

For UK Healthcare Professionals Only

Prescribing Information: ▼ Winlevi 10 mg/g cream

Consult the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Winlevi (clascoterone) is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. Paediatrics (<12 years): The safety and efficacy of Winlevi have not been established in paediatric patients under 12 years of age.

Administration and dosage: A thin uniform layer (approximately 1 g, corresponding to two fingertip units) of cream should be applied cutaneously to the affected area twice a day, in the morning and the evening. The affected areas should be clean and dry before application. Do not spot treat for optimal efficacy. Hands should be washed before and after applying Winlevi cream. If patients forget to take a dose of Winlevi, they should be instructed to apply the next dose at the usual time. Patients should be instructed to not apply a double dose to make up for forgotten doses. A re-evaluation of patient treatment at 12 weeks should be considered if it is necessary to continue or restart treatment after this period and treatment should be continued after medical review and under regular supervision. Paediatric population: Use in adolescents (12 – 18 years of age): dose adjustment is not required when Winlevi is administered to adolescents aged 12 – 18 years. The safety and efficacy of clascoterone in children below 12 years of age have not yet been established. Renal or hepatic impairment: No studies have been conducted in patients with renal or hepatic impairment. Given the very low systemic levels of clascoterone detected in blood after application of therapeutic or supra-therapeutic doses of Winlevi, no dose adjustment or special considerations are anticipated for patients with renal or hepatic impairment. Elderly: Clinical studies of clascoterone did not include sufficient numbers of subjects aged 65 years of age and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Contraindications: Hypersensitivity to the active substance or to any of the excipients

Warnings and precautions: Winlevi is for external use only. Not for ophthalmic, oral or vaginal use. Winlevi should not be applied to cuts, abrasions, eczematous or sunburned skin. Accidental transfer of cream into eyes, mouth or other mucous membranes should be avoided. If contact with mucous membranes occurs, rinse thoroughly with water. Local Skin Reactions: clascoterone may induce local irritation (oedema, erythema/redness, pruritus, scaling/ dryness, skin atrophy, stinging/burning, striae rubrae, telangiectasia). Concomitant use with other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect and products with high concentrations of alcohol, astringents, spices or lime) should be limited. Hypothalamic-pituitary-adrenal (HPA) Axis Suppression: HPA axis suppression was observed and may occur during or after treatment with clascoterone. All Phase 2 maximum use clinical-trial subjects with HPA-axis suppression returned to normal HPA axis function 4 weeks after stopping treatment. Conditions, which augment systemic absorption, include use over large surface areas, prolonged use and the use of occlusive dressings. If HPA axis suppression develops, consider withdrawing the medicinal product. HPA axis suppression was observed in 1/20 (5%) of adult subjects and in 2/22 (9%) of adolescent subjects. Paediatric patients may be more susceptible to systemic toxicity. Hyperkalaemia: elevated potassium levels were observed in some subjects treated with Winlevi or with the vehicle during the clinical trials. Excipients: contains 25 mg cetyl alcohol in each gram. Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis). Winlevi also contains 250 mg propylene glycol in each gram. Propylene glycol may cause skin irritation.

Side effects: From clinical studies, the most frequently observed side effects included erythema/redness, scaling/dryness. Very common ($\geq 1/10$); erythema/redness, scaling/dryness. Common ($\geq 1/100$ to $< 1/10$); pruritus, stinging/burning, oedema, striae rubrae, skin atrophy, telangiectasia, hyperkalaemia. Rare ($\geq 1/10,000$ to $< 1/1,000$); polycystic ovaries, amenorrhoea. Consult SmPC for further information regarding side effects.

Legal category: Prescription only medicine

Pack size and NHS price: tube of 60 g £19.43

Marketing Authorization Numbers: PL 25258/0425

Marketing Authorization Holder: Glenmark Pharmaceuticals Europe Limited, Laxmi House, 2-B Draycott Avenue, Kenton, Middlesex. HA3 0BU. United Kingdom

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Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/>. Adverse events should also be reported to Glenmark Pharmaceuticals Europe Ltd medical_information@glenmarkpharma.com or call 0800 458 0383

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