

# OUR SKIN TELLS A STORY



Jefferies Virtual Healthcare Conference  
June 1-4, 2021

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Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.

# Cassiopea Overview

- Publicly traded on SIX - Cosmo Pharma holds 46.6%
- Innovative late stage pipeline of 4 dermatology NCE products
- Winlevi (clascoterone cream) 1% - First in Class<sup>1</sup> Topical Androgen Receptor (AR) Inhibitor Targeting Acne - Approved by the FDA as a novel drug<sup>1</sup>- August 26, 2020

NCE: new chemical entity

Source: 1. US FDA. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020>

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# Cassiopea Pipeline

## PRODUCT

## PROPOSED INDICATION

**WINLEVI®**  
**(clascoterone cream 1%)**  
Androgen receptor inhibitor

**Acne Vulgaris**



**Clascoterone solution**  
Androgen receptor inhibitor

**Androgenetic alopecia in males**



**Clascoterone solution**  
Androgen receptor inhibitor

**Androgenetic alopecia in females**



**CB-06-01**  
Antibiotic

**Acne**



**CB-06-02**  
Immune modulator

**Genital warts**



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# Agenda

- Winlevi (clascoterone cream) 1%
- Commercial Update
- Clascoterone Solution Update

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**Winlevi**<sup>®</sup>  
(clascoterone)  
cream 1%

Acne is the most prevalent skin condition in the U.S...yet the last new mechanism of action approved by the FDA was almost **40** years ago<sup>1,2</sup>

50

Million sufferers in US<sup>3</sup>

\$5

Billion US market<sup>4</sup>

24

Million prescriptions<sup>4</sup>

70%

Total Prescriptions written in the Dermatology Office<sup>4</sup>



Source: 1. Thielitz A, Gollnick H. *Am J Clin Dermatol*. 2008;9(6):369-81; 2. Costa CS et al. *Cochrane Database Syst Rev* 2018;11:CD009435. 3. Skin Conditions by the numbers. American Academy of Dermatology. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. 4. IQVIA National Prescription Audit Sept. 2019.

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# Winlevi (clascoterone) cream 1% Approval Marks the Introduction of a **New Class of Topical Therapy to Dermatology**<sup>1,2</sup>

First in Class Topical Androgen Receptor Inhibitor<sup>1</sup>

Approved for the topical treatment of acne in patients 12 years of age and older<sup>2</sup>

Tackles the androgen hormone component of acne in both males & females<sup>2,3</sup>

The most frequent observed local skin reaction was mild erythema<sup>1,3</sup>



1. US FDA. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020> 2. Winlevi Prescribing Information - <https://www.winlevi.com/assets/WINLEVI-clascoterone-cream-prescribing-info-08-2020.pdf> 3. US FDA Drug Trial Snapshot: WINLEVI. September 3, 2020. <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trial-snapshot-winlevi>



# Approval of Winlevi<sup>®</sup> (clascoterone) cream 1% Fills a Long-Standing Gap in Topical Acne Therapy<sup>1,2</sup>

Multi-factorial disease results in a complementary approach to treat acne

## Drugs that normalize follicular keratinization

Retinoids

## Drugs that inhibit sebaceous gland function

Topical Androgen Receptor Inhibitor



## Drugs with anti-inflammatory effects

Retinoids

Antibiotics

Benzoyl peroxide

## Drugs with antibacterial effects

Benzoyl peroxide

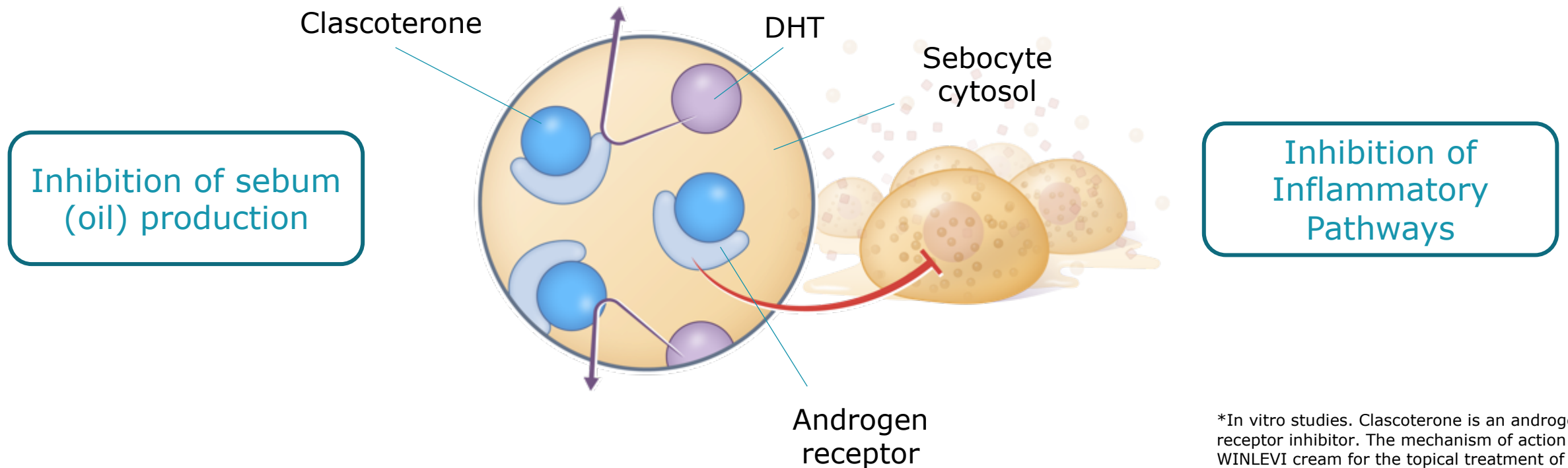
Antibiotics

Source: 1. Zaenglein AL et al. J Am Acad Dermatol 2016;5:945-73. 2. Del Rosso JQ et al. J Drugs Dermatol. 2020;19(3 Suppl 1):s30-35

