South Beach Symposium
clinical + aesthetic dermatology
SBS PART I
THE MEDICAL DERMATOLOGY Summit
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TOP ACNE TREATMENTS 2021

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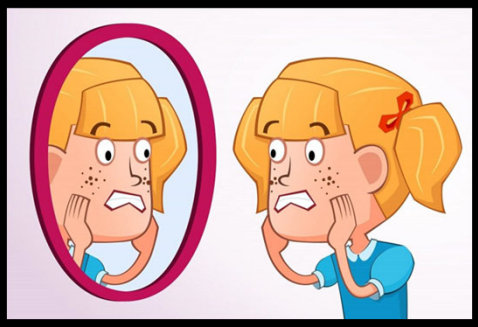

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Disclosures

ACLARIS*^#
ALMIRALL*^#
AMGEN (CELGENE)*^#
ANAPTYS BIO*
ARCUTIS*
ATHENEX*
BAUSCH (ORTHO DERMATOLOGY)*^#
BIOFRONTERA^#
BIOPHARMX*^
BIORASI*
BOTANIX*
BRICKELL*
CARA THERAPEUTICS*
CASSIOPEA*^
DERMATA^
ENCORE^#
EPI HEALTH*^#
FERNDALE^#

GALDERMA*^#
GENENTECH*#
INCYTE*^
LEO PHARMA*^#
LA ROCHE POSAY^
LILLY (DERMIRA)*^#
MC2^
NOVAN*^
PFIZER*^#
RALEXAR*
REGENERON*^#
SANOFI-GENZYME^#
SOLGEL*^
SONOMA (INTRADERM)^
SUN PHARMA*^#
UCB *^#
VERRICA^#
VYNE (FOAMIX/MENLO) *^#

* Research Investigator
^ Consultant/Advisor
# Speaker

UPDATED 01-06-2021

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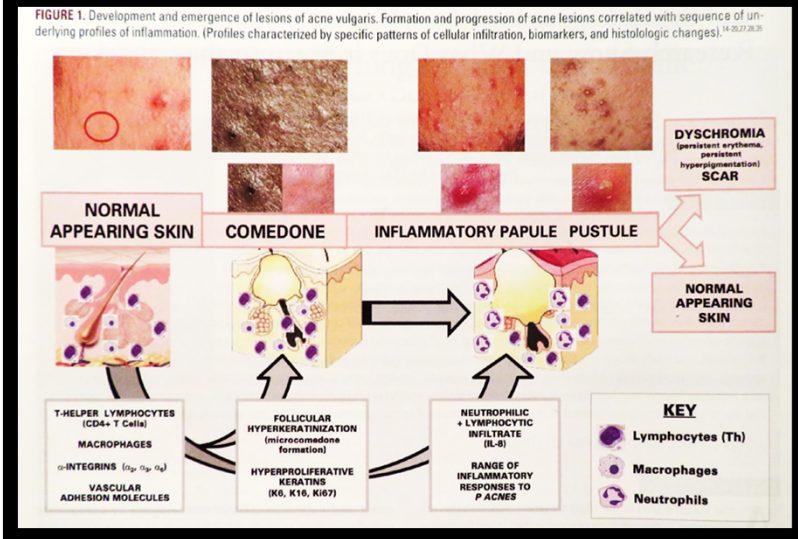

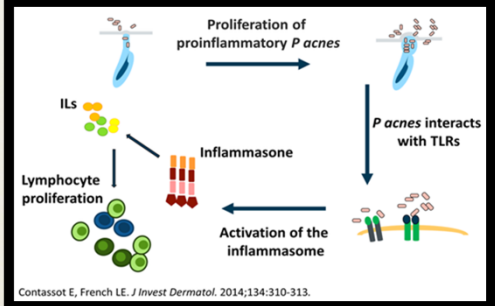

Del Rosso JQ, Kircik LH. J Drugs Dermatol. 2013;12:109s-115s
Zaenglein AL, Thiboutot DM. In: Bolognia J et al, Eds. Dermatology, Elsevier, 2018;588-603

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TABLE. TREATMENT ALGORITHM FOR THE MANAGEMENT OF ACNE VULGARIS IN ADOLESCENTS AND YOUNG ADULTS[4]

	Mild	Moderate	Severe
First-line treatment	Benzoyl peroxide (BP) OR topical retinoid OR topical combination therapy[a] (BP + antibiotic) OR (retinoid + BP) OR (retinoid + BP + antibiotic)	Topical combination therapy[a] (BP + antibiotic) OR (retinoid + BP) OR (retinoid + BP + antibiotic) OR (oral antibiotic + topical retinoid + BP) OR (oral antibiotic + topical retinoid + BP + topical antibiotic)	Oral antibiotic plus topical combination therapy[a] (BP + antibiotic) OR (retinoid + BP) OR (retinoid + BP + antibiotic) OR Oral isotretinoin
Alternative treatment	Add topical retinoid or BP (if not already applied) OR Consider alternate retinoid OR Consider topical dapsone	Consider alternate combination therapy OR Consider change in oral antibiotic OR Add combined oral contraceptive or oral spironolactone (females) OR Consider oral isotretinoin	Consider change in oral antibiotic OR Add combined oral contraceptive or oral spironolactone (females) OR Consider oral isotretinoin

[a]May be prescribed as a fixed combination product or as a separate component.

Reprinted with permission from Zaenglein AL, Pathy AL, Schlosser BJ, et al. *J Am Acad Dermatol*. 2016;74(5):945-973.e33.

Reprinted from the *Journal of the American Academy of Dermatology*, 74(5), Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris, 945-973.e33, © 2016, with permission from Elsevier.

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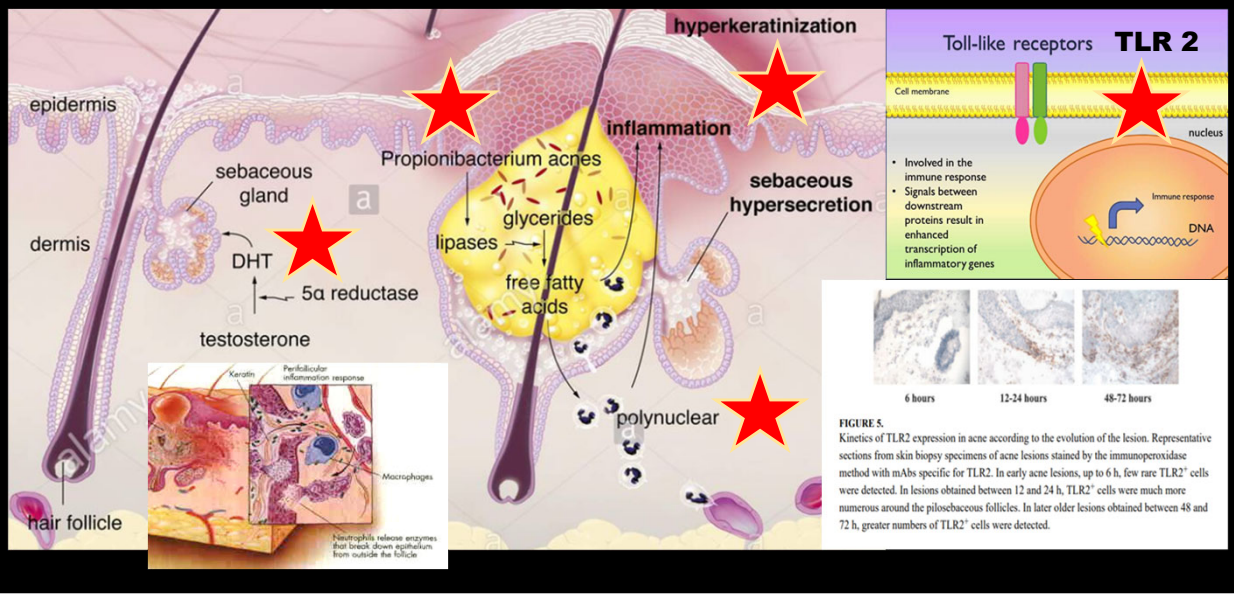
Topical Application of Acne Medications



