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Approval of the marketing authorisation for Winlevi (clascoterone)

Re-examination leads to recommendation to approve

After re-examining its initial opinion, the European Medicines Agency has recommended approving the marketing authorisation for the medicine Winlevi for treating acne vulgaris.

The Agency had initially refused the application on 25 April 2025. After re-examination on 25 August 2025, the Agency recommended that marketing authorisation could be granted but with a restricted indication in adolescents.

The company that applied for authorisation was Cassiopea S.p.A.

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

Winlevi is a cream for treating acne vulgaris in adults and acne vulgaris on the face in adolescents 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.

How does Winlevi work?

The active substance in Winlevi, clascoterone, blocks receptors (proteins) for androgens (male sex hormones like testosterone) which cause glands in the skin to produce oils. These oils cause the pores in the skin to become blocked with excess oil and skin cells, resulting in acne.

By blocking these receptors, clascoterone is expected to reduce activity of the glands. However, the exact way the medicine works 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 1,440 adults and children from the age of 9 years who had acne affecting the face. The studies compared Winlevi with a placebo (dummy) cream when applied twice daily on affected skin for 12 weeks. The studies looked at the proportion of people using either cream who had clear or almost clear skin and a meaningful improvement in symptom scores.

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What were the main reasons for initially refusing the marketing authorisation?

The Agency noted that Winlevi is a new class of medicine that blocks receptors for androgens locally in the skin. However, there is a risk of the medicine being absorbed in the blood and suppressing the working of three organs: the hypothalamus and pituitary glands in the brain and the adrenal glands. The suppression of these organs (called HPA axis suppression) 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 proposed by the company to minimise 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 had applied for, namely the treatment of acne vulgaris in patients 12 years of age and older.

What happened during the re-examination?

During the re-examination, the company proposed additional measures to minimise the risk of HPA axis suppression in adolescents. The Agency's human medicines committee (CHMP) considered the proposed measures and also considered advice from a panel of experts.

What were the conclusions of the re-examination?

The CHMP noted that suppression of the HPA axis is an important potential risk and agreed with a number of measures to minimise it, particularly in adolescents. These include limiting the dose, monitoring treatment and providing educational material to healthcare professionals. In addition, Winlevi should only be used in adolescents for acne vulgaris on the face and the medicine should only be prescribed by doctors experienced in diagnosing and treating acne vulgaris.

The Agency concluded that with these measures the benefits of Winlevi outweigh its risks and recommended granting a marketing authorisation.