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# Clascoterone is an androgen receptor inhibitor: *In Vitro* Activity

**Clascoterone competes with DHT for binding to the androgen receptor<sup>1,2\*</sup>**



\*In vitro studies. Clascoterone is an androgen receptor inhibitor. The mechanism of action of WINLEVI cream for the topical treatment of acne vulgaris is unknown.

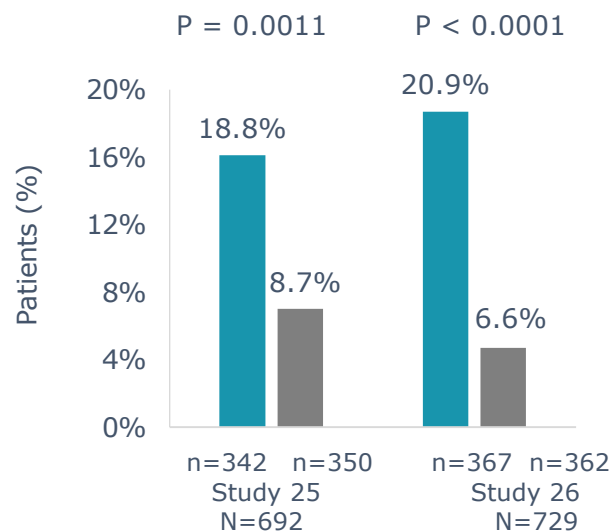
Source: 1. Ferraboschi P et al. Med Chem Commun 2014;5:904-14; 2. Rosette C, et al. J Drugs Dermatol. 2019; 18(5):412-418. <https://www.ncbi.nlm.nih.gov/pubmed/31141847>

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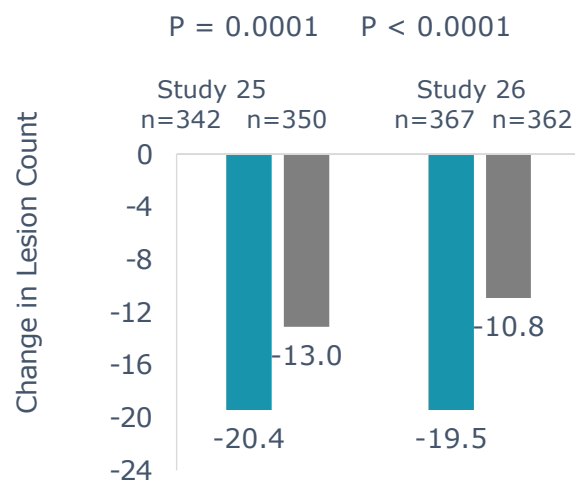
# Two Pivotal Phase III Trials, WINLEVI (clascoterone) Cream, 1% Demonstrated Statistically Significant Efficacy vs. Vehicle—IGA Success and Absolute Reduction in Lesion Count<sup>1,2</sup> Age 12 and older

## EFFICACY (CO-PRIMARY ENDPOINTS) ITT (WEEK 12)

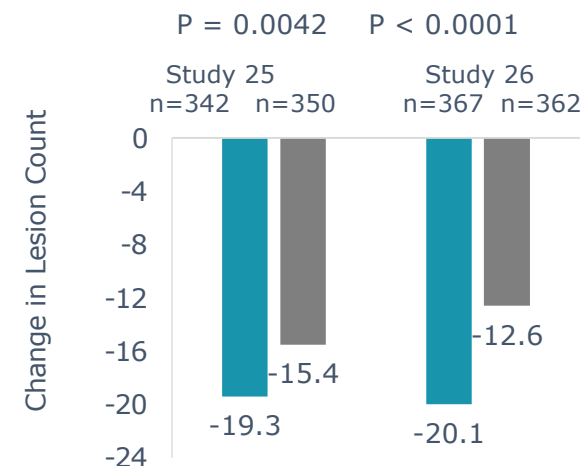
### 2 Point Reduction in IGA & IGA score of 0 (clear) or 1 (almost clear)