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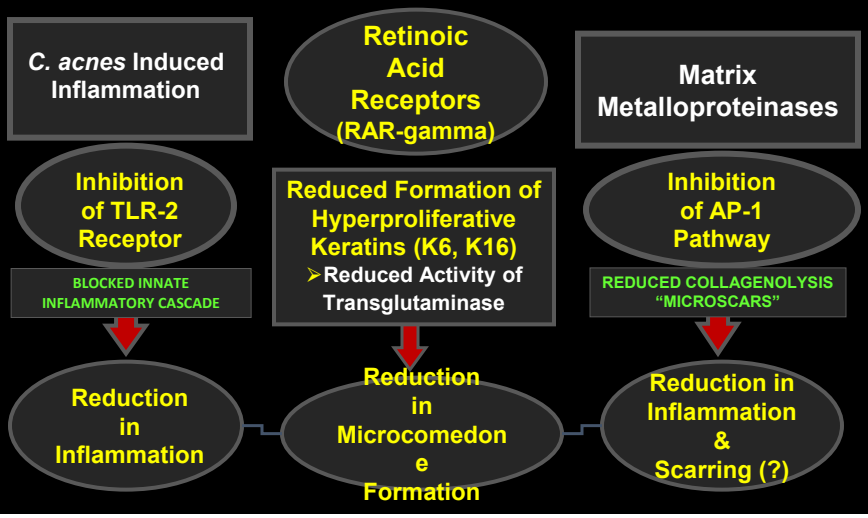
Topical Retinoids Mechanism of Action and Impact on Pathophysiology



Del Rosso, JQ. Skin & Aging 2004.

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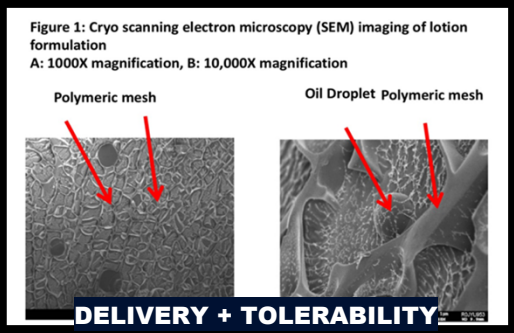
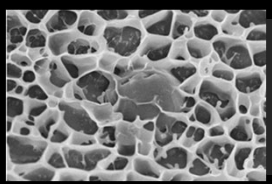
Tretinoin 0.05% Lotion in Acne Vulgaris

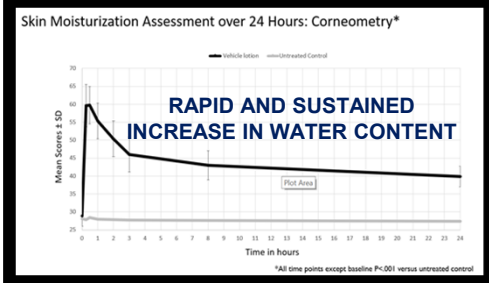
Relevant Vehicle Characteristics

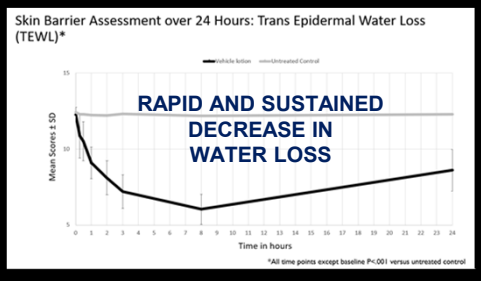




10,000X Magnification Honeycomb Mesh showing Emulsion or Oil Droplets

Kircik L, et al. Poster presentations. Fall Clinical Dermatology, Las Vegas, NV, October 2018.





30 FEMALE VOLUNTEERS

BILATERAL TESTING ON VOLAR FOREARMS

TREATED AND UNTREATED SIDES

ASSESSMENT OVER 24 HOURS

NO ADVERSE REACTIONS

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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)

Del Rosso JQ, Pariser D, et al. Poster presentation, SCALE Meeting, Nashville, TN, May 2018

Harper JC, et al. J Dermatolog Treat. 2019 Apr 2:1-8.

Figure 1: Percent Change in Mean Inflammatory Lesions from Baseline to Week 12 (ITT Population, LS Mean data). Study 301 in blue and 302 in red; vehicle data shown in corresponding dotted lines)

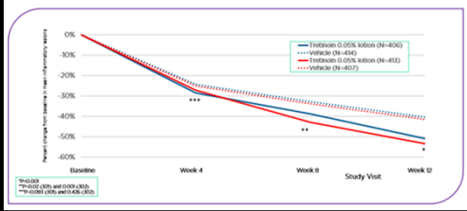
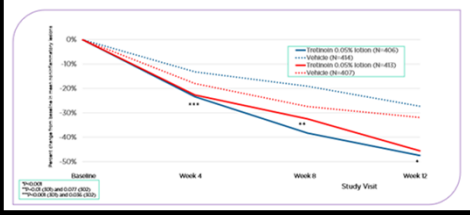


Figure 2: Percent Change in Mean Noninflammatory Lesions from Baseline to Week 12 (ITT Population, LS Mean data). Study 301 in blue and 302 in red; vehicle data shown in corresponding dotted lines)



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

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POST HOC ANALYSES FROM PIVOTAL TRIALS

ASIAN POPULATION (N=69)
AGE 12-48 YRS
EFFICACY AND TOLERABILITY CONFIRMED
Han G, et al. J Drugs Dermatol. 2019;18(9):910-916

PREADOLESCENT POPULATION (N=154)
AGE ≤13 YRS
EFFICACY AND TOLERABILITY CONFIRMED
Eichenfield L et al. Ped Dermatol. 2019;36(2): 193-199

