TOP ACNE TREATMENTS 2021

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Touro University Nevada
Henderson, Nevada
**Disclosures**

ACLARIS\*\^\#  
ALMIRALL\*\#  
AMGEN (CELGENE)\*\#  
ANAPHTYS BIO*  
ARCUTIS*  
ATHENE\*  
BAUSCH (ORTHO DERMATOLOGY)\*\#  
BIOFRONTERA\#  
BIOPHARMX\*  
BIORASI*  
BOTANIX*  
BRICKELL*  
CARA THERAPEUTICS*  
CASSIOPEA\*  
DERMAT\*  
ENCORE\#  
EPI HEALTH\*\#  
FERNADEK\#  
GALDERMA\*\#  
GENENTECH\*\#  
INCYTE\^  
LEO PHARMA\*\#  
LA ROCHE POSAY\#  
LILLY (DERMIRA)\*\#  
MCZ\#  
NOVAN\#  
PFIZER\#\#  
RALEXAR*  
REGENERON\#\#  
SANOFI-GENZYME\#\#  
SOLGEL\#  
SONOMA (INTRADERM)\#  
SUN PHARMA\*\#  
UCB \*\#  
VERRICA\#  
VYNE (FOAMIX/MENLO) \*\#\#  

* Research Investigator  
^ Consultant/Advisor  
# Speaker

**Figure 1.** Development and emergence of features of acne vulgaris: formation and progression of acne lesions correlated with sequence of unifying profiles of inflammation. (Profiles characterized by specific patterns of cellular infiltrates, biochemistry, and histologic changes.)

**Topical Application of Acne Medications**

![Diagram showing the effects of topical acne medications on the skin, highlighting the role of TLR 2 in inflammation and sebaceous hypersecretion.](image-url)

**TABLE. TREATMENT ALGORITHM FOR THE MANAGEMENT OF ACNE VULGARIS IN ADOLESCENTS AND YOUNG ADULTS**

<table>
<thead>
<tr>
<th></th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First-line</strong></td>
<td>Benzoyl peroxide (BP) or</td>
<td>Topical combination therapy* (BP + antibiotic) or ( \text{retinoid + BP} ) or (oral antibiotic + topical retinoid + ( \text{BP} )) or (oral antibiotic + topical retinoid + ( \text{BP} )) or (oral antibiotic + topical retinoid + ( \text{BP} ))</td>
<td>Oral antibiotic plus topical combination therapy* (BP + antibiotic) or (retinoid + ( \text{BP} )) or (oral antibiotic + topical retinoid + ( \text{BP} )) or (oral antibiotic + topical retinoid + ( \text{BP} )) or (oral antibiotic + topical retinoid + ( \text{BP} ))</td>
</tr>
<tr>
<td><strong>Alternative</strong></td>
<td>Add topical retinoid or BP if not already applied</td>
<td>Consider alternate combination therapy or ( \text{add combined oral contraceptives or oral spironolactone} ) (females) or Consider oral isorotinoin</td>
<td>Consider change in oral antibiotic or Add combined oral contraceptives or oral spironolactone (females) or Consider oral isorotinoin</td>
</tr>
</tbody>
</table>

Topical Retinoids Mechanism of Action and Impact on Pathophysiology

- C. acnes Induced Inflammation
- Inhibition of TLR-2 Receptor
- Reduction in Inflammation

- Retinoic Acid Receptors (RAR-gamma)
- Reduced Formation of Hyperproliferative Keratins (K6, K16)
- Reduced Activity of Transglutaminase
- Inhibition of AP-1 Pathway
- Reduction in Inflammation & Scarring (?)

- Matrix Metalloproteinases
- Reduced Formation of Hyperproliferative Keratins (K6, K16)
- Reduced Activity of Transglutaminase
- Inhibition of TLR-2 Receptor
- Inhibition of AP-1 Pathway

- Reduced Formation of Hyperproliferative Keratins (K6, K16)
- Reduced Activity of Transglutaminase
- Inhibition of TLR-2 Receptor
- Inhibition of AP-1 Pathway

- Reduction in Inflammation & Scarring (?)

