

PRESCRIBING INFORMATION

(Please consult the Summary of Product Characteristics (SmPC) before prescribing.)

Vaniqa 11.5% Cream eflornithine

Active Ingredient: eflornithine 115 mg per gram (as hydrochloride monohydrate).

Excipients with known effect:

Each gram of cream contains 47.2 mg of cetostearyl alcohol, 14.2 mg of stearyl alcohol, 0.8 mg of methyl parahydroxybenzoate and 0.32mg of propyl parahydroxybenzoate

Indication: Treatment of facial hirsutism in women.

Dosage and Administration: Should be applied to the affected area twice daily, at least eight hours apart. Application should be limited to the face and under the chin. Maximal applied doses used safely in clinical trials were up to 30 grams per month. Improvement in the condition may be noticed within eight weeks and continued treatment may result in further improvement and is necessary to maintain beneficial effects. Discontinue if no beneficial effects are noticed within four months of commencing therapy. Patients may need to continue to use hair removal methods (e.g. shaving or plucking) in conjunction with Vaniqa. Application of Vaniqa should be no sooner than 5 minutes after use of other hair removal method, as increased stinging or burning may occur. A thin layer of the cream should be applied to clean and dry affected areas. The cream should be rubbed in thoroughly. The medicinal product should be applied such that no visual residual product remains on the treated areas after rub-in. Hands should be washed after applying this medicinal product. For maximal efficacy, the treated area should not be cleansed within four hours of application. Cosmetics (including sunscreens) can be applied over the treated areas, but no sooner than five minutes after application. The condition should improve within eight weeks of starting treatment. *Paediatric populations:* The safety and efficacy of Vaniqa in children 0-18 years has not been established. *Hepatic /renal impairment:* caution should be used when prescribing Vaniqa. *Consult SmPC for further information.*

Contraindications, Warnings, etc:

Contraindications: Hypersensitivity to eflornithine or to any of the excipients.

Warnings & Precautions: Excessive hair growth can result from serious underlying disorders (e.g. polycystic ovary syndrome, androgen secreting neoplasm) or certain active substances (e.g. cyclosporin, glucocorticoids, minoxidil, phenobarbitone, phenytoin, combined oestrogen-androgen hormone replacement therapy). These factors should be considered in the overall medical treatment of patients who might be prescribed Vaniqa. For cutaneous use only. Contact with eyes or mucous membranes (e.g. nose or mouth) should be avoided. Transient stinging may occur if applied to abraded or broken skin. If skin irritation or intolerance develops, the

frequency of application should be reduced temporarily to once a day. If irritation continues, treatment should be discontinued and the physician consulted. Contains cetostearyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) as well as methyl parahydroxybenzoate and propylparahydroxybenzoate which may cause allergic reactions (possibly delayed). *Interactions:* No interaction studies have been performed. *Fertility, Pregnancy and lactation:* Women should not use Vaniqa whilst pregnant or breastfeeding. *Ability to drive and use machines:* Vaniqa has no or negligible effects on the ability to drive and use machines.

Undesirable Effects: *These are ranked under heading of frequency using the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$).* *Very common:* acne. *Common:* pseudofolliculitis barbae, alopecia, stinging skin, burning skin, dry skin, pruritus, erythema, tingling skin, irritated skin, rash, folliculitis. *Uncommon:* bleeding skin, furunculosis. *Rare:* rosacea, skin neoplasm, skin cysts, vesicubullous rash. *Consult SmPC in relation to other adverse effects.*

Legal Category: POM

Marketing Authorisation Number(s): EU/1/01/173/003

NHS Cost: (excluding VAT)
Tube containing 60g - £56.87

Marketing Authorisation Holder:

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Date of Revision: 08/2017

Item code: UKEFL3336(1)

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Almirall Ltd.