*These results are supplied for informational purposes only.*
*Prescribing decisions should be made based on the approved package insert in the country of prescription*

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| Sponsor/company: | sanofi-aventis | clinicaltrials.gov Identifier: | NCT00785681 |
| | | Study Code: | LACAC_L_04302 |
| Generic drug name: | Lactic acid | Date: | 21/Aug/2009 |

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| Title of the study: | Dermatological evaluation of topic compatibility (primary and accumulated dermical irritability, dermical sensibility)– Dermacyd PH_DETINBACK Sweet Flower (LACAC_L_04302) | | |
| Investigator(s): | Sergio Schalka<br>*MEDCIN – Instituto da Pele*<br>Avenida Dr. Carlos de Moraes Barros, nº 304, Osasco, São Paulo | | |
| Study center(s): | 1 BR center | | |
| Publications (reference): | None | | |
| Study period:<br>Date first subject enrolled: 28-Jul-2008<br>Date last subject completed: 04-Sep-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 PH_DETINBACKSweet Flower. | | |
| Methodology: | Single-center, open label, comparative study. | | |
| Number of subjects: | Planned: 50-60 | 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 to be present in the clinic at the days and scheduled time and Informed Consent Form (ICF) signature. | | |
| Investigational product:<br>Dose:<br>Administration: | Lactic acid<br>Patients received some applications over the skin.<br>Topical usage. | | |
| Duration of treatment: 6 weeks | | Duration of observation: 6 weeks | |

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| Reference therapy:<br>Dose:<br>Administration: | Dermacyd PH_DETINLYN Sweet Flower<br>Patients received some applications over the skin.<br>Topical usage. |
| Criteria for evaluation: | |
| Safety: | -Compatibility evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follow:<br>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.<br>-Level of skin irritation in the tested region, evaluated by the presence of :<br>- erythema, edema, desquamation, vesiculation, ardor and itching and their intensity and causality:<br>- Causality: not related, possible related, probably related or definitely related.<br>- 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).<br>-The sum of the occurrences was divided by the number of volunteers that present reaction, representing the mean of positive cutaneous answer to the product. The value was shown with standard deviation, mode and median.<br>-Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality. |
| Summary: | A total of 53 female volunteers were enrolled to the study. None of the patients analyzed had cutaneous reaction. |
| Safety results: | No volunteer presented skin reaction. |
| Date of report: | 03-Aug-2009 |