TRETINOIN 0.05% LOTION ONCE DAILY MODERATE-SEVERE ACNE

ADULT AND ADOLESCENT FEMALE POPULATION (N=909)
AGE 9-58 YRS
EFFICACY AND TOLERABILITY CONFIRMED
Kircik L, et al. J Drugs Dermatol. 2019;18(2): 178-188

HISPANIC POPULATION (N=766)
AGE 11-50 YRS
EFFICACY AND TOLERABILITY CONFIRMED
Cook-Bolden F, et al. J Drugs Dermatol. 2019;18(1):32-38

10

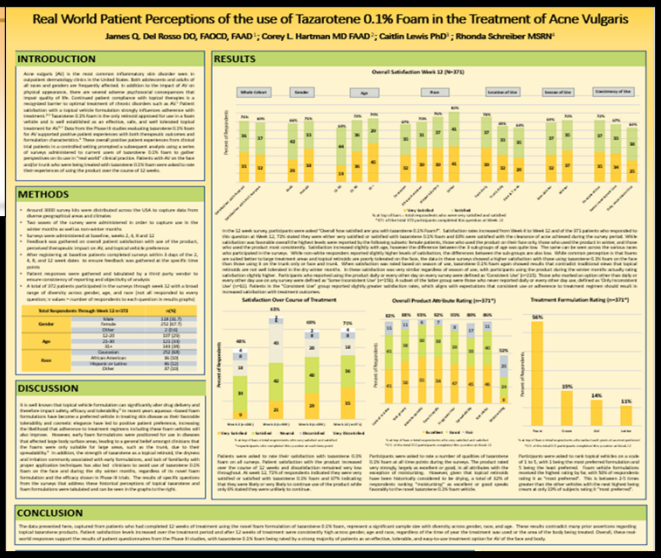
TAZAROTENE 0.1% FOAM EXPERIENCE PROGRAM

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


Real World Patient Perceptions of the use of Tazarotene 0.1% Foam in the Treatment of Acne Vulgaris

James Q. Del Rosso DO, FAOCD, FAAD[1]; Corey L. Hartman MD FAAD[2]; Caitlin Lewis PhD[3]; Rhonda Schreiber MSRN[4]

INTRODUCTION

METHODS

RESULTS

DISCUSSION

CONCLUSION

Del Rosso JQ, et al. Poster presentation. Fall Clinical Dermatology, Las Vegas, Nevada, October 2019.

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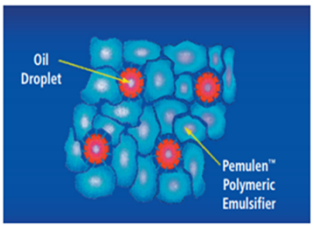
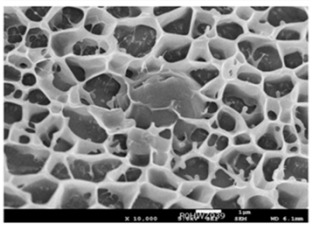
Tazarotene 0.045% Lotion
Polymeric Emulsion Lotion Formulation

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





10,000X magnification of honeycomb mesh showing emulsion droplet

Tanghetti E, et al. J Drugs Dermatol. 1;18(6): 542-548 / Del Rosso JQ, Pariser D, et al. Poster presentation, SCALE Meeting, Nashville, TN, May 2018 / Harper JC, et al. J Dermatolog Treat. 2019 Apr 2:1-8.

12

Tazarotene 0.045% Lotion in Acne Vulgaris

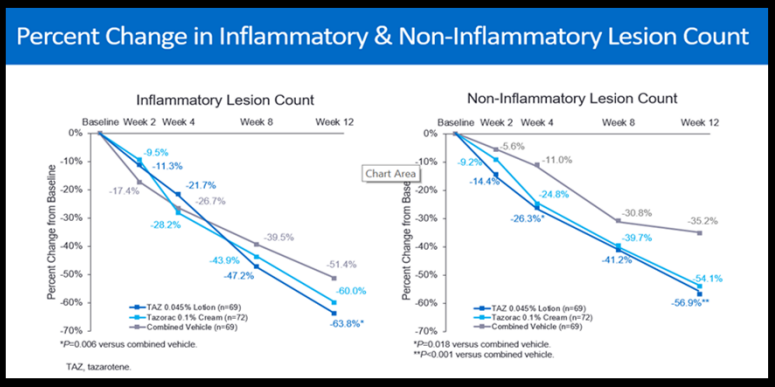
Once Daily – 12-Week Phase 2 Comparative Study

≥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)

Tanghetti E, et al. J Drugs Dermatol. 1;18(6): 542-548



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

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Tazarotene 0.045% Lotion in Acne Vulgaris

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%
VISIBLE SIGNS
TAZ LOTION = 0%
TAZ CREAM = 5.6%

Tanghetti E, et al. J Drugs Dermatol. 1;18(6): 542-548

Treatment-Emergent and Related Adverse Events Through Week 12

	Tazarotene 0.045% Lotion (n=68)	Tazorac 0.1% Cream (n=71)	Combined Vehicle (n=67)
Subjects reporting any TEAE	10 (14.7%)	19 (26.8%)	9 (13.4%)
Subjects reporting any SAE	0 (0.0%)	0 (0.0%)	0 (0.0%)
Subjects who discontinued due to TEAE	0 (0.0%)	1 (1.4%)	0 (0.0%)
Severity of AEs reported			
Mild	6 (8.8%)	12 (16.9%)	9 (13.4%)
Moderate	2 (2.9%)	7 (9.9%)	0 (0.0%)
Severe	2 (2.9%)	0 (0.0%)	0 (0.0%)
Relationship to study drug			
Related	2 (2.9%)	4 (5.6%)	0 (0.0%)
Unrelated	8 (11.8%)	15 (21.1%)	9 (13.4%)
Treatment Related AEs reported by ≥1% subjects			
Application site pain	2 (2.9%)	3 (4.2%)	0.(0.0%)
Application site erythema	0 (0.0%)	1 (1.4%)	0 (0.0%)
Application site exfoliation	0 (0.0%)	1 (1.4%)	0 (0.0%)
Application site dryness	0 (0.0%)	1 (1.4%)	0 (0.0%)
Erythema	0 (0.0%)	1 (1.4%)	0 (0.0%)

No deaths occurred in this study.
AE, adverse event; TEAE, treatment-emergent adverse event; SAE, serious adverse event.

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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

Tan J, Thiboutot D, Popp G, et al. J Am Acad Dermatol. 2019;80(6):1691-1699.