### Absolute change from baseline in non-inflammatory lesion count



### Absolute change from baseline in inflammatory lesion count



■ Winlevi N=709  
■ Vehicle N=712

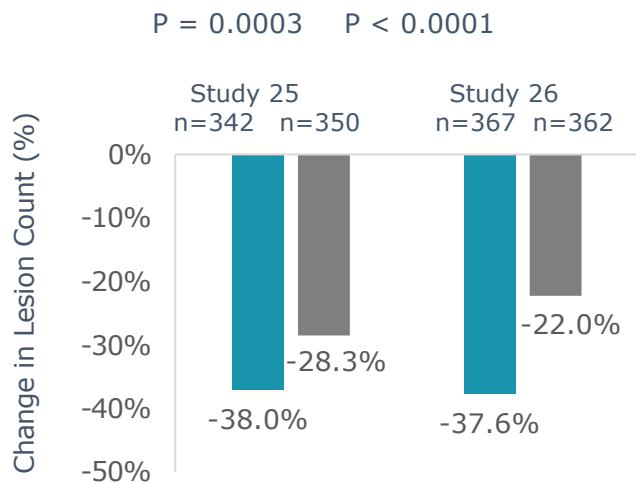
1. Hebert A, et al. JAMA Dermatol. JAMA Dermatol. 2020;156(6):621-630 . doi:10.1001/jamadermatol.2020.0465. 2. Winlevi ® [Package Insert]. Cassiopea 2020. Statistical significance if P < 0.05 significance level  $\alpha=0.05$

Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.

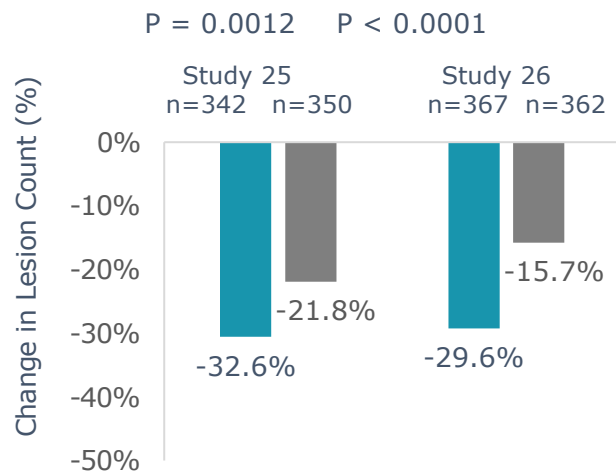
# In Two Pivotal Phase III Trials, WINLEVI (clascoterone) Cream, 1% Demonstrated Statistically Significant Efficacy vs. Vehicle - Percent Reduction in Lesions<sup>1,2</sup> Age 12 and older

## EFFICACY (SECONDARY ENDPOINTS) ITT (WEEK 12)

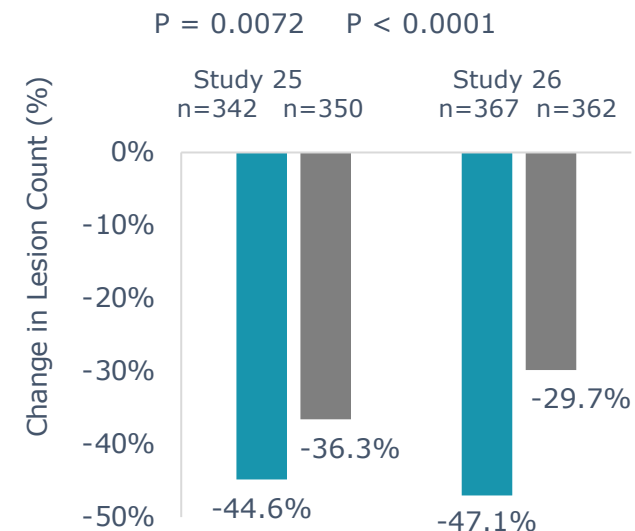
**Percent reduction from baseline in total lesion count**



