25 August 2025
EMA/CHMP/244647/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Winlevi

clascoterone

On 25 August 2025, the Committee for Medicinal Products for Human Use (CHMP), following a re-examination procedure, adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Winlevi, intended for the treatment of facial acne vulgaris in adolescents and acne vulgaris in adults.

The applicant for this medicinal product is Cassiopea S.p.A.

Winlevi contains the active substance clascoterone for topical use and will be available as 10 mg/g cream (ATC code: D10AX06). Clascoterone is an androgen receptor inhibitor that showed to antagonize the effects of androgens in primary human sebocytes *in vitro*. This reduces sebum production and the accumulation of inflammatory mediators, which are known drivers of acne pathogenesis.

The benefits of Winlevi were shown in two pivotal Phase 3 studies in adults and adolescents. After 3 months of twice daily application on the face, a greater proportion of patients responded to treatment with Winlevi than to vehicle. Response was defined as an investigator's global assessment (IGA) score of 0 (clear skin) or 1 (almost clear skin) on a 5-point scale and an IGA reduction of at least 2-points compared to baseline. Across the two studies, the proportion of responders was 19.5% with Winlevi, compared with 7.7% with vehicle. In patients with a baseline IGA of 3 (moderate acne), the success rate was 18.9% with Winlevi and 6.6% with vehicle, and in those with baseline IGA of 4 (severe acne), it was 10.4% and 1.8% respectively.

The most common side effects are local skin reactions such as erythema, scaling/dryness, pruritus and stinging/burning.

The full indication is:

Adults

Winlevi is indicated for the treatment of acne vulgaris.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Adolescents (from 12 to < 18 years of age)

Winlevi is indicated for the treatment of facial acne vulgaris.

Treatment with Winlevi should be initiated and supervised by a physician experienced in the diagnosis and treatment of acne vulgaris.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.