

## Winlevi® (clascoterone) – New drug approval

- On August 27, 2020, [Cassiopea announced](#) the FDA approval of [Winlevi \(clascoterone\)](#) cream for the topical treatment of acne vulgaris in patients 12 years of age and older.
- Clascoterone is an androgen receptor inhibitor. The mechanism of action of Winlevi cream for the topical treatment of acne vulgaris is unknown.
- The safety and efficacy of Winlevi was evaluated in two randomized, vehicle-controlled clinical studies of 1,440 patients with facial acne. Efficacy was measured at week 12 and evaluated the reduction in inflammatory and non-inflammatory lesions.
  - Patients treated with Winlevi demonstrated greater reductions in inflammatory and non-inflammatory lesions compared to patients in the vehicle group.
- Warnings and precautions of Winlevi include local skin reaction and hypothalamic-pituitary-adrenal axis suppression.
- The most common adverse reactions (7% - 12%) with Winlevi use were erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in > 3% of patients and were reported in a similar percentage of patients treated with vehicle.
- The recommended dose of Winlevi is the application of a thin, uniform layer twice per day, in the morning and the evening to the affected area.
  - Winlevi cream is for topical use only. Winlevi cream is not for ophthalmic, oral or vaginal use.
- Cassiopea's launch plans for Winlevi are pending. Winlevi will be available as a 1% cream.