**Percent reduction from baseline in non-inflammatory lesion count**



**Percent reduction from baseline in inflammatory lesion count**



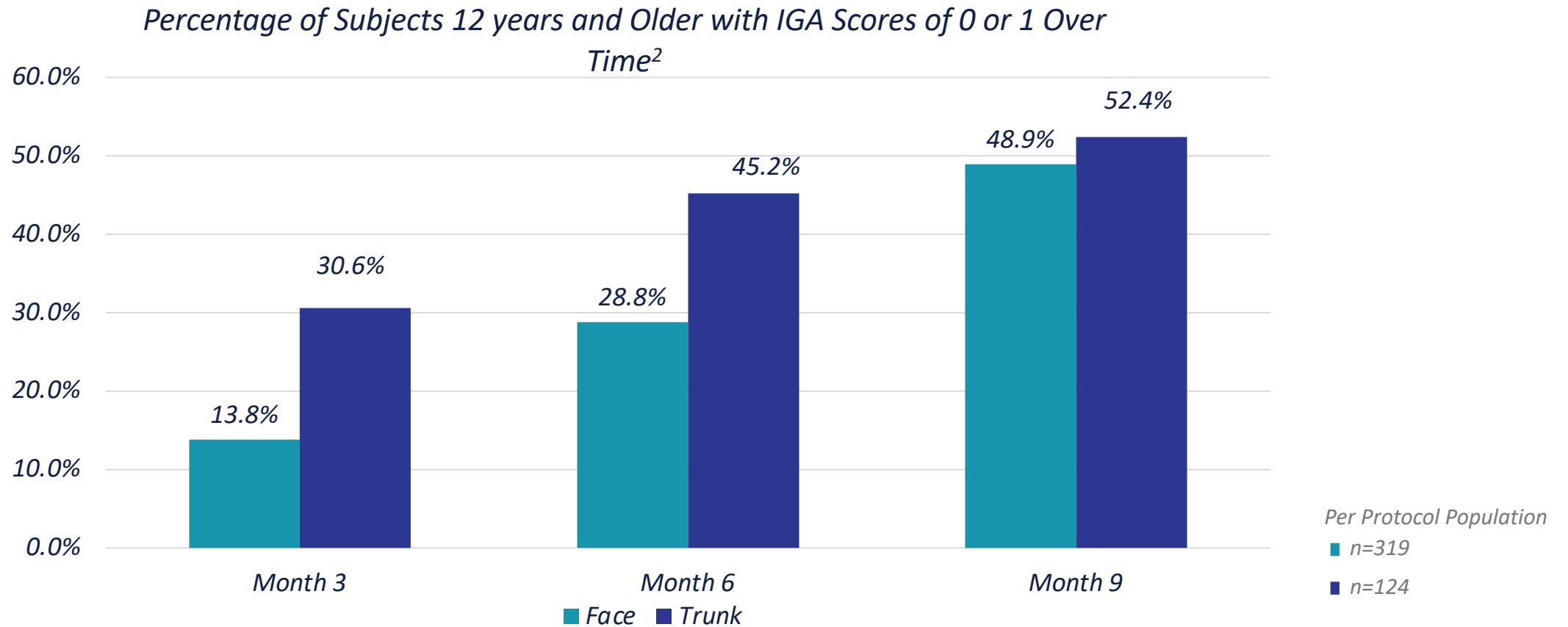
■ Winlevi    ■ Vehicle  
N=709    N=712

1. Hebert A, et al. JAMA Dermatol. Published online April 22, 2020. doi:10.1001/jamadermatol.2020.0465. 2. Winlevi ® [Package Insert]. Cassiopea 2020. Statistical significance if P < 0.05 significance level  $\alpha=0.05$

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# Clascoterone Cream 1% Phase III Open Label Extension Study: Secondary Endpoint: Efficacy Summary<sup>1,2</sup>



**Patients on study treatment for the maximum period of 12 months on face and 9 months on trunk had an IGA score of 0 or 1 in 56.3% and 61.7% of the cases respectively**

1. Eichenfield L, Hebert A, Gold LS, et al. *J Am Acad Dermatol*. 2020;83(2):477-485 2. Data on File. Cassiopea. 2020

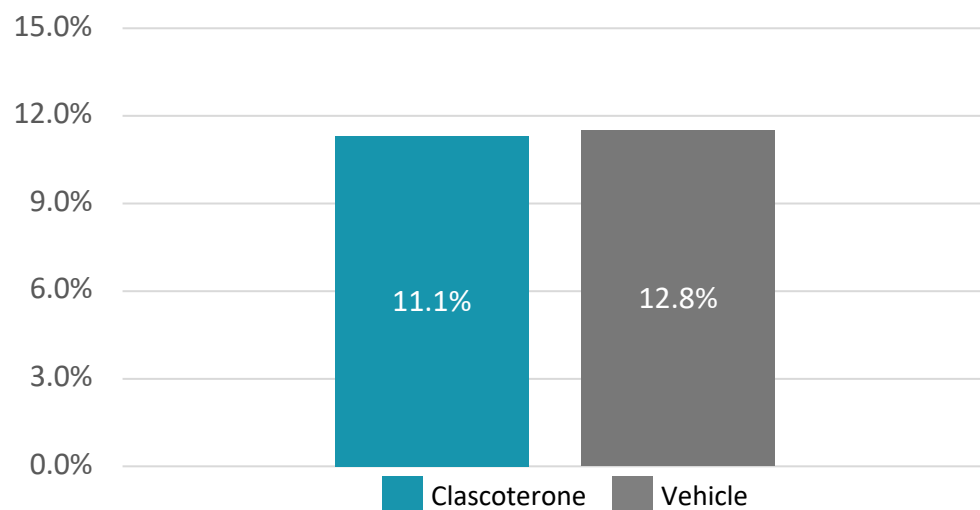
Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.

# Winlevi Safety Profile—Phase 3 Studies & Open Label Extension<sup>1,2</sup>— Indicated Population<sup>3</sup>

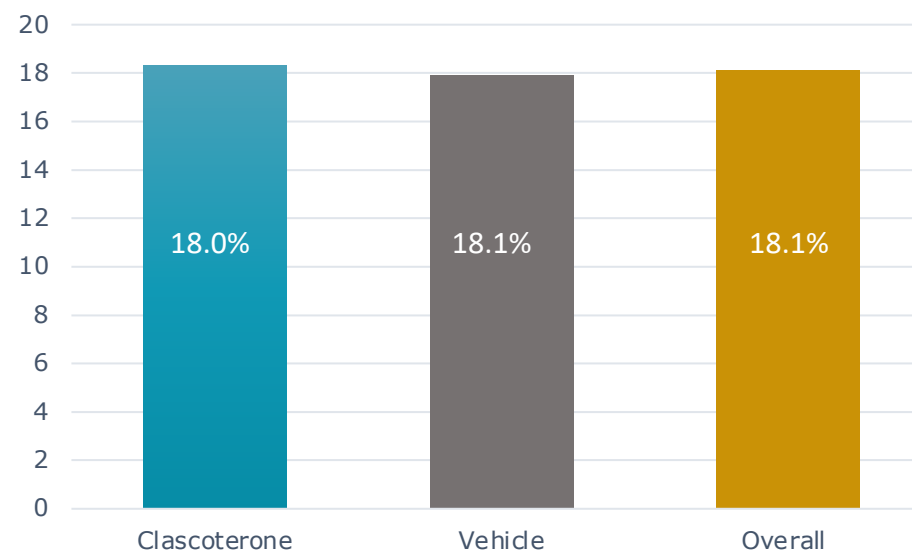
Phase 3 trials across 1,421 patients demonstrated side effects similar to vehicle<sup>1,3</sup>