Del Rosso, JQ. Skin & Aging 2004.

Tretinoin 0.05% Lotion in Acne Vulgaris Relevant Vehicle Characteristics

- 30 FEMALE VOLUNTEERS
- BILATERAL TESTING ON VOWAR FOREARMS
- TREATED AND UNTREATED SIDES
- ASSESSMENT OVER 24 HOURS
- NO ADVERSE REACTIONS

Figure 1: Cryo scanning electron microscopy (SEM) imaging of lotion formulation
A: 1000X magnification, B: 10,000X magnification

Polymeric mesh
Oil Droplet Polymeric mesh

DELIVERY + TOLERABILITY

10,000X Magnification Honeycomb Mesh showing Emulsion or Oil Droplets

Skin Moisturization Assessment over 24 Hours: Corneometry™

RAPID AND SUSTAINED INCREASE IN WATER CONTENT

Skin Barrier Assessment over 24 Hours; Trans Epidermal Water Loss (TEWL)

RAPID AND SUSTAINED DECREASE IN WATER LOSS

Tretinoin 0.05% Lotion in Acne Vulgaris
Once Daily – 12-Week Phase III Monotherapy Studies

>9 Years of Age with Facial Acne (N=1640)

Moderate to Severe Acne at Baseline

Two Randomized (1:1) Controlled Studies

Greater Improvements in Skin Oiliness, Patient Satisfaction and QoL with active vs vehicle (Week 12 vs Baseline)

WEEK 12
Mean % Reduction Inflammatory Lesions
50.9% - 53.4% (Tretinoin) vs 40.4% - 41.5% (Vehicle)

Mean % Reduction Comedonal Lesions
47.5% - 45.6% (Tretinoin) vs 27.3% - 31.9% (Vehicle)

All Comparisons P<0.001

POST HOC ANALYSES FROM PIVOTAL TRIALS

ASIAN POPULATION (N=69)
AGE 12-48 YRS
Efficacy and Tolerability Confirmed

PREADOLESCENT POPULATION (N=154)
AGE ≤13 YRS
Efficacy and Tolerability Confirmed

TRETINOIN 0.05% LOTION ONCE DAILY MODERATE-SEVERE ACNE

HISPANIC POPULATION (N=766)
AGE 11-50 YRS
Efficacy and Tolerability Confirmed

ADULT AND ADOLESCENT FEMALE POPULATION (N=909)
AGE 9-58 YRS
Efficacy and Tolerability Confirmed
TAZAROTENE 0.1% FOAM EXPERIENCE PROGRAM

PATIENT SAMPLE SIZE = 203
(WKS 2, 4, 8, 12)
57% FEMALE

82% TREATED FACE
(53% FACE ONLY / 29% BOTH)

4 WEEKS: 78% ACNE IMPROVED
64% VERY OR MODERATELY IMPROVED

12 WEEKS: 70% VERY SATISFIED OR SATISFIED
65% VERY LIKELY OR LIKELY TO CONTINUE USE


Tazarotene 0.045% Lotion Polymeric Emulsion Lotion Formulation

1. Tazarotene encapsulated in oil droplets, with moisturizing ingredients (light mineral oil, diethyl sebacate)
2. Oil droplets uniformly dispersed within O/W emulsion & separated 3-dimensional mesh matrix or honeycomb-like structure
3. Humectant – sorbitol – dispersed in water phase
4. Mesh network allows the oil droplets and moisturizing components to spread uniformly onto the skin.
5. Mesh breaks upon contact with salts on the skin surface, depositing all the ingredients uniformly onto the skin.