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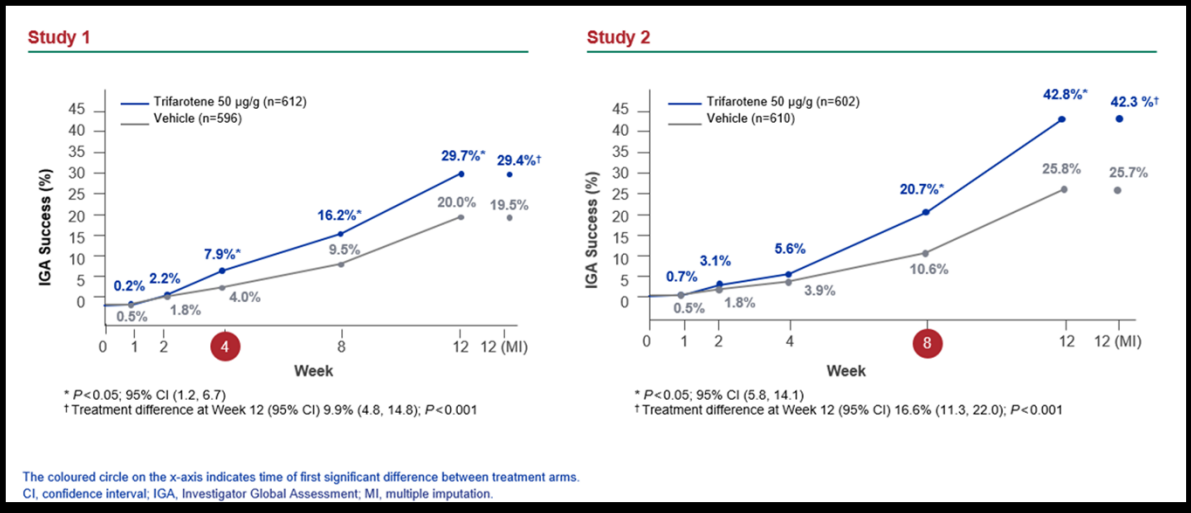
Trifarotene Cream IGA* Success

Phase 3 Randomized Controlled Studies in Moderate Facial Acne



*IGA = Investigator Global Assessment

Tan J, Thiboutot D, Popp G, et al. J Am Acad Dermatol. 2019;80(6):1691-1699.

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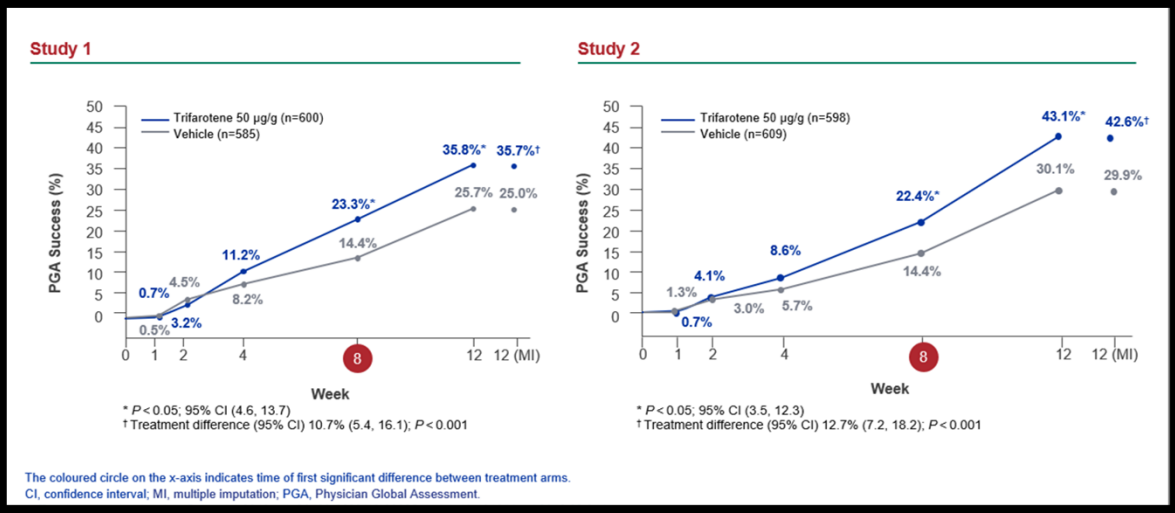
Trifarotene Cream PGA* Success

Phase 3 Randomized Controlled Studies: Moderate Truncal Acne



*PGA = Physician Global Assessment

Tan J, Thiboutot D, Popp G, et al. J Am Acad Dermatol. 2019;80(6):1691-1699.

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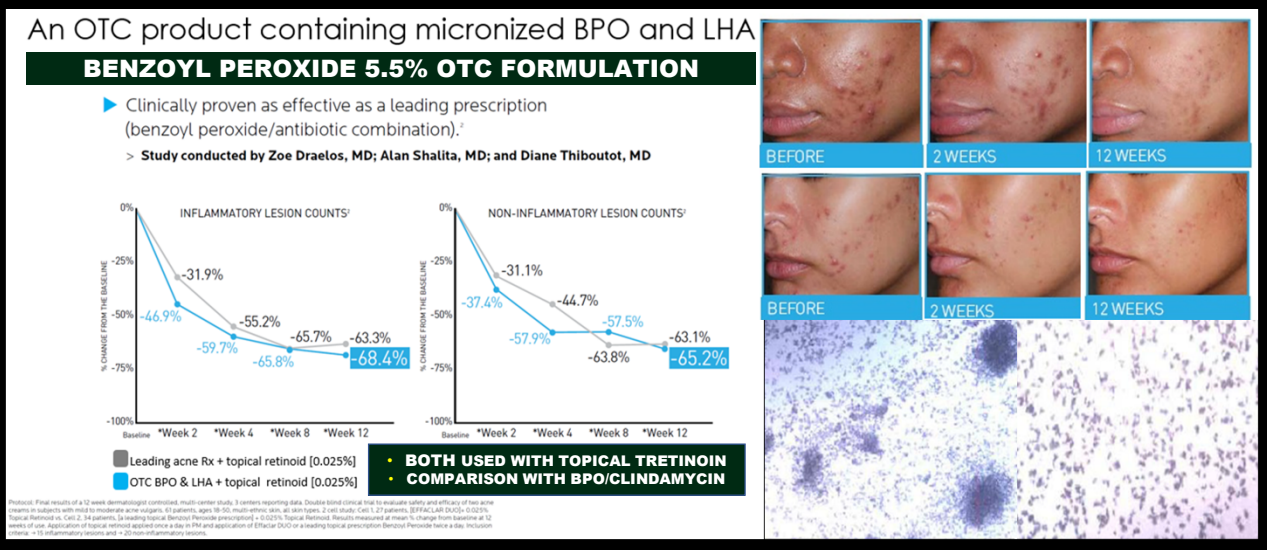
BENZOYL PEROXIDE "STAND ALONE" FORMULATION



Draelos ZD, Shalita AR, Thiboutot D, et al. A multicenter, double-blind study to evaluate the efficacy and safety of 2 treatments in participants with mild to moderate acne vulgaris. Cutis. 2012;89(6):287-293. LHA, lipohydroxy acid

