutaneous reaction.
Date of report:	05-Feb-09