A More Efficient Delivery System for Active and Functional Excipients

Tazarotene 0.045% Lotion in Acne Vulgaris
Once Daily – 12-Week Phase 2 Comparative Study

>12 Years of Age with Facial Acne (N=210)
Moderate to Severe Acne at Baseline

Tazarotene 0.045% Lotion (n=69) vs Tazarotene 0.1% Cream (n=72) vs Vehicles (n=69)

WEEK 12
Mean % Reduction Inflammatory Lesions
63.8% TAZ 0.045% LOTION vs 60% TAZ 0.1% CREAM

Mean % Reduction Comedonal Lesions
56.9% TAZ 0.045% LOTION 54.1% TAZ 0.1% CREAM

Summary of Adverse Events vs Tazarotene 0.1% Cream

DISCONTINUATIONS
TAZ LOTION = 0%
TAZ CREAM = 1.4%

AE RELATED TO DRUG
TAZ LOTION = 2.9%
TAZ CREAM = 5.6%

LOCAL TOLERABILITY (>1% SUBJECTS)
“PAIN”
TAZ LOTION = 2.9%
TAZ CREAM = 4.2%

Tazarotene 0.045% Lotion in Acne Vulgaris
Treatment-Emergent and Related Adverse Events Through Week 12

<table>
<thead>
<tr>
<th></th>
<th>Tazarotene 0.045% Lotion (n=69)</th>
<th>Tazarotene 0.1% Cream (n=71)</th>
<th>Combined Vehicle (n=69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects reporting any TEAE</td>
<td>10 (14.7%)</td>
<td>19 (26.5%)</td>
<td>9 (13.4%)</td>
</tr>
<tr>
<td>Subjects reporting any SAE</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Subjects who discontinued due to TEAE</td>
<td>0 (0.0%)</td>
<td>1 (1.4%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Severity of AEs reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>6 (8.8%)</td>
<td>12 (16.9%)</td>
<td>9 (13.4%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>2 (2.9%)</td>
<td>7 (9.9%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Severe</td>
<td>2 (2.9%)</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Relationship to study drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Related</td>
<td>2 (2.9%)</td>
<td>4 (5.6%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Unrelated</td>
<td>8 (11.8%)</td>
<td>15 (21.1%)</td>
<td>9 (13.4%)</td>
</tr>
</tbody>
</table>

No deaths occurred in this study.

AE, adverse event; TEAE, treatment-emergent adverse event; SAE, serious adverse event.
Trifarotene Cream
Phase 3 Studies in Moderate Facial AND Truncal Acne

- Trifarotene is a RARγ-selective topical retinoid in a cream (50 µg/g)
- Development program evaluated efficacy and safety in both FACIAL and TRUNCAL ACNE
- Two 12-week, double-blinded, multicenter, vehicle controlled studies
  - Once daily trifarotene cream (n=1209) or vehicle cream (n=1183)
  - Randomization pattern 1:1
- TRUNCAL ACNE (Data at 12 Weeks) Study 1 Study 2
  - Mean % Change Inflammatory Lesions 57.4% vs 50.0% 65.4% vs 51.1%
  - Mean % Change Non-Inflammatory Lesions 49.1% vs 40.3% 55.2% vs 45.1%
- Majority of adverse events local tolerability reactions early in therapy
  - Consistent with topical retinoid therapy – managed with proper skin care
  - Fewer reactions on trunk

Trifarotene Cream PGA* Success
Phase 3 Randomized Controlled Studies: Moderate Truncal Acne

**Study 1**

- Trifarotene 50 µg/g (n=608)
- Vehicle (n=608)

<table>
<thead>
<tr>
<th>Week</th>
<th>PGA Success (%)</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>2.0%</td>
</tr>
<tr>
<td>1</td>
<td>8.2%</td>
</tr>
<tr>
<td>2</td>
<td>14.4%</td>
</tr>
<tr>
<td>3</td>
<td>23.3%</td>
</tr>
<tr>
<td>4</td>
<td>28.7%</td>
</tr>
<tr>
<td>12 (MJD)</td>
<td>25.0%</td>
</tr>
</tbody>
</table>

