

EFLORNITHINE (Vaniqa®)

Position statement



Bath and North East Somerset,
Swindon and Wiltshire
Integrated Care Board

Eflornithine cream (Vaniqa®) is considered an intervention of low clinical value and is not routinely commissioned by BSW ICB. It is not considered that eflornithine cream is suitable for use within the BSW health economy due to limitations in existing clinical trial data and after due consideration of population needs versus available funding.

Introduction

Eflornithine 11.5% cream is an irreversible inhibitor of ornithine decarboxylase, an enzyme involved in the production of the hair shaft by the hair follicle. It slows hair growth and reduces the size of the hairs, so they become less coarse and less visible.

Eflornithine 11.5% cream is only licensed for the treatment of facial hirsutism in women over 18 years of age (1).

- Eflornithine 11.5% cream offers very little benefit for the management of facial hirsutism in women. There is limited evidence for clinical efficacy and patient satisfaction with eflornithine. Furthermore, there are no trials comparing eflornithine with established hirsutism treatments such as co-cyprindiol (2,3,4).
- It needs to be used indefinitely but the long-term benefits and safety have not been established past 24 weeks (4).
- The treatment of facial hirsutism from any cause is not routinely funded within BSW ICB.
- NICE Clinical Knowledge Summary provides guidance on the management of hirsutism in premenopausal and postmenopausal women (5).
- 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, phenobarbitone, phenytoin, combined oestrogen androgen hormone replacement therapy) (1).
- **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 most women with hirsutism.**

Summary of evidence base

- The efficacy of eflornithine has been demonstrated in several trials, none of which have been fully published.
- 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.
- Most adverse events associated with eflornithine are skin related and mild in nature, with burning, tingling or stinging skin, erythema or rash more frequently reported in the eflornithine group. The most commonly reported adverse event in both groups was acne (very common) and pseudofolliculitis barbae (common $\geq 1/10$).
- 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. (6) Maximal applied doses used safely in clinical trials were up to 30 grams per month. Refer to SPC for further information.

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Cost

Costs £56.87 per 60g tube (7); the annual cost of Vaniqa® is approximately £370 per patient based on usage of 30g/month.

UK Licensed Products for Hirsutism	Cost per 28 days (June 22)
Eflornithine 11.5% cream	£28.44 for 30g
Generic co-cyprindiol 2000/35 (cyproterone acetate 2mg, ethinylestradiol 35 micrograms)	£3.60 for 21 tablets plus 7-day pill free interval

Recommended Actions

Prescribers should consider:

- Hirsutism may be self-managed with mechanical and cosmetic means at no cost to the NHS.
- Women who are overweight or obese should be encouraged to lose weight.
- Eflornithine does not offer permanent hair removal, it slows hair growth such that users require less frequent hair removal by other methods (e.g., shaving, plucking, waxing, electrolysis, laser treatment). Hair removal will need to continue (regrowth occurs within 8 weeks).
- It is important that the patient is properly assessed, and underlying causes addressed as hirsutism can result from serious medical conditions or from medication.

References

1. Summary of Product Characteristics. Vaniqa® [Vaniqa 11.5% cream - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#) (Accessed 27/6/22)
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3. Somani N, Turvy D. Hirsutism: an evidence-based treatment update. Am J Clin Dermatol. 2014 Jul;15(3):247-66. doi: 10.1007/s40257-014-0078-4. PMID: 24889738. <https://pubmed.ncbi.nlm.nih.gov/24889738/> (Accessed 27/6/22)
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5. NICE CKS. Hirsutism – management. Revised July 2020; (Accessed 27/6/22) <https://cks.nice.org.uk/topics/hirsutism/>
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