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

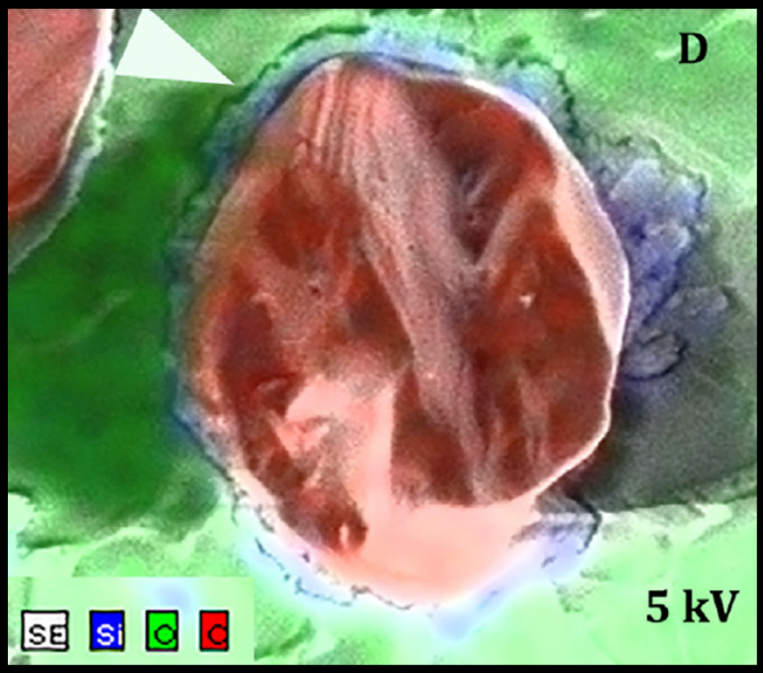
Contains microcapsules which compartmentalize the active ingredient(s)

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

Erlich M, et al. Structure elucidation of silica-based core-shell microencapsulated drugs for topical applications by cryogenic scanning electron microscopy. J Colloid Interface Sci. 2020;579:778-785.



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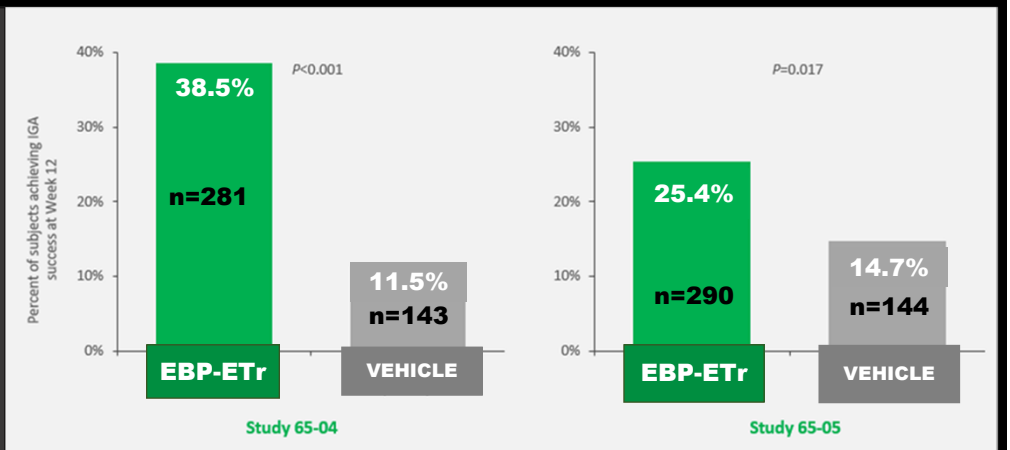
Encapsulated Benzoyl Peroxide 3% / Encapsulated Tretinoin 0.1% Cream Daily for Acne Vulgaris

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

Poster presentation. Winter Clinical Dermatology, Kona, Hawaii, January 2020.

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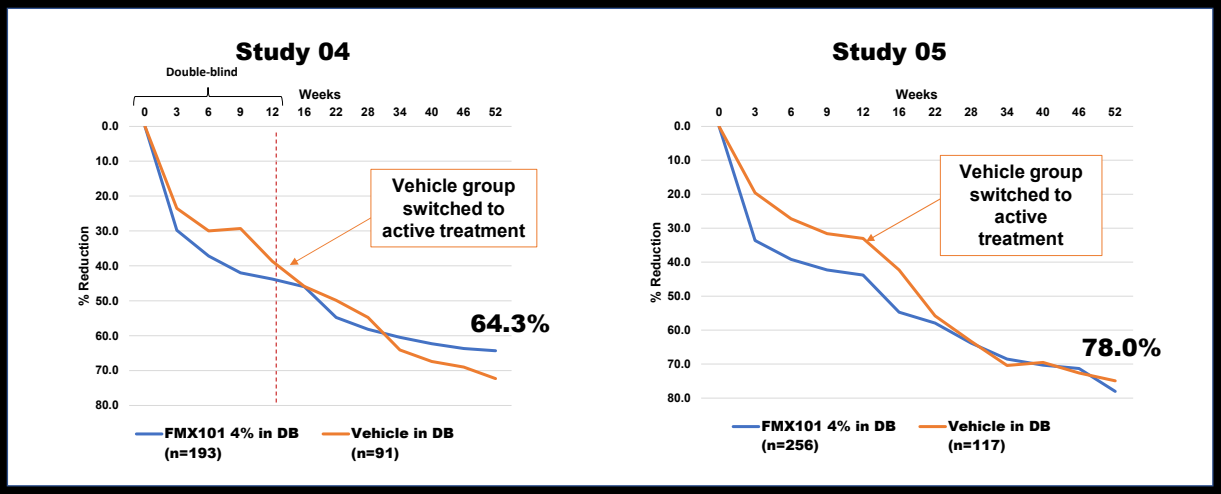
MINOCYCLINE 4% FOAM ONCE DAILY

LONG TERM SAFETY DATA – MODERATE/SEVERE ACNE

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



1. Raoof TJ et al. *J Am Acad Dermatol.* 2019; doi: 10.1016/j.jaad.2019.05.078. [Epub ahead of print]
2. Gold LS et al. *J Am Acad Dermatol.* 2019;80(1):168-177.
3. Data on File, Foamix Pharmaceuticals

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Minocycline Distribution

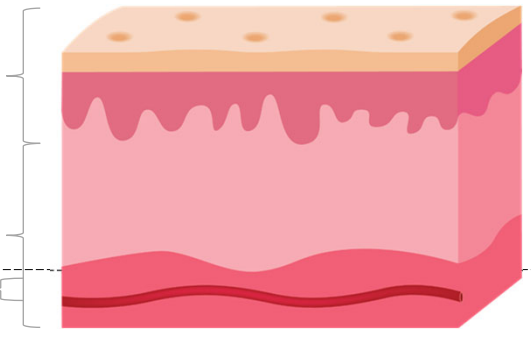
PREFERENTIAL CONCENTRATIONS IN SKIN >>> PLASMA

ORAL MINOCYCLINE (1mg/kg) at Day 21

EPIDERMIS[1]: 3.7 µg/mL

DERMIS[1]: 2.3 µg/mL

PLASMA[2] Mean C_{max} = 850 ng/mL



TOPICAL MINOCYCLINE 4% FOAM (10mg/cm²)

EPIDERMIS[3]: 560.21 µg/mL

DERMIS[3]: 17.50 µg/mL

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

Approximately half of minocycline delivered to the epidermis was recovered from the sebaceous appendages[1]

1 Macdonald H et al. *Clin Pharmacol Ther.* 1973;14(5):852-861 2 Jones TM. *J Drugs Dermatol.* 2017;16(10):1022-1028. 3 Data on file: MedPharm Study No. 474-1701-1702.