* P = 0.05; 95% CI (4.6, 13.7)
† Treatment difference (95% CI) 10.7% (5.4, 16.1); P = 0.001

**Study 2**

- Trifarotene 50 µg/g (n=508)
- Vehicle (n=608)

<table>
<thead>
<tr>
<th>Week</th>
<th>PGA Success (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.7%</td>
</tr>
<tr>
<td>1</td>
<td>3.0%</td>
</tr>
<tr>
<td>2</td>
<td>8.7%</td>
</tr>
<tr>
<td>3</td>
<td>14.4%</td>
</tr>
<tr>
<td>4</td>
<td>22.4%</td>
</tr>
<tr>
<td>12 (MJD)</td>
<td>30.1%</td>
</tr>
</tbody>
</table>

* P = 0.05; 95% CI (3.6, 12.3)
† Treatment difference (95% CI) 12.7% (7.2, 18.2); P = 0.001

The colored circle on the x-axis indicates time of first significant difference between treatment arms.
CI: confidence interval; MJD: multiple imputation; PGA: Physician Global Assessment.

*PGA = Physician Global Assessment

BENZOYL PEROXIDE “STAND ALONE” FORMULATION

An OTC product containing micronized BPO and LHA

**BENZOYL PEROXIDE 5.5% OTC FORMULATION**

- Clinically proven as effective as a leading prescription (benzoyl peroxide/antibiotic combination).¹
  - Study conducted by Zoe Draelos, MD; Alan Shalita, MD; and Diane Thiboutot, MD

- INFLAMMATORY LESION COUNTS:
  - Leading acne Rx + topical retinoid (10.25%)
  - OTC BPO & LHA + topical retinoid (0.025%)
  - OTC BPO & LHA + topical retinoid (0.025%)

- NON-INFLAMMATORY LESION COUNTS:
  - Leading acne Rx + topical retinoid (10.25%)
  - OTC BPO & LHA + topical retinoid (0.025%)
  - OTC BPO & LHA + topical retinoid (0.025%)

- BOTH USED WITH TOPICAL TRETINOIN
- COMPARISON WITH BPO/CLINDAMYCIN

Colorized freeze-fracture scanning electron micrograph of microencapsulated benzoyl peroxide (benzoyl peroxide is brown and the shell is white [arrow]).

Contains microcapsules which compartmentalize the active ingredient(s).

Slower release and more sustained delivery of active ingredient(s).

Controlled release of active ingredient(s) from microcapsules can extend drug delivery after a single application.

Decreased potential for rapid release of high concentrations of the drug that may induce local skin tolerability reactions.


Encapsulated Benzoyl Peroxide 3% / Encapsulated Tretinoin 0.1% Cream Daily for Acne Vulgaris

IGA Endpoint Success Week 12 / 90% Moderate / Age >9 Years

Mean Age 20–21 Years

Mean Inflammatory Lesions 28–33

Mean Comedonal Lesions 44–48

>90% LOCAL SKIN TOLERABILITY REACTIONS RATED AS MILD / IMPROVED OVER TIME WITH CONTINUED USE

MINOCYCLINE 4% FOAM ONCE DAILY
LONG TERM SAFETY DATA – MODERATE/SEVERE ACNE

>9 YEARS OF AGE – CHANGE IN INFLAMMATORY LESIONS (ILs)

**Study 04**

<table>
<thead>
<tr>
<th>Weeks</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
<th>12</th>
<th>16</th>
<th>22</th>
<th>28</th>
<th>34</th>
<th>40</th>
<th>46</th>
<th>52</th>
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<tbody>
<tr>
<td>% Reduction</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>FMX101 4% in DB (n=193)</td>
<td>0</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>20</td>
<td>25</td>
<td>30</td>
<td>35</td>
<td>40</td>
<td>45</td>
<td>50</td>
<td>55</td>
</tr>
<tr>
<td>Vehicle in DB (n=91)</td>
<td>0</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>16</td>
<td>20</td>
<td>24</td>
<td>28</td>
<td>32</td>
<td>36</td>
<td>40</td>
<td>44</td>
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</table>

