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.

Comparison of Epiduo Associated With Lymecycline Versus Epiduo Vehicle Associated With Lymecycline in Acne Vulgaris (TEAM)

This study has been completed.

Sponsor:
Galderma
Information provided by (Responsible Party):
Galderma
ClinicalTrials.gov Identifier:
NCT01014689

First received: November 16, 2009
Last updated: April 17, 2012
Last verified: April 2012
History of Changes

Purpose

Randomized, controlled, multi-center, double-blind, parallel-group comparison study in Subjects with moderate to severe acne vulgaris on the face.

The purpose of this study is to demonstrate the efficacy of Adapalene 0.1% / Benzoyl Peroxide (BPO) 2.5% Gel associated with Lymecycline 300mg Capsules compared to Adapalene 0.1% /Benzoyl Peroxide 2.5% Vehicle Gel associated with Lymecycline 300mg Capsules, in the treatment of moderate to severe acne vulgaris.

The safety of the two treatment regimens will also be evaluated.

Condition	Intervention	Phase

Acne Vulgaris	Drug: Adapalene/ BPO gel with Lymecycline capsules Drug: Adapalene/ BPO vehicle gel with Lymecycline capsules	Phase 3

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Efficacy and Safety Comparison of Epiduo Gel Associated With Lymecycline 300 mg Capsules Versus Epiduo Vehicle Gel Associated With Lymecycline 300 mg Capsules in the Treatment of Moderate to Severe Acne Vulgaris

Resource links provided by NLM:

MedlinePlus related topics: Acne

Drug Information available for: Adapalene

U.S. FDA Resources

Further study details as provided by Galderma:

Primary Outcome Measures:

- Percent Change From Baseline in Total Lesion Count [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  Percent change from Baseline in Total Lesion count (sum of Non-Inflammatory and Inflammatory lesions) at Week 12.

Secondary Outcome Measures:

- Success Rate on the Investigator's Global Assessment (IGA) at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]

  Percentage of Subjects "Clear" or "Almost Clear" on 6-point IGA scale(0=clear, 1=almost clear, 2=mild, 3=moderate, 4=severe and 5=very severe) at Week 12.

Enrollment: 378

Study Start Date: August 2009

Study Completion Date: May 2010

Primary Completion Date: April 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Adapalene 0.1% / BPO 2.5% gel	Drug: Adapalene/ BPO gel with Lymecycline capsules Gel: Topical to the face, once daily in the evening Capsule: 1 capsule once daily in the morning Other Name: Adapalene/BPO with Lymecycline
Placebo Comparator: Adapalene 0.1% / BPO 2.5% Vehicle Gel	Drug: Adapalene/ BPO vehicle gel with Lymecycline capsules Gel: Topical to the face, once daily in the evening Capsule: 1 capsule once daily in the morning Other Name: Adapalene/BPO vehicle with Lymecycline

Eligibility

Ages Eligible for Study: 12 Years to 35 Years (Child, Adult)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Male or female Subjects of any race, aged 12 to 35 years inclusive,
2. Subjects with moderate to severe facial acne vulgaris (Investigator's Global Assessment score of 3 or 4),

Exclusion Criteria:

1. Subjects with more than 3 nodules or cysts on the face
2. Subjects with acne conglobata, acne fulminans, secondary acne (chloracne, drug-induced acne, etc.),

3. Subjects with a wash-out period for topical treatment on the face less than: Corticosteroids, antibiotics, antibacterials, antiseptics, retinoids, other anti-inflammatory drugs or other acne treatments (2 weeks), Zinc containing drugs (1 week), Phototherapy devices for acne and cosmetic procedures (1 week)
4. Subjects with a wash-out period for systemic treatment less than:Acne therapy containing zinc (4 weeks), Corticosteroids, antibiotics (4 weeks), Other acne treatments (6 months), Ciproterone acetate / Chlormadinone acetate (6 months), Spironolactone / Drospirenone (3 months)
5. Subjects with impaired hepatic (ALT/AST > 3xULN and bilirubin > 1.5xULN) or renal (creatinine clearance greater than 60 ml/min) functions based on a blood sample,
6. Subjects with known intolerance to lactose,

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01014689

Locations

Australia

Galderma Investigator site
Camberra, Australia

Galderma Investigator site
Kogarah, Australia

Galderma Investigator site
Melbourne, Australia

Galderma Investigator site
Sydney, Australia

Belgium

Galderma Investigator site
Bruxelles, Belgium

Galderma Investigator site
Gent, Belgium

Galderma Investigator site
Leuven, Belgium

Brazil

Galderma Investigator site
Belo Horizonte, Brazil

Galderma Investigator site
Sao Paulo, Brazil

France

Galderma Investigator site
Bordeaux, France

Galderma Investigator site
Cannes, France

Galderma Investigator site
Martigues, France

Galderma Investigator site
Nantes, France

Galderma Investigator site
Pantin, France

Galderma Investigator site
Pierre Benite, France

Germany

Galderma Investigator site
Cuxhaven, Germany

Galderma Investigator site
Darmstadt, Germany

Galderma Investigator site
Frankfurt, Germany

Italy

Galderma Investigator site
Catania, Italy

Galderma Investigator site
Ferrara, Italy

Mexico

Galderma Investigator site
Mexico city, Mexico

Galderma Investigator site
Monterrey, Mexico

Galderma Investigator site
Tlalnepantla, Mexico

Galderma Investigator site
Zapopan, Mexico

Poland

Galderma Investigator site
Lodz, Poland

Sweden

Galderma Investigator site
Eskilstuna, Sweden

Galderma Investigator site
Farsta, Sweden

Galderma Investigator site
Hagersten, Sweden

Sponsors and Collaborators

Galderma

Investigators

Study Director: Florence Paliargues **Galderma**

More Information

Responsible Party:	Galderma
ClinicalTrials.gov Identifier:	NCT01014689 History of Changes
Other Study ID Numbers:	RD.03.SPR.**29080**
Study First Received:	November 16, 2009
Results First Received:	August 12, 2011
Last Updated:	April 17, 2012
Health Authority:	Belgium: Federal Agency for Medicinal Products and Health Products

Belgium: Institutional Review Board
France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)
France: Institutional Ethical Committee
Australia: Human Research Ethics Committee
Australia: National Health and Medical Research Council
Sweden: Institutional Review Board
Sweden: Swedish Research Council
Poland: Ethics Committee
Poland: Ministry of Health
Italy: Ethics Committee
Italy: Ministry of Health
Brazil: Ethics Committee
Brazil: Ministry of Health
Mexico: Ethics Committee
Mexico: Ministry of Health
Germany: Ethics Commission
Germany: Ministry of Health

Keywords provided by Galderma:

acne vulgaris

Additional relevant MeSH terms:

Acne Vulgaris	Analgesics
Acneiform Eruptions	Sensory System Agents
Skin Diseases	Peripheral Nervous System Agents
Sebaceous Gland Diseases	Physiological Effects of Drugs
Adapalene	Anti-Inflammatory Agents
Adapalene, Benzoyl Peroxide Drug Combination	Antirheumatic Agents
Lymecycline	Dermatologic Agents
Anti-Inflammatory Agents, Non-Steroidal	Anti-Bacterial Agents
Analgesics, Non-Narcotic	Anti-Infective Agents

ClinicalTrials.gov processed this record on November 15, 2016

TO TOP