

EMA/317209/2025  
EMA/H/C/006138

## Winlevi (*clascoterone*)

An overview of Winlevi and why it is authorised in the EU

### What is Winlevi and what is it used for?

Winlevi is a medicine 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 is Winlevi used?

Winlevi is available as a cream to be applied to the area affected by acne twice a day, in the morning and the evening, with at least eight hours between applications.

The medicine can only be obtained with a prescription. Treatment should be started and supervised by a doctor experienced in the diagnosis and treatment of acne.

For more information about using Winlevi, see the package leaflet or contact your doctor or pharmacist.

### How does Winlevi work?

The active substance in Winlevi, clascoterone, blocks receptors (targets) 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 the activity of the glands. However, the exact way the medicine works on acne is not well understood.

### What benefits of Winlevi have been shown in studies?

Winlevi was investigated in two main studies involving 1,440 patients who had acne affecting the face. The studies compared Winlevi with a placebo (dummy) cream when applied twice daily on affected skin.

Overall, 19.5% of people using Winlevi had clear or almost clear skin after 12 weeks of treatment, compared with 7.7% of people using the dummy cream. In addition, the number of inflammatory and

non-inflammatory lesions both reduced by around 19 in people using Winlevi, while the reductions in people using the dummy cream were 14 and 12, respectively.

## **What are the risks associated with Winlevi?**

For the full list of side effects and restrictions with Winlevi, see the package leaflet.

The most common side effects with Winlevi (which may affect up to 1 in 10 people) include local skin reactions such as erythema (reddening of the skin), scaling/dryness, itching and stinging/burning. These reactions usually resolve on their own during use of Winlevi.

Winlevi must not be used during pregnancy.

## **Why is Winlevi authorised in the EU?**

Acne is a chronic (long-lasting) inflammatory skin condition affecting up to 85% of teenagers and can significantly impact self-esteem, social interactions and overall quality of life. At the time of Winlevi's authorisation, there was an unmet medical need particularly in males, adolescents or people requiring androgen-targeted therapy but for whom systemic treatment (by mouth or injection) was not suitable. The main studies showed that Winlevi has a modest but statistically significant and clinically relevant effect on acne, which will benefit many patients including those without suitable alternatives.

There is a theoretical risk that the active substance clascoterone could enter the bloodstream and potentially reduce the activity of 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. However, there have been no reports of such effects in studies or clinical practice, and the Agency concluded that the safety of Winlevi was acceptable with appropriate measures. These include restricting the use in adolescents to the treatment of acne on the face, limiting the dose, monitoring treatment and providing educational material to healthcare professionals and patients.

The European Medicines Agency therefore decided that Winlevi's benefits are greater than its risks and that it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Winlevi?**

The company that markets Winlevi will provide doctors expected to prescribe the medicine with educational material containing important information about the potential risk in adolescents and during pregnancy.

Patients using the medicine will be given a card with information about Winlevi's potential to cause harm to an unborn baby, the need to exclude pregnancy before starting treatment and the importance of using contraception during treatment and for at least 10 days after stopping treatment with Winlevi.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Winlevi have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Winlevi are continuously monitored. Suspected side effects reported with Winlevi are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Winlevi**

Winlevi received a marketing authorisation valid throughout the EU on 17 October 2025.

Further information on Winlevi can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/winlevi](https://ema.europa.eu/medicines/human/EPAR/winlevi).

This overview was last updated in 10-2025.