Vehicle group switched to active treatment

64.3%

**Study 05**

<table>
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<tr>
<th>Weeks</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
<th>12</th>
<th>16</th>
<th>22</th>
<th>28</th>
<th>34</th>
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<tbody>
<tr>
<td>% Reduction</td>
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<td></td>
</tr>
<tr>
<td>FMX101 4% in DB (n=256)</td>
<td>0</td>
<td>5</td>
<td>10</td>
<td>15</td>
<td>20</td>
<td>25</td>
<td>30</td>
<td>35</td>
<td>40</td>
<td>45</td>
<td>50</td>
<td>55</td>
</tr>
<tr>
<td>Vehicle in DB (n=117)</td>
<td>0</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>16</td>
<td>20</td>
<td>24</td>
<td>28</td>
<td>32</td>
<td>36</td>
<td>40</td>
<td>44</td>
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</tbody>
</table>

Vehicle group switched to active treatment

78.0%

3. Data on File, Foamix Pharmaceuticals

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Minocycline Distribution
PREFERENTIAL CONCENTRATIONS IN SKIN >>> PLASMA

**ORAL MINOCYCLINE**
(1mg/kg) at Day 21

- **EPIDERMIS**: 3.7 μg/mL
- **DERMIS**: 2.3 μg/mL

**PLASMA**
Mean $C_{max} = 850$ ng/mL

Approximately half of minocycline delivered to the epidermis was recovered from the sebaceous appendages

**TOPICAL MINOCYCLINE 4% FOAM**
(10mg/cm²)

- **EPIDERMIS**: 560.21 μg/mL
- **DERMIS**: 17.50 μg/mL

**PLASMA**
2 (4g/day for 21 days)
Mean $C_{max} = 1.3$ ng/mL

2 Jones TM. J Drugs Dermatol. 2017;16(10):1022-1028
**Antibiotic Susceptibility vs Resistance: Concentration-Dependent Mutant Selection Window (MSW) vs Mutant Prevention Concentration (MPC)**

**MUTANT PREVENTION CONCENTRATION (MPC)**
Antibiotic concentration that blocks the growth of ALL single-step bacterial mutants

**MUTANT SELECTION WINDOW (MSW)**
Range between the MIC and MPC within which resistant mutants are likely to emerge.

If drug levels fall in the MSW for a prolonged period, resistant mutant bacterial strains are likely to develop

**MINIMUM INHIBITORY CONCENTRATION (MIC<sub>50</sub>)**
Lower boundary of the MSW is the MIC, or the drug concentration at which growth of 10^5 wild-type bacterial cells is blocked.

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**Topical Androgen Receptor Inhibitor**

- Androgen inhibition known to correlate with improvement in acne
- Clascoterone 1% Cream Twice Daily
  - First FDA-approved topical androgen receptor (AR) inhibitor, ≥12 years of age
  - Mode of action supported by multiple laboratory studies
  - Inhibition of androgen binding to AR reduces sebum production and cytokine release by sebocytes
  - Efficacy and safety established including in MUSE studies
  - Long term study demonstrated efficacy for facial and truncal acne (IGA)

Clascoterone 1% Cream 1% vs Vehicle Cream Twice Daily
Phase III Trials - IGA Success & Absolute Acne Lesion Change – Baseline → Week 12

Safety and Efficacy (Primary Endpoints) ITT (Week 12)