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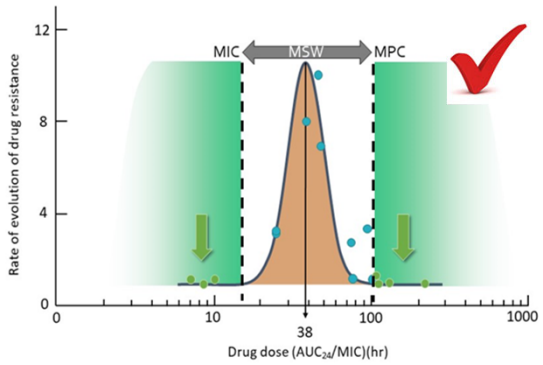
Antibiotic Susceptibility vs Resistance : Concentration-Dependent

Mutant Selection Window (MSW) vs Mutant Prevention Concentration (MPC)

Figure 1: Evidence for existence of mutant selection window (MSW)



A model example of *Streptococcus pneumoniae* treated with moxifloxacin showed that drug doses outside the MSW did not selectively enrich for resistant mutants

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

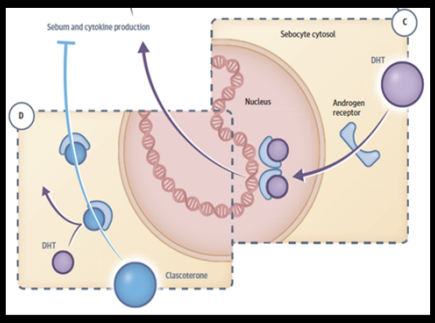
MINIMUM INHIBITORY CONCENTRATION (MIC_{50})

Lower boundary of the MSW is the MIC, or the drug concentration at which growth of 10^5 wild-type bacterial cells is blocked.

23

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)



Hebert A, et al. JAMA Dermatol. Published online April 22, 2020. Trifu V, et al. Br J Dermatol. 2011;165:177-183. 3. Mazzetti A, et al . J Drugs Dermatol. 2019;18(6):563-568. Mazzetti A, et al. J Drugs Dermatol. 2019;18(6):570-575. 5. Rosette C et al. J Drugs Dermatol. 2019; 18(5):412-418.

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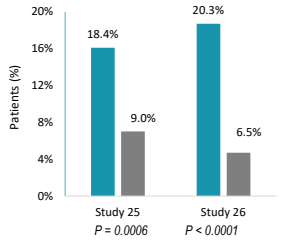
Clascoterone 1% Cream 1% vs Vehicle Cream Twice Daily

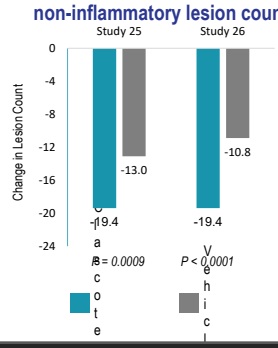
Phase III Trails - IGA Success & Absolute Acne Lesion Change – Baseline → Week 12

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

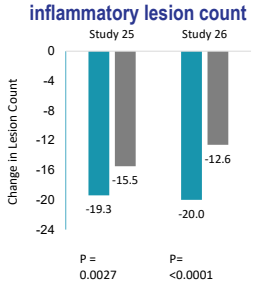
2 Point Reduction in IGA & IGA score of 0 (clear) or 1 (almost clear)



Absolute change from baseline in non-inflammatory lesion count



Absolute change from baseline in inflammatory lesion count



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

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
Sample Size	• Study 25: N = 708 • Study 26: N = 732

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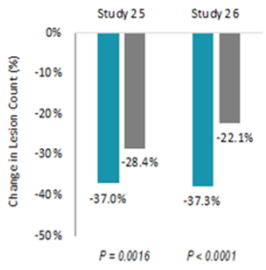
Clascoterone 1% Cream 1% vs Vehicle Cream Twice Daily

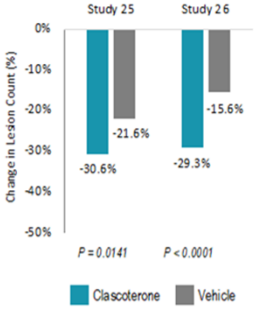
Phase III Trails - Percent Reductions in Acne Lesions - Baseline → Week 12

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

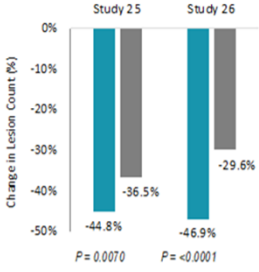
Percent reduction from baseline in total lesion count



Percent reduction from baseline in non-inflammatory lesion count



Percent reduction from baseline in inflammatory lesion count



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

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
Sample Size	• Study 25: N = 708 • Study 26: N = 732

26

BENZOYL PEROXIDE (BP) 9.8% EMOLLIENT FOAM ONCE DAILY *SHORT CONTACT* THERAPY ON TRUNK *P ACNES* REDUCTION STUDY

J Drugs Dermatol. 2012 Jul;11(7):830-3.

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

Leyden JJ[1], Del Rosso JQ.

Author information

2-3 Minute Contact → Wash off

Abstract

Benzoyl peroxide (BP) exerts its therapeutic effect for acne vulgaris through reduction of Propionibacterium acnes. A 1.0 to 2.0 log reduction in P acnes has been demonstrated primarily on the face with use of "leave-on" BP formulations, but also with some BP cleansers. In addition to use for facial acne vulgaris, cleanser formulations of BP are commonly used for truncal acne vulgaris due to ease of use on a large body-surface area 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 recognized and standardized methods to accurately determine P acnes colony counts. A previous study demonstrated that a BP 8% cleanser did not reduce counts of P acnes on the back when subjects were instructed to apply the cleanser in the shower, allow it to dry for 20 seconds on the skin, and then rinse off the cleanser. Evaluation of specified time intervals between application on the back and rinsing with BP formulations would help to better define the necessary skin contact time associated with high reductions of P acnes (>90%), recognizing also the potential roles of BP concentration and vehicle. This 2 week study using quantitative bacteriologic cultures evaluates the effectiveness of BP 9.8% emollient foam in reducing P acnes levels on the back with 2 minutes of skin contact time and compares results with a BP 5.3% "leave-on" emollient foam formulation. Short contact therapy utilizing a 2 minute skin contact time with BP 9.8% emollient foam used once daily over a 2 week duration was highly effective in reducing the quantity of P acnes organisms on the back and provided comparable colony count reduction to "leave on" therapy using BP 5.3% emollient foam.