The open label trial involving 600 patients from the parent Phase 3 studies showed similar TEAE levels<sup>2,3</sup>

Pooled Safety Data – TEAE\* Study 25, 26



Study 27 Percent of Subjects with TEAEs—by parent study



TEAE - treatment-emergent adverse event

1. Hebert A, et al. JAMA Dermatol. 2020;156(6):621-630. doi:10.1001/jamadermatol.2020. 2. Eichenfield L, Hebert A, Gold LS, et al. J Am Acad Dermatol. 2020;83(2):477-485; 2. Data on File. Cassiopea. 2020.

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# WINLEVI (clascoterone) Cream, 1% Incidence of New or Worsening Local Skin Reactions (LSRs) reported by $\geq 1\%$ of Patients $\geq 12$ Years

## Incidence of New or Worsening Local Skin Reactions Reported by $\geq 1\%$ of Patients Treated with Winlevi After Day 1 in 12-Week Controlled Clinical Trials

	<b>Winlevi (N=687<sup>a</sup>)</b>	<b>Vehicle Cream (N=662<sup>a</sup>)</b>
<b>Edema</b>	25 (3.6%)	23 (3.5%)
<b>Erythema/reddening</b>	84 (12.2%)	101 (15.3%)
<b>Pruritus</b>	52 (7.6%)	55 (8.3%)
<b>Scaling/ dryness</b>	72 (10.5%)	68 (10.3%)
<b>Skin atrophy</b>	11 (1.6%)	17 (2.6%)
<b>Stinging/burning</b>	28 (4.1%)	28 (4.2%)
<b>Striae rubrae</b>	17 (2.5%)	10 (1.5%)
<b>Telangiectasia</b>	8 (1.2%)	12 (1.8%)

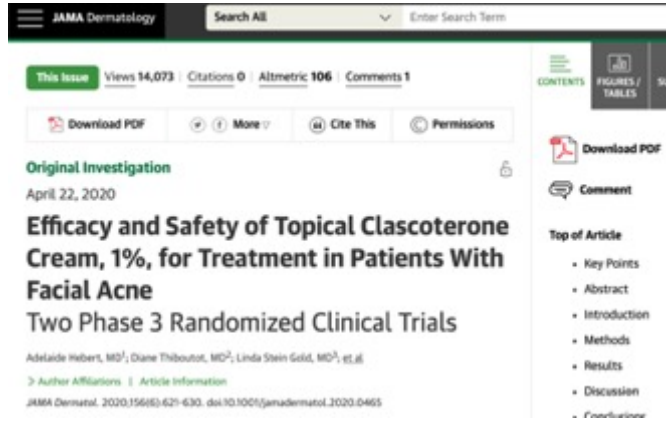
a. The denominators for calculating the percentages were the 674 of 709 subjects treated with WINLEVI cream and 656 of 712 subjects treated with vehicle in these trials who had local skin reaction results reported after Day 1. LSR severity was recorded trace, minimal, mild, moderate or severe. Most were trace/minimal/mild.

Source: Winlevi® [Package insert]. Cassiopea; 2020

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# Winlevi Medical Affairs

Trending as top article – Nearly 31,000 views/downloads



- 7 published clinical articles in high profile peer reviewed medical journals by Cassiopea
  - 8 additional published journal articles from KOLs
- 23 Posters and Abstracts

- Robust KOL support in trade journals—Dermatology Times, Dermatology World
- Widely viewed CME programming
- MedScape, JDD acne education on androgen receptors in acne

- 24 Meeting Sponsorships
- Since 2019, 275+ Podium Mentions by KOLS with 60 in 2020 and 25 in 2021
- 2 accepted presentations at AAD 2020, 2021 (postponed-COVID)

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# Commercial Update

# Key US Acne Market Insights and Positioning

- Acne market continues to be an important market in Dermatology
  - High volume, concentrated target market with 8,200 providers accounting for almost 60% of prescriptions
- Unmet need among providers for a novel approach, especially targeting the hormonal aspect for all acne patients
  - Over the counter retinoids and BPOs are paving the way for innovative prescriptions
  - Antibiotic stewardship in acne has increased the need for alternatives
  - Spironolactone (oral anti-androgen) used off label for acne is the third highest prescribed drug in Dermatology for any indication, limited use to females only
- Acne is treated with polypharmacy, using multiple, complementary drugs to address varying parts of the disease
- Market research demonstrates clear positioning for WINEVI around the unique mechanism of action and significant market share uptake predicted among segmented high value providers

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# Market Research confirms WINLEVI can be positioned as a foundation for acne treatment

Clear Differentiation as a **first in class** Topical Androgen Receptor Inhibitor

*"All acne has a hormone component, it's a matter of to what extent. If Product X treats the hormone aspect of it and can work for both male and female, then **all patients should be on it, like a retinoid.**"*  
Derm

