Clinical Study Synopsis for Public Disclosure

These results are supplied for informational purposes only in the interest of scientific disclosure. The synopsis may include approved and non-approved uses, doses, formulations, treatment regimens and/or age groups. This information is not intended to substitute for informed medical advice. You should not use this information to diagnose or treat a health problem or disease without consulting with a Healthcare Professional. Before prescribing any product mentioned in this Register, Healthcare Professionals should always refer to the specific approved product labeling information in their country. The results from a single trial may not reflect the overall results and need to be considered in the context of the totality of the available clinical research results for a product.

Anti Propionibacterium(P.) Acnes Activity of Epiduo® Gel Compared to Benzoyl Peroxide (BPO) 2.5% Gel

This study has been completed.

Sponsor:
Galderma

Information provided by:
Galderma

ClinicalTrials.gov Identifier:
NCT01188538

First received: August 24, 2010
Last updated: July 13, 2011
Last verified: July 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: June 9, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Investigator); Primary Purpose: Treatment
Condition:	Acne Vulgaris
Interventions:	Drug: Epiduo gel Drug: BPO

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
40 patients have been enrolled in one site in Poland: First subject included: March 3, 2010; last subject out: August 23, 2010

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description

Epiduo Gel	No text entered.
Benzoyl Peroxide (BPO) Gel	No text entered.

Participant Flow: Overall Study

	Epiduo Gel	Benzoyl Peroxide (BPO) Gel
STARTED	20	20
COMPLETED	20	19
NOT COMPLETED	0	1
Lost to Follow-up	0	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Epiduo Gel	No text entered.
Benzoyl Peroxide (BPO) Gel	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Epiduo Gel	Benzoyl Peroxide (BPO) Gel	Total
Number of Participants [units: participants]	20	20	40
Age [units: participants]			
<=18 years	3	4	7
Between 18 and 65 years	17	16	33
>=65 years	0	0	0
Age [units: years] Mean (Standard Deviation)	22.9 (4.5)	21.4 (2.9)	22.1 (3.8)
Gender [units: participants]			
Female	18	16	34
Male	2	4	6
Region of Enrollment [units: participants]			
Poland	20	20	40

Outcome Measures

Show All Outcome Measures

1. Primary: Change From Baseline (Log10 Cfu/cm²) in Count of Follicular P. Acnes [Time Frame: Week 12]

Show Outcome Measure 1

2. Secondary: Percent Change (%) in Inflammatory Lesion Counts [Time Frame: Week 12]

Show Outcome Measure 2

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.
There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. Restriction Description: No text entered.

Results Point of Contact:

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No publications provided

Responsible Party:	Farzaneh SIDOU Clinical Project Manager, Galderma
ClinicalTrials.gov Identifier:	NCT01188538 History of Changes
Other Study ID Numbers:	RD.03.SPR.29084
Study First Received:	August 24, 2010
Results First Received:	June 9, 2011
Last Updated:	July 13, 2011
Health Authority:	Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

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