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Update as of 8 May 2025:

The company for Winlevi has requested a re-examination of EMA's April 2025 opinion. Upon receipt of the grounds of this request, the Agency will re-examine its opinion and issue a final recommendation.

Refusal of the marketing authorisation for Winlevi (clascoterone)

The European Medicines Agency has recommended the refusal of the marketing authorisation for Winlevi, a medicine intended for treating acne vulgaris.

The Agency issued its opinion on 25 April 2025. The company that applied for authorisation, Cassiopea S.p.A, may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is Winlevi and what was it intended to be used for?

Winlevi was developed as a medicine for treating acne vulgaris in people from 12 years of age. Acne vulgaris (also known as acne) is a condition in which pores in the skin become blocked with excess oil and skin cells.

Winlevi contains the active substance clascoterone and was to be available as a cream.

How does Winlevi work?

The active substance in Winlevi, clascoterone, blocks receptors (proteins) for androgens (male sex hormones like testosterone). By blocking these receptors, it is expected to reduce activity of glands in the skin that cause acne. However, the exact effect of the medicine on acne vulgaris is not well understood.

What did the company present to support its application?

The company presented data from two main studies involving 1440 adults and children from the age of 9 years who had acne vulgaris affecting the face. The studies compared Winlevi with a placebo

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

(dummy) cream when applied twice daily on affected skin for 12 weeks. The studies looked at the proportion of people taking either cream who had clear or almost clear skin and a significant improvement in symptom scores.

What were the main reasons for refusing the marketing authorisation?

The Agency noted that Winlevi is a new class of medicine that blocks receptors for androgens. However, there is a risk of the medicine suppressing the working of three organs: the hypothalamus and pituitary glands in the brain and adrenal glands. The suppression of these organs could lead to impaired growth and sexual maturation, which is a major concern in adolescents. Although the company presented data to show that the risk was low, the Agency considered that these data, as well as measures the company proposed to minimize the risk, were not sufficient to approve the medicine for patients from 12 years to less than 18 years of age.

Due to concerns about the risk in adolescents, the Agency concluded that the benefits of Winlevi did not outweigh its risks and it recommended refusing marketing authorisation for what the company applied for, namely the treatment of acne vulgaris in patients 12 years of age and older.

Does this refusal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no consequences for patients in clinical trials with Winlevi. There are currently no ongoing clinical trials or compassionate use programs involving Winlevi in the European Union.