**90% of Healthcare Providers** exposed to clascoterone cream 1% said they would be **extremely likely to prescribe** the product

Almost all Physicians surveyed agreed: **There is a need for topical treatment** to target acne **triggered** by **hormones**

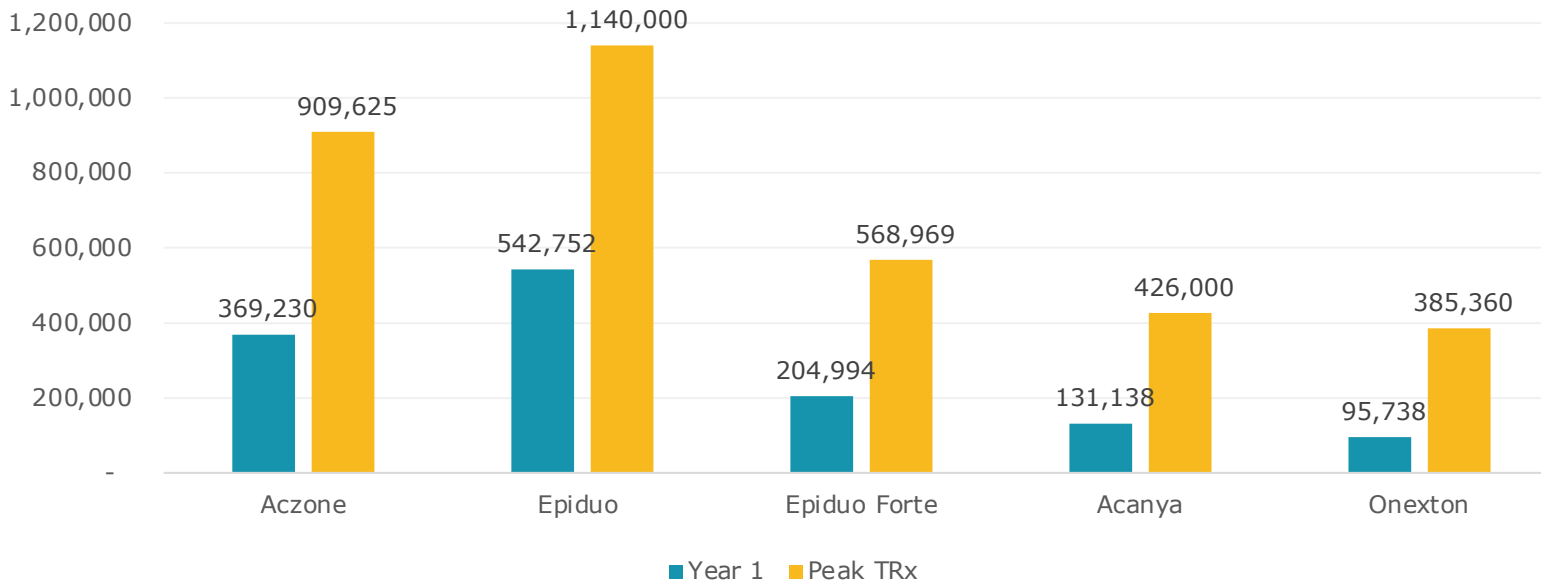
Overall physicians reported a **high preference share**, driven primarily by clascoterone's new & unique mode of action

Source: IQVIA Primary Market Segmentation Research July- Sept 2019. Qualitative research n=50. Q. How likely are you to prescribe Product X for your acne patients? *Number of HCPs; Rating 1-7: 1 = Not Likely; 4 = Somewhat Likely 7 = Extremely Likely*

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# Market research confirms interest in WINLEVI is similar to Epiduo and Aczone.

Acne Launch Surrogates: Year 1 & Peak TRx Volume



*"This is not only a new product, but also novel product. It's a good option for both men and women struggling with hormonal acne. I would definitely use it!"*

*–High Priority Segment Derm*

Source: IQVIA NPA Sept. 2019 Data, Aczone & Epiduo Peak Volume in 2015, Acanya 2013, Onexton 2016

## Provider Response to clascoterone cream 1%

- Average **clascoterone efficacy ratings** were similar to products like **Adapalene, and Aczone Gel 7.5%®**, given that it provided decent reduction in inflammatory lesions and sufficient long term efficacy (especially in truncal acne)
- **Clascoterone had the highest tolerability rating** of all the products that were rated, given its very positive tolerability profile and its small rate of discontinuation
- HCPs saw most value of Winlevi in **moderate patients** so they can target **both the inflammation and the hormonal** component of acne in these patients
- Reported market share of 18-24%

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# Market Access

## Summary Insights and Coverage Progress

- Payers continue to provide coverage for acne patient visits and products
- While price is a key driver for coverage decisions, innovation and new MOA does matter
  - Drugs over \$600 WAC monthly cost may have higher restrictions - \$550 WAC set
  - Clascoterone in a unique category as a first in class androgen receptor inhibitor
    - Possibly decreasing steps through other drugs as there are no other drugs in the class
- Coverage expected in at least 70% of commercial lives without highly restrictive PAs or multiple step edits for an acceptable Net price per month to the payer
- Partnered with a syndicated National Account Team (NAM) of 8 with U.S. Payer engagements and clascoterone clinical reviews started July 2020
- Contracting Negotiations have been initiated with Payers representing 98% of all Commercial lives (165MM) - 3 contracts signed, 3+ to be signed in 4-8 weeks

