

EFLORNITHINE 11.5% Cream (Vaniqa®) for hirsutism

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of EFLORNITHINE 11.5% Cream (Vaniqa®) for hirsutism.

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Key messages:

- Eflornithine 11.5% cream offers very little benefit for the management of hirsutism in women. There is limited evidence for efficacy and patient satisfaction with eflornithine. Furthermore, there are no trials comparing eflornithine with established hirsutism treatments such as co-cyprindiol.^{1,4,5,7}
- Eflornithine 11.5% cream is only licensed for the treatment of facial hirsutism in women over 18 years of age.
- If hirsutism is mild and does not significantly interfere with the woman's quality of life reassure and advise that no additional treatment is required.³
- It is important that a patient is properly assessed and underlying causes addressed before pharmacological therapy is considered as hirsutism can result from serious underlying disorders (e.g. polycystic ovary syndrome, androgen secreting neoplasm) or certain medications (e.g. ciclosporin, glucocorticoids, minoxidil, phenobarbitone, phenytoin, combined oestrogen-androgen hormone replacement therapy).⁶
- Self-funded cosmetic treatments for reduction in hair growth or hair removal (e.g. shaving, plucking, laser treatment, electrolysis) should be the primary options for the majority of women with hirsutism.⁷
- Patients may need to continue to use a hair removal method (e.g. shaving or plucking) in conjunction with eflornithine.⁶
- [NICE Clinical Knowledge Summary](#) provides guidance on the management of hirsutism in premenopausal and postmenopausal women.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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Effectiveness^{1,2,4,5,7,10}

The two main double-blind randomised vehicle (placebo) controlled trials involved 596 women treated for a duration of 24 weeks (plus 8 weeks follow up without any treatment), assessed the efficacy of eflornithine 11.5% cream compared to vehicle. The primary efficacy measure was a four-point Physicians Global Assessment of improvement or worsening of the condition compared to baseline.

In each of these studies statistically significant improvement for eflornithine versus eflornithine vehicle was seen. These improvements resulted in a corresponding reduction in the darkening appearance of the facial skin associated with the presence of terminal hair. Improvement in the condition was seen within 8 weeks of starting eflornithine. The degree of improvement continued throughout the study but declined once treatment had stopped. The difference between the treatment groups was no longer significant 8 weeks after cessation of treatment. A randomised, split face, single-blinded controlled trial of topical eflornithine vs no eflornithine after intense pulsed light (IPL) therapy treatments in 22 women with facial hirsutism showed potential to maintain IPL-induced hair reduction in hirsute patients.

Safety

Very common and common side effects experienced include acne, pseudo folliculitis barbae, alopecia, stinging skin, burning skin, dry skin, pruritus, erythema, tingling skin, irritated skin, rash, folliculitis.⁶

There is a theoretical risk of skin atrophy with long-term use of eflornithine but published controlled trials to date have been too brief to assess this risk.²

Maximal applied doses used safely in clinical trials were up to 30 grams per month.⁶

Refer to SPC⁶ for further information.

Cost

Cost is £56.87 per 60 g tube (approximately £370 per patient per year based on usage of 30 g/28 days).^{8,9}

The annual spend across Pan Mersey in 2015 was about £91,000. This has now reduced; however, spend across Pan Mersey is currently about £25,000 per annum.

The estimated prevalence of hirsutism is 5–15% in women of reproductive age³.

UK licensed products for hirsutism	Cost per 28 days ^{8,9}
Eflornithine 11.5% cream	£28.44 for 30g
Generic co-cyprindiol 2000/35 (cyproterone acetate 2 mg, ethinylestradiol 35 micrograms)	£3.59 for 21 tablets
Dianette®	£2.57 for 21 tablets

Patient factors

Caution should be used when prescribing eflornithine in patients with severe renal impairment.

Women who are pregnant or planning pregnancy should use an alternative means to manage facial hair. Women should not use eflornithine whilst breastfeeding.

Prescribing information

Eflornithine 11.5% cream is not recommended for prescribing due to limited evidence.

References

1. Scottish Medicines Consortium. [Eflornithine 11.5% cream \(Vaniqa®\) Resubmission. The Scottish Medicines Consortium issues advice on eflornithine 11.5% cream \(Vaniqa®\) for the treatment of facial hirsutism in women.](#) Accessed online 08 October 2019.
2. Drug and Therapeutics Bulletin. Does eflornithine help women face hirsutism? British Medical Journal 2007, 45(8): 62-64.
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4. Keele University: Midlands Therapeutics Review and Advisory Committee. [Eflornithine \(Vaniqa®\) for the treatment of facial hirsutism in women.](#) January 2006.
5. Somani N and Turvy J. Hirsutism: An Evidence-Based Treatment Update. Am J Clin Dermatol (2014) 15:247–266.
6. [Summary of Product Characteristics:](#) Vaniqa 11.5% cream. Accessed online 08 October 2019.
7. NHS PrescQIPP. Bulletin 57. [Drop List: Eflornithine review v2.0](#) December 2013 (archived).

8. National Health Service Business Services Authority. Electronic Drug Tariff, October 2019. Accessed 08 October 2019.
9. British National Formulary Accessed on-line 08 October 2019.
10. Vissing A, Taudorf E, Haak C, Philipsen P, Haedersal M: Adjuvant Eflornithine to maintain IPL-induced hair reduction in women with facial hirsutism. JEADV; 2016; 30:314-319.