2 Point Reduction in IGA & IGA score of 0 (clear) or 1 (almost clear)

<table>
<thead>
<tr>
<th></th>
<th>Study 25</th>
<th>Study 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>18.4%</td>
<td>9.0%</td>
</tr>
<tr>
<td>1</td>
<td>20.3%</td>
<td>6.5%</td>
</tr>
<tr>
<td>P</td>
<td>0.0008</td>
<td>0.0007</td>
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</table>

Absolute change from baseline in non-inflammatory lesion count

<table>
<thead>
<tr>
<th></th>
<th>Study 25</th>
<th>Study 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in lesion count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
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</table>

Absolute change from baseline in inflammatory lesion count

<table>
<thead>
<tr>
<th></th>
<th>Study 25</th>
<th>Study 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in lesion count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Sample Size

- Study 25: N = 708
- Study 26: N = 732

Adverse Events

- There were no treatment-related serious adverse events among patients treated with clascoterone
- Local skin reactions, if present, were predominantly classified as mild

MODERATE TO SEVERE ACNE VULGARIS / AGES >9 YEARS / 12-WEEK STUDY

Clascoterone 1% Cream 1% vs Vehicle Cream Twice Daily
Phase III Trails - Percent Reductions in Acne Lesions - Baseline → Week 12

Safety and Efficacy (Secondary Endpoints) ITT (Week 12)

Percent reduction from baseline in total lesion count

<table>
<thead>
<tr>
<th></th>
<th>Study 25</th>
<th>Study 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in lesion count (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.0016</td>
<td>&lt;0.0016</td>
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Percent reduction from baseline in non-inflammatory lesion count

<table>
<thead>
<tr>
<th></th>
<th>Study 25</th>
<th>Study 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in lesion count (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.0014</td>
<td>&lt;0.0001</td>
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</table>

Percent reduction from baseline in inflammatory lesion count

<table>
<thead>
<tr>
<th></th>
<th>Study 25</th>
<th>Study 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in lesion count (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.0010</td>
<td>&lt;0.0010</td>
</tr>
</tbody>
</table>

Sample Size

- Study 25: N = 708
- Study 26: N = 732

Adverse Events

- There were no treatment-related serious adverse events among patients treated with clascoterone
- Local skin reactions, if present, were predominantly classified as mild
BENZOYL PEROXIDE (BP)  
9.8% EMOLLIENT FOAM ONCE DAILY  
SHORT CONTACT THERAPY ON TRUNK  
P ACNES REDUCTION STUDY

The effect of benzoyl peroxide 9.8% emollient foam on reduction of Propionibacterium acnes on the back using a short contact therapy approach.

2-3 Minute Contact → Wash off

Optimized: 
Benzoyl peroxide (BP) acts to therapeutic effect on acne vulgaris through reduction of Propionibacterium acnes. A 1 to 2-log reduction of P. acnes has been demonstrated primarily on the face with use of “base” BP formulations, but also with some BP cleansers. In addition to these facial acne vulgaris, cleanser formulations of BP are currently used for truncaal acne vulgaris due to ease of use on large body surfaces and to avoid bleaching of fabric. To date, evaluation of P. acnes reduction on the trunk has not been well studied with BP formulations, especially with the use of well-recognized and standardized methods to accurately determine P. acnes colony counts. A previous study demonstrated that a BP 3% cleanser did not reduce counts of P. acnes on the back when subjects were instructed to apply the cleanser over the shaver, allow it to dry for 20 seconds on the skin, and then rinse-off the cleanser. Evaluation of specific time intervals between application of the back and rinsing with BP formulations would be better clarified. The necessary skin contact time associated with high reductions of P. acnes (100e), recognizing also the potential time of BP penetration and vehicle. This 2-week study using quantitative. 