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# Winlevi Launch Approach

- Adopted a step wise approach to investment and launch preparation
  - Built a US management team with extensive dermatology experience in over 20 derm launches
  - 2 step launch approach: Market Access Launch at PDUFA (Sept. 2020), Commercial Sales Launch Fall 2021
- Built a solid foundation for launch
  - Extensive Medical Affairs program has rapidly increased awareness of clascoterone new MOA and clinical data in the dermatology community
  - Marketing research conducted on positioning, messaging and market segmentation
  - Market access research conducted on value proposition, downstream payer analysis/pricing and market access launch has begun
- In order to increase operating efficiency we have evaluated multiple commercialization options and we plan to make an announcement within the next 30-60 days on the selected commercialization transaction
  - Transactions that give access to additional products
  - Structures of external or contract support
  - M&A or licensing options to optimize commercialization and profitability before building own organization

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A close-up photograph of a person's hair, likely on the scalp, with a hand gently touching it. The hair is dark brown and appears to be thinning or receding. The background is a solid teal color.

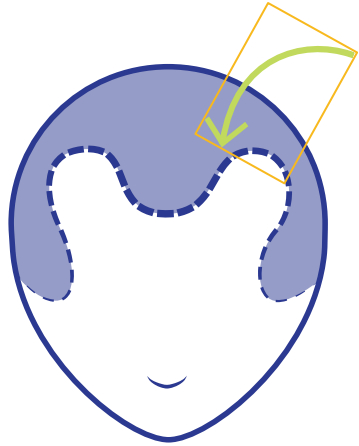
# OUR SCIENCE TELLS A STORY

Clascoterone Solution 7.5%  
First in Class Androgen Receptor Inhibitor  
Targeting Androgenetic Alopecia

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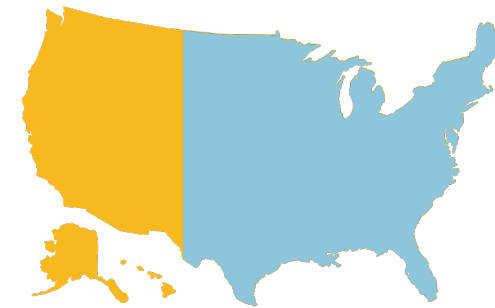
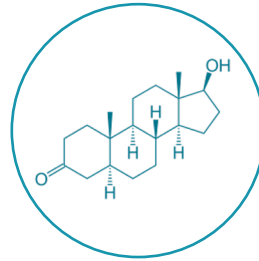
Clascoterone solution is under investigation and is not FDA approved.

# US Androgenetic Alopecia Market



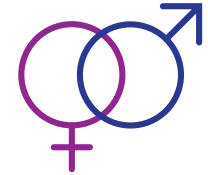
**Androgenetic alopecia**, also known as **pattern baldness**, is characterized by the progressive loss of terminal hairs on the scalp in a characteristic pattern<sup>1</sup>

It is caused by high concentrations of **dihydrotestosterone (DHT)** at the hair-follicle, which shortens the hair growth cycle in those with a genetic predisposition<sup>1</sup>



**80-95 million** Americans suffer from Androgenetic alopecia<sup>3</sup>

**Both men and women** are impacted<sup>2</sup>



Known psychosocial complications of androgenetic alopecia include **depression, low self-esteem, and less frequent and enjoyable social engagement**<sup>2</sup>

Studies have indicated that **women are more likely to suffer from psychological complications than men**<sup>2</sup>



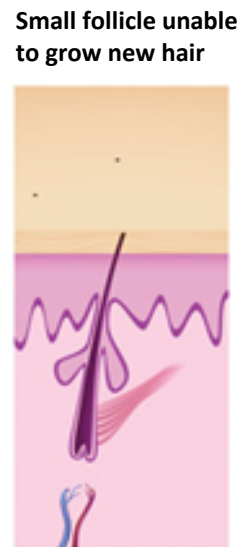
**Only 4-9 million** patients are estimated to get treatment

Treatment options are limited to old therapies developed

**20 -30 years ago**<sup>4</sup>



# Clascoterone Solution: A Potential New Topical Treatment for Androgenetic Alopecia in Males and Females<sup>1,2</sup>



DHT = Dihydrotestosterone

## Existing Treatments

### Propecia™ (finasteride)

- Has anti-androgenic activity on follicle by inhibiting 5 alpha reductase, an enzyme required for synthesis of DHT<sup>3</sup>
- However, serious side effects due to hormonal imbalance<sup>3</sup>
- Not indicated for women<sup>3</sup>

### Minoxidil®

- ◆ Shows a vasodilator effect, ensuring a better flow of nutrients to the papilla<sup>3</sup>

## Clascoterone Solution A Novel Topical Androgen Receptor Inhibitor

- Antagonizes DHT's negative effects on dermal papilla by competing with DHT at the androgen receptor<sup>1</sup>
- Reduces hair miniaturization<sup>1</sup>
- Reduces dermal inflammation<sup>1</sup>