BP WASH FORMULATION NOT EFFECTIVE IN REDUCING *P ACNES*

JUNE 2017 611 VOLUME 16 • ISSUE 6

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The Efficacy and Safety of Azelaic Acid 15% Foam in the Treatment of Truncal Acne Vulgaris

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[b]JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV

Touro University Nevada, Henderson, NV

[c]Mount Sinai Medical Center, New York, NY; Physicians Skin Care, PLLC, Louisville, KY

ABSTRACT

Intro: Truncal acne is often associated with facial acne, but there are fewer options for an effective topical treatment on the trunk. Given the advent of foam formulations with enhanced percutaneous absorption and convenient application due to easy spreadability on skin, the previously held idea that effective treatment of truncal acne requires oral treatment is challenged. Azelaic acid cream has been previously approved for acne vulgaris, thus azelaic acid foam may be a viable treatment option for truncal acne.

ORIGINAL RESEARCH

Management of Truncal Acne Vulgaris with Topical Dapsone 7.5% Gel

by JAMES Q. DEL ROSSO, DO; LEON KIRCIK, MD; and EMIL TANGHETTI, MD

Dr. Del Rosso is with JDR Dermatology Research and Thomas Dermatology in Las Vegas, Nevada, and is also Adjunct Clinical Professor at Touro University Nevada in Henderson, Nevada. Dr. Kircik is Clinical Associate Professor of Dermatology at Icahn School of Medicine at Mount Sinai in New York, New York, and is Medical Director at Indiana University Medical Center in Indianapolis, Indiana. Dr. Tanghetti is Medical Director at the Center for Dermatology and Laser Surgery in Sacramento, California.

J Clin Aesthet Dermatol. 2018;11(8):45–50

ABSTRACT

The majority of available data on the prevalence, grading, and management of acne vulgaris (AV) are based on studies that evaluate facial AV. Data are limited in all of these areas with truncal AV. This study evaluates the efficacy and safety of topical management of truncal AV involving the chest and back in a three-center, open-label, 16-week study. Enrolled subjects (N=20), 12 years of age or older, applied dapsone 7.5% gel once daily as monotherapy. The primary endpoint of the study was the percent of subjects who achieved a two-grade improvement and a rating of clear or almost clear based on the Investigator Global Assessment scale. Secondary endpoints included percent reductions of inflammatory, non-inflammatory (comedonal), and total lesions at Week 16 compared to baseline. Tolerability and safety were assessed over the duration of the study.

KEYWORDS: Acne vulgaris, acne, truncal, topical, gel, dapsone

Acne vulgaris (AV) is the most common cutaneous disorder seen in ambulatory dermatology practice among the pediatric and adult populations.[1] The vast majority of data on the epidemiology and management of AV are based on studies evaluating facial AV, with prevalence and treatment data far more limited for truncal AV.[2,3] Studies completed over the past decade have reported that truncal AV (chest and/or back) affects approximately 50 to 60 percent of individuals who present with AV, than in cases warranting treatment with oral isotretinoin, combination therapy with a topical regimen is recommended, especially concomitant with oral antibiotic therapy in patients with truncal AV where use of an oral agent is deemed necessary.[3,5–7,11] However, many cases of truncal AV can be mild to moderate in severity, and thus could potentially respond adequately to a topical regimen as initial treatment or as maintenance therapy after discontinuation of oral antibiotic therapy.[4,7,11]

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Azelaic Acid 15% Foam in Truncal 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

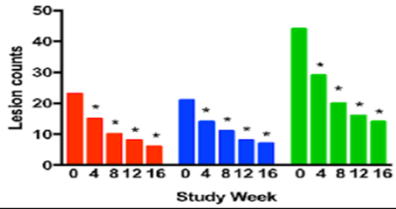
74% Reduction Inflammatory Lesions Week 12

Favorable Tolerability

45% CLEAR/ALMOST CLEAR + 39% MILD

FIGURE 1. Mean inflammatory, non-inflammatory (comedonal), and total lesion counts. There were significant reductions in mean lesion counts within the first 4 weeks of treatment and were sustained or improved throughout the remainder of the study. All subjects experienced reductions in inflammatory, non-inflammatory, and total lesion counts by the week 16 visit.

*$P<0.05$



Hoffman L, et al. J Drugs Dermatol. 2017;16(6):611-615.

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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

Del Rosso JQ, Kircik L, Tanghett E. J Drugs Dermatol. 2018;11:45-50.

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 %

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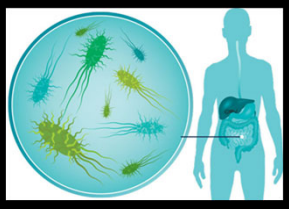
Oral Antibiotic Therapy in Acne Vulgaris

- 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 demonstrsted (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



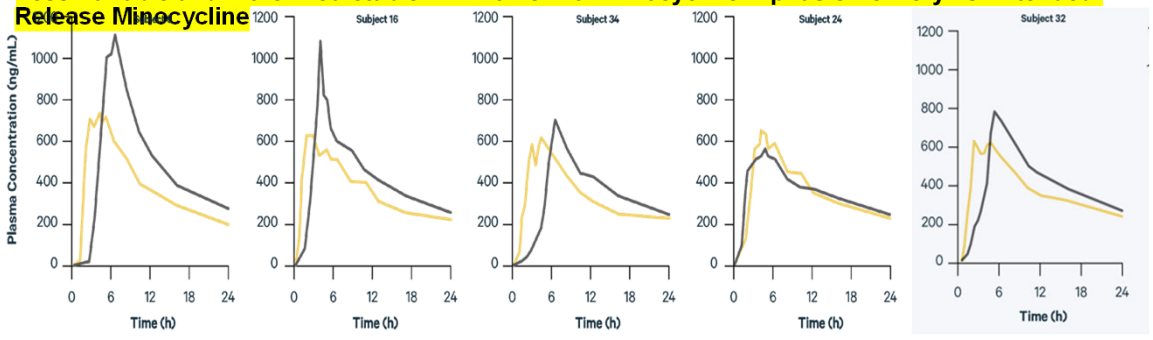
Moore AY, et al. Future Microbiol. 2019; 14(14): 1235–1242. Batool Z, et al. J Investig Dermatol. 2020;140(7):S79. Haidari W, et al. Ann Pharmacother. 2020;54(2):164-170. Zhanel G, et al. Antimicrobial agents and chemotherapy. 2019:63(1).