BP WASH FORMULATION NOT EFFECTIVE IN REDUCING P ACNES

Azelaic Acid 15% Foam in Truncaal Acne  
Twice Daily – 16-Week Pilot Monotherapy Study (N=20)

>12 Years of Age with Chest/Back Acne  
94% Moderate Severity at Baseline  
Baseline Inflammatory Lesions = 34  
Progressive Lesion Reduction with 35% Week 4  
74% Reduction Inflammatory Lesions Week 12  
Favorable Tolerability

Azelaic Acid 15% Foam in Truncaal Acne  
Twice Daily – 16-Week Pilot Monotherapy Study (N=20)

45% CLEAR/ALMOST CLEAR + 39% MILD

Dapsone 7.5% Gel in Truncal Acne
Once Daily – 16-Week Pilot Monotherapy Study (N=20)

>12 Years of Age
with Chest/Back Acne

80% Moderate
20% Severe
at Baseline

Progressive Lesion
Reduction at
All Time Points

Favorable Tolerability


- **INFLAMMATORY LESION REDUCTION**
  - Week 4: 35%
  - Week 10: 62%
  - Week 16: 74%

- **COMEDONAL LESION REDUCTION**
  - Week 4: 20%
  - Week 10: 52%
  - Week 16: 69%

- **% CLEAR/ALMOST CLEAR + 2 GRADE IMPROVEMENT**
  - Week 4: 20%
  - Week 10: 25%
  - Week 16: 52%

Oral Antibiotic Therapy in Acne Vulgaris

- **Sarecycline Once Daily (based on patient weight)**
  - Third generation tetracycline evaluated by FDA only for acne
  - >9 years of age, efficacy and safety established
    - Can be taken with or without food
    - Effective for truncal acne demonstrated (secondary evaluation based on IGA)
    - Low rate of adverse effects of special interest
    - Narrow spectrum tetracycline – differs from prior tetracyclines used for acne
      - High activity against *C. acnes, S. aureus, and S. pyogenes*
      - Low/negligible activity against gram-negative and anaerobic bacteria
      - Reduced potential for antibiotic resistance due to decreased selection pressure

Minocycline Biphasic Delivery with Immediate- and Sustained-Release Pellets (MUPS)

- 25% immediate and 75% sustained release of minocycline hydrochloride
- Steady-state plasma concentration
- Functionally scored tablet has an even distribution of drug on each side of the score line
- A spherical core coated with micronized minocycline hydrochloride

Less Variable and More Predictable PK Profile with Minocycline Biphasic Delivery vs Extended-Release Minocycline

MINOCYCLINE BIPHASIC DELIVERY

MINOCYCLINE EXTENDED RELEASE

ORAL ISOTRETINOIN
ADVANCES THAT CAN REDUCE RISK OF RELAPSE
Lidose Isotretinoin vs Conventional Isotretinoin (Brand and Generic) Formulations With and Without Food

**Fed State**

- **LIDOSE 40 mg**
- **CONVENTIONAL 40 mg**

Mean Plasma Isotretinoin Concentration (ng/mL) vs Time (h)

**Fasting State**

- **LIDOSE 40 mg**
- **CONVENTIONAL 40 mg**

Mean Plasma Isotretinoin Concentration (ng/mL) vs Time (h)

**EQUAL IN PRESENCE OF HIGH FAT INTAKE (50 GRAMS)**

2. Sun Pharms, data on file.

>80% INCREASE IN GI ABSORPTION WITH LIDOSE FORMULATION WITHOUT FOOD

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Comparative Pharmacokinetics of MICRONIZED-Isotretinoin 32-mg Formulation and Lidose-Isotretinoin 40 mg WITHOUT FOOD

- **Fasted-state Micronized-isotretinoin 32 mg (N=18)**
- **Fasted-state Lidose-isotretinoin 40 mg (N=18)**

Concentration (ng/mL) vs Hours After Dosing

**TWO-FOLD GREATER GI ABSORPTION WITH MICRONIZED FORMULATION WITHOUT HIGH FAT MEAL**

THANK YOU

IN DR. DEL ROSSO'S ACNE & ROSACEA LECTURE LIKE...