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

Sponsor/company:	sanofi-aventis	**ClinialTrials.gov Identifier:**	NCT00377000
		Study Code:	DL6021-0505
Generic drug name:	Clindamycin 1%/ Benzoyl Peroxide 5%	**Date:**	05/Oct/2007

Title of the study: A Pilot, Multi-Center, Patient Preference Study Comparing Two Clindamycin / Benzoyl Peroxide Gels

Investigators: R. Fried, MD, PhD, W. P. Werschler MD

Study Center(s): Two (2) investigative sites in the U.S.

Study period: IIIQ05-IQ06 | **Clinical Phase:** Pilot Study

Objectives: To collect patient preference information comparing two clindamycin / benzoyl peroxide gels

Number of Patients: This was a multicenter study conducted by qualified investigators at 2 clinical sites in the U.S. 30 patients were planned to be enrolled at each site (total of 60 patients).

Methodology: Patients in this randomized, multi-center, parallel group, study were randomly assigned per site in a 1:1 ratio to one of two groups: 1) BenzaClin® Topical Gel (clindamycin 1% / benzoyl peroxide 5% gel) Pump in the morning for 2 weeks, followed by 2 week wash out, then Duac® Topical Gel (clindamycin 1% / benzoyl peroxide 5%) Tube in the morning for 2 weeks; 2) Duac® Topical Gel (clindamycin 1% / benzoyl peroxide 5%) Tube in the morning, followed by 2 week wash out, then BenzaClin® Topical Gel (clindamycin 1% / benzoyl peroxide 5% gel) Pump in the morning for 2 weeks. Products were masked in an effort to blind the patients from the treatment identity.

Diagnosis & criteria for inclusion:

1. Patients with a clinical diagnosis of acne vulgaris of mild to moderate severity (Investigator Global Score of 1.5 to 3.0).
2. Male or female patients must be inclusive of the ages of 12 to 30 years of age.
3. Females of childbearing potential, in addition to having a negative urine pregnancy test at Visit 1, must be willing to use an acceptable form of birth control during the study. For the purpose of this study, the following are considered acceptable methods of birth control: oral contraceptives; contraceptive patches/rings/implants; Norplant®; Depo-Provera®; double barrier methods (e.g., condom and spermicide); IUD; abstinence with a documented second acceptable method of birth control should the patient become sexually active.
4. Patients 18 years of age or older must provide Institutional Review Board (IRB) approved written informed consent. Patients under 18 years of age must have IRB approved written informed consent from a parent or legal guardian. Patients 12 – 17 years of age must complete an IRB approved assent form for minors.
5. Patients must be willing and able to understand the requirements of the study, abide by the restrictions, apply the medication as instructed, and return for the required study visits.
6. Patients must be in good health and free from any clinically significant disease, other than acne vulgaris, that might interfere with the study evaluations.
7. Patients, who use make-up, must have used the same brand of make-up for a minimum period of 2 weeks prior to Baseline and agree to not change make-up brands or types during the study.

Main Exclusion Criteria:

1. Patients who are pregnant, nursing, or planning a pregnancy within the study period.
2. Patients who have more than 2 nodulo-cystic lesions on the face, excluding the nose.
3. Patients who have a known hypersensitivity to any ingredients in the test products including clindamycin and benzoyl peroxide.
4. Patients who have been treated with prescription and/or over-the-counter topical products, or had a procedure performed that may impact study assessments (e.g., topical corticosteroids, products containing retinols, salicylic acid, benzoyl peroxide or topical anti-inflammatories on facial areas within 2 weeks prior to study entry).
5. Patients who have any systemic or dermatological disorder that has the potential to interfere with the evaluations (e.g., rosacea, seborrheic dermatitis, perioral dermatitis, corticosteroid-induced acne vulgaris, carcinoid syndrome, mastocytosis, acneform eruptions caused by medication, facial psoriasis, facial eczema, etc.).
6. Patients with clinically significant unstable medical disorders, life-threatening disease, or current malignancies.
7. Patients who engage in activities that involve excessive or prolonged exposure to sunlight.
8. Patients who consume excessive amounts of alcohol, abuse drugs, or have any condition that would compromise compliance with this protocol.
9. Patients who have been treated with an investigational drug or investigational device within a period of 30 days prior to study entry.
10. Alcoholic toners, astringents, medicated topical preparations (prescriptions and over-the-counter), or medicated make-up on the facial treatment area.

Main Exclusion Criteria (Continued):

11. Abrasive cleansers or washes to the facial area (See Protocol, Appendix 1 for washing procedure).
12. New cosmetics, or new cleansers applied to the face.
13. Patients must not wear make-up at the visits, so as not to interfere with the evaluations.
14. Patients should not use a sauna within 48 hours prior to each visit.

Test product, dose and mode of administration: The study medication supplied by the sponsor consisted of:

- Product "A" - BenzaClin® Topical Gel (clindamycin 1% / benzoyl peroxide 5% gel) in a pump manufactured by Dermik Laboratories.
- Product "B" – Duac® Topical Gel (clindamycin 1% / benzoyl peroxide 5%) in a tube manufactured by Stiefel Laboratories.

Criteria for Evaluation:

EFFICACY

- Primary Efficacy Variable: Patient Preference Questionnaire evaluation; including product use, patient knowledge and impression of acne, as well as patient treatment.

SAFETY

- Primary Safety Variable: Incidence of all adverse events reported during the study were summarized.

Statistical Methods: All statistical analyses were performed using SAS software version 8.2. All statistical tests were two-sided with a significance level of 0.05, unless stated otherwise. When the assumptions for the planned testing methods did not hold, transformations or nonparametric methods were employed. No adjustments were made for any multiple testing.

Study Population: In total, 60 patients were included in the Intent-to-Treat (ITT) population. . A total of 58 of 60 patients (96.7%) completed the study. The majority of patients were female (56.7%), Caucasian (100%), and had fair complexions (65.0%). Age ranged from 12-29 years of age with mean age of 17.0 years.

Safety Results: The overall incidence of adverse events was low (<12%) and was comparable between treatment group (5.2% and 6.7%, for the pump and tube groups, respectively). The severity (mild, moderate, or severe) was assessed by the study site for all AEs collected on the CRF. The overall severity of AEs was comparable between treatment groups with all AEs considered mild or moderate in intensity. Investigators in the study were asked to assess if adverse events were product related by answering the CRF question – "is there a reasonable possibility that the study medication caused the event?". Overall, one AE was considered to be related to treatment; Patient # 039 reported contact dermatitis one day after starting the tube treatment. The event was considered "definitely" related to study product by the investigator and caused discontinuation of the patient from the study.

Efficacy Results: for the primary preference question "Assuming similar medication is in each, which container would you most prefer to use to treat your acne?", more patients preferred the pump (62.1%) compared to the tube (37.9%). This difference in preference was not statistically significant (p=0.068). Similar results were observed with the per-protocol population (pump – 58.5% vs. tube – 41.5%, p=0.326). For all secondary questions, except one, patients preferred the pump compared to the tube. Greater than 70% of patients preferred the pump over the tube in "ease of use" and "messiness". For the secondary question "Which container do you think was the most convenient?" more patients preferred the tube (58.6%) compared the pump (41.4%).

Date of Report: January 23, 2007