30

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

Data on File. EPI Health, Charleston, South Carolina

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ORAL ISOTRETINOIN ADVANCES THAT CAN REDUCE RISK OF RELAPSE

ORIGINAL RESEARCH

An Open-label, Phase IV Study Evaluating Lidose-isotretinoin Administered without Food in Patients with Severe Recalcitrant Nodular Acne: Low Relapse Rates Observed Over the 104-week Post-treatment Period

by JAMES Q. DEL ROSSO, DO; LINDA STEIN GOLD, MD; JEANETT SEGAL; and ANDREA L. ZAENGLEIN, MD

ABSTRACT

JCAD

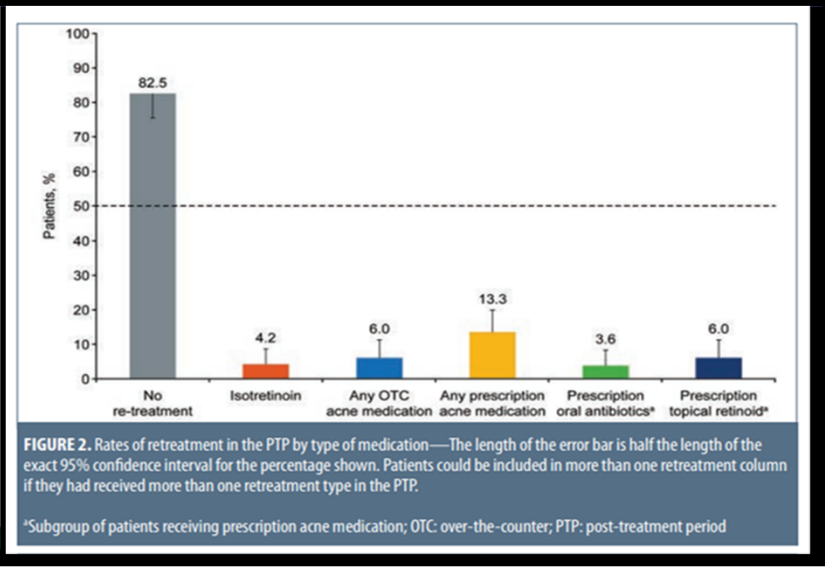

FIGURE 2. Rates of retreatment in the PTP by type of medication—The length of the error bar is half the length of the exact 95% confidence interval for the percentage shown. Patients could be included in more than one retreatment column if they had received more than one retreatment type in the PTP.

*Subgroup of patients receiving prescription acne medication; OTC: over-the-counter; PTP: post-treatment period

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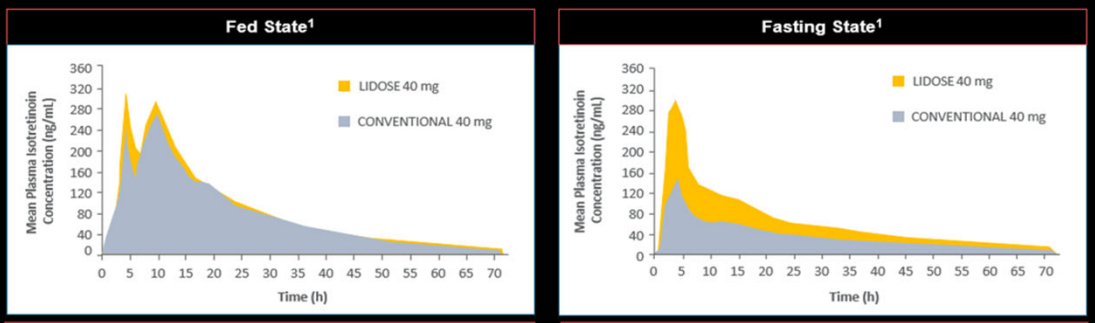
Lidose Isotretinoin vs Conventional Isotretinoin
(Brand and Generic) Formulations With and Without Food



EQUAL IN PRESENCE OF HIGH FAT INTAKE (50 GRAMS)

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

1. Webster GF, et al. *J Am Acad Dermatol.* 2013;69(5):762-767.
2. Sun Pharma, data on file.

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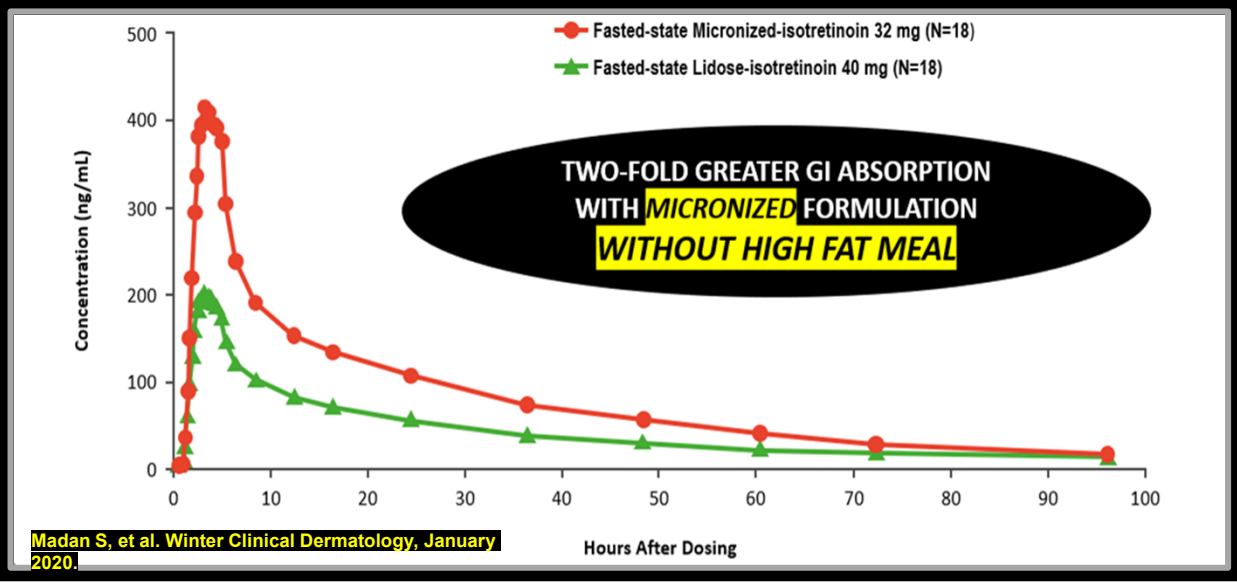
Comparative Pharmacokinetics of MICRONIZED-Isotretinoin
32-mg Formulation and Lidose-Isotretinoin 40 mg *WITHOUT FOOD*



Madan S, et al. Winter Clinical Dermatology, January 2020.

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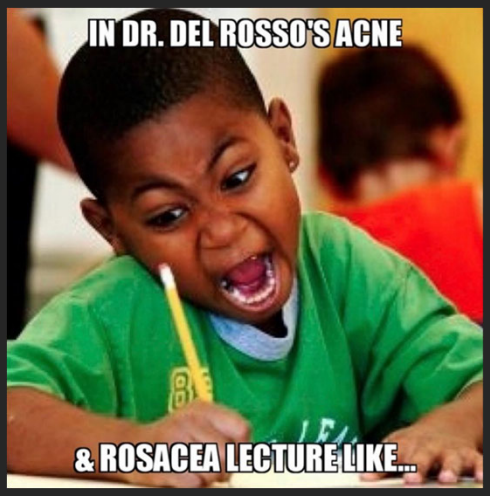
THANK YOU



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