1. Rosette C, Rosette N, Mazzetti A et al.. *J Drugs Dermatol*. 2019; 18(2)197-201. 2. Cassiopea S.p.A.: Elevating the science of dermatology with new therapeutics. Nature Dealmakers. 2020; Nov 30, 2020. 3. Ashique S, et al. . *Nat Prod Bioprospect*. 2020;10(6):345-365. doi:10.1007/s13659-020-00267-9

# Clascoterone Solution Clinical Program Status

## Status:

- Phase 2 dose ranging study in males successful and most effective dose identified at 7.5% BID
- End of Phase 2 Meeting with FDA held
- Special Protocol Assessment for Phase 3 Program submitted to FDA and Type A meeting held
- Development of Patient Reported Outcome questionnaire underway
- Special Protocol Assessment for Phase 3 Program to be re-submitted to FDA
- Extensive Medical Affairs program has increased visibility in the Dermatology community
- Phase 2 study in females enrollment completed

## Next Steps:

- Phase 2 data in females top line results 3Q21
- Finalize Special Protocol Assessment for Phase 3 Program in males with FDA
- Initiate Activities for Phase 3 trials in males – after agreement with FDA on SPA

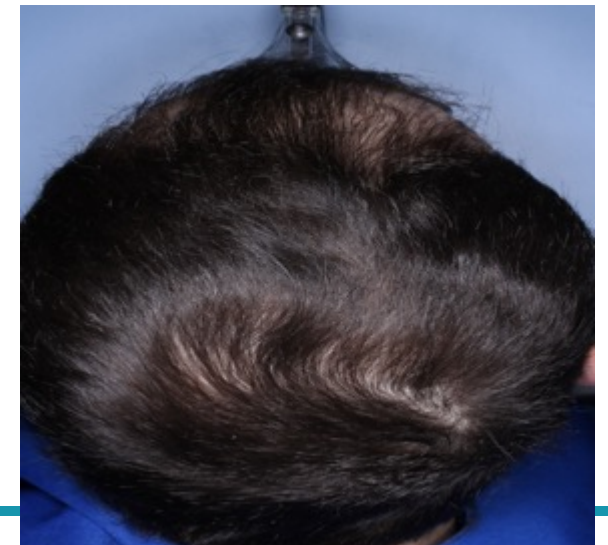
Representative photos.

Blume-Peytavi U, et al. S11223 – ). Presented at the 2019 AAD Annual Conference. S034 Late-breaking Research Saturday March 2, 2019. Washington DC. <https://bit.ly/330h2nt>

7.5% Solution BID Baseline



Month 6



# Key Market Insights & Opportunity for Breezula



## Simple Tx Algorithm, poised for market disruption

- Few therapeutic options for Physicians, limited to finasteride and minoxidil, results in underdeveloped AGA Market
  - No promotional competition on the horizon
- ✓ HCPs were highly receptive to the product profile, emphasizing the novel mechanism and impressive clinical photographs – 60% reported adoption



## Highly Engaged & Motivated Patient Base

- Over 70% of patients express a high level of concern and impact on their lives
  - Most common treatment is Rogaine, along with vitamins & supplements
  - Women have fewer options than men
  - Forhims, keeps.com have impacted the distribution model directly to consumers
- ✓ Almost half of the patients surveyed said they would be extremely likely to request a Rx, with another 30% moderately likely.



## Payers call this a “lifestyle” drug category

- Finasteride and minoxidil are not considered covered drugs
  - Payers express unlikely to cover future AGA drugs
  - Cosmetic disease, rather than medical
- ✓ Breezula could be priced \$100-200 per month like other lifestyle drugs

Source: Triangle Insights Group Primary Market Research Among Patients, Payers and Physicians Q3-4 2018

# Upcoming Company Milestones

- Winlevi (clascoterone) cream, 1% launch
  - Market Access launch ongoing, Sales launch fall 2021
- Announce topline results for Phase 2 program for Clascoterone Solution in Females 3Q21
- Finalize SPA with FDA on Phase 3 program for Clascoterone Solution in males

# Cassiopea SpA

## Information

**Number of shares:** 10,750,000

**Listing:** SIX Swiss exchange, Main board

**ISIN:** IT0005108359

**Ticker:** SKIN

## Contacts

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Pierpaolo Guzzo, CFO

[pguzzo@cassiopea.com](mailto:pguzzo@cassiopea.com)

# WINLEVI<sup>®</sup> (clascoterone) cream, 1% Indication & Important Safety Information

## INDICATIONS AND USAGE

WINLEVI<sup>®</sup> (clascoterone) cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

## DOSAGE AND ADMINISTRATION

- Apply a thin layer (approximately 1 gram) to affected area twice daily (morning and evening). Avoid contact with eyes, mouth, and mucous membranes.
- Not for ophthalmic, oral or vaginal use.

## DOSAGE FORM AND STRENGTHS

Cream 1%.

## CONTRAINDICATIONS

None.

## WARNINGS AND PRECAUTIONS

Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with WINLEVI cream. If these effects occur, discontinue or reduce the frequency of application of WINLEVI cream.

- Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with clascoterone.
- Attempt to withdraw use if HPA axis suppression develops.
- Pediatric patients may be more susceptible to systemic toxicity.
- Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials.

## ADVERSE REACTIONS

Most common adverse reactions occurring in 7 to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle.

See

<https://www.winlevi.com/assets/WINLEVI-clascoterone-cream-prescribing-info-08-2020.pdf> for full prescribing information