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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:	NCT00712868
		Study Code:	LACAC_L_03447
Generic drug name:	Lactic acid	Date:	17/July/2009

Title of the study:	LACTAFEM Acceptability of Lactacyd femina (LACAC_L_03447)			
Investigator(s):	Luz Maria Bravo, MD - Coordinating Investigator			
Study center(s):	110 Gynecologists *Mexico*			
Publications (reference):	No publications have been done yet			
Study period: Date first patient enrolled: 15-Jun-2008 Date last patient completed: 13-Aug-2008	Date of first signedinformed consent Date of last patient last visit	Phase of development: Phase IV		
Objectives:	To demonstrate the safety and acceptability of Lactacyd femina in normal and usual usage conditions.			
Methodology:	Women between 18-60 years old visiting their gynecologists were invited to participate by using Lactacyd femina, for external use during 21 consecutive days.			
Number of patients/subjects:	Planned: 400	Randomized: NA	Treated: 559	
Evaluated:	Efficacy/Pharmacodynamics: NA	Safety: adverse events	Pharmacokinetics: NA	
Diagnosis and criteria for inclusion:	<u>Diagnosis</u>: Women 18-60 years old, symptomatic or asymptomatic to vulvo-gyneacological infections. <u>Inclusion Criteria:</u> 1. Woman between 18 and 60 years old 2. Integral skin in the tested region 3. Willingness to follow the study procedures and to be present in the clinic at scheduled days and time for follow-up. 4. Patients who signed Informed Consent letter. <u>Exclusion Criteria:</u> 5. Pregnancy or breastfeeding women 6. Use of anti-inflammatory of immune-suppression drugs 7. Topical medication use at the tested region 8. Active cutaneous gynaecological disease which may interfere in study results 9. Personal history of allergic disease at the area to be treated 10. Allergic or atopic history 11. Patients with no Informed Consent letter signed.			

Investigational product: Dose: Administration:	Lactacyd Femina 1 to 3 times a day External use	
Duration of treatment: 21 days		Duration of observation: 21 days
Reference therapy:	NA	
Criteria for evaluation:	Clinical and local tolerability after 21 days Treatment satisfaction survey	
Safety:	Adverse events reported by the patient or noted by the investigator".	
Statistical methods:	A sample size of 456 patients was determined to ensure an 80% power to conclude the study, with an overall 5% significance level and an estimated alpha error of 5%. Descriptive statistics for parameters of interest will be performed. The safety analysis will be performed on the safety population consisting in all the patients who will be included in the study and who will receive the study product for at least one time. The primary analysis will be performed with the safety data. The secondary analysis will be performed with demographics data.	
Materials and Methods	At baseline visit patients were informed consent and the following data was recorded: demographics, history of gynecological infections, medical history, concomitant diseases and medications, presence of medication for gynecological infections, risk factors and were given with a daily registry, study product for 21 days and a patient questionnaire. A follow up visit was done 14 (+-7) days after baseline where the physician would record patient satisfaction of product use, treatment adherence and possible adverse events. Patient questionnaire included inquiries regarding personal hygienic habits and frequency and satisfaction results of product use.	

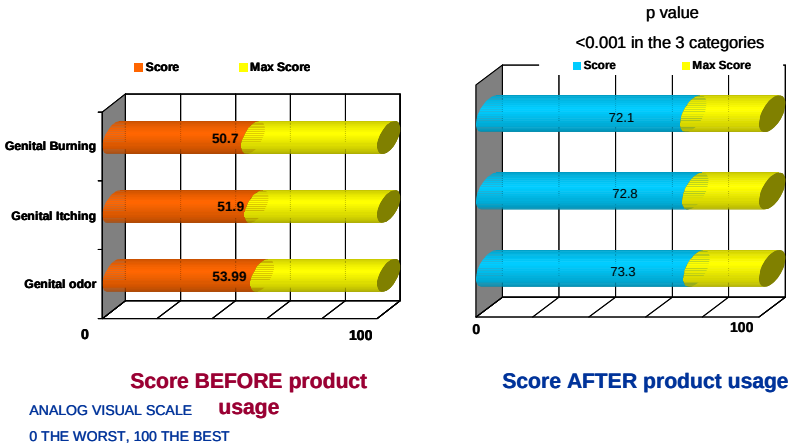
Summary:

One-hundred and ten gynecologists included a total of 559 females, between 18 and 60 years old. Mean age 35 years; 57% reported to be married; 49% with college degree. 92.1% (N=515) reported data to determine the presence of vulvovaginal or gynecological infections, whereas 50.5% of them were positive to either of such conditions.

Overall, 270 (48.3%) patients were receiving prescribed medication for vulvovaginal or gynecological infections. No major concomitant conditions were present at the time of recruitment.

68% of patients used the study product for more than 14 days; 89% reported to use it for at least once a day.

Average scores before product was used in terms of genital burning, itching and odor, assessed by an analog visual scale (where 0 was worst and 100 the best condition) were 50, 52 and 54, correspondingly. Symptoms were assessed once again, after product use, with scores of 72, 73 and 73 (p <0.001 vs. baseline).



Overall wellbeing average score was 94.6, where fragrance, product softness, easy to use, general wellbeing, freshness and clean sensation were also assessed by patients after use of the product.

Satisfaction indicators yielded the following: 92% of patients would recommend its use; 92% would not change the product; 94% were satisfied; and 85% reported treatment adherence.

Safety results:	Overall, only 20 patients (3.6%) reported some adverse event, mainly burning sensation (7 patients, 1.3%); itching in 6 patients (1.1%) and irritation in 6 (1.1%). Product related adverse events were reported by 15 patients (2.7%): 6 (1.1%) of them reported itching, burning sensation and irritation.

Product Related Adverse Event	N=559	%
Total of Patients with an adverse event	15	2.7
-Burning sensation	6	1.07
-Irritation	6	1.07
-Itching	6	1.07
-Other	3	0.18

Only nine (1.61%) patients reported withdrawal due to AE as follows:

Withdrawal due to AE	N=559	%
Total	9	1.61
- Irritation	2	0.36
- Burning sensation	1	0.18
- Next-morning pill	1	0.18
- Itching	1	0.18
- Urinary urgency	1	0.18
- Irritation sensation	1	0.18
- Vaginal infection	1	0.18
- Mild irritation	1	0.18

Date of report:	18-Jun-2009