EFLORNITHINE (Vaniqa®) cream

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of EFLORNITHINE 11.5% cream for facial hirsutism

Key messages:

- Eflornithine 11.5% cream offers very little benefit for the management of facial 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, consider no additional treatment. Hirsutism is not usually associated with any significant medical abnormality.\(^3\)
- 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.
- 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.
- In individual cases, patients currently receiving therapy with Eflornithine that is not recommended according to this prescribing policy statement should only continue their treatment if benefit has been noticed within 8 weeks. Use should be discontinued if no beneficial effects are noticed within four months of commencing therapy.\(^6\) (reference SPC)

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.
The efficacy of eflornithine has been demonstrated in a number of 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.

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

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

Refer to SPC for further information.

Costs £56.87 per 60 g tube (approximately £370 per patient per year based on usage of 30 g/month).

Current spend across Pan Mersey is about £91,000 per annum.

Hirsutism affects 5 to 15% of women.

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.

Eflornithine may offer advantages over existing therapy for some women as it avoids the risks associated with systemic therapy such as DVT associated with co-cyprindiol.

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

REFERENCES