GUIDELINES FOR PRESCRIBING EFLORNITHINE (VANIQA®) FOR FACIAL HIRSUTISM

Indication

Eflornithine is licensed for treatment of facial hirsutism in women over the age of 18 years.

Initiation

Initiation of treatment may occur in primary or secondary care. Women should have tried all other treatment options (unless contraindicated for their use), before initiation of treatment with eflornithine, as per the Scottish Medicines Consortium (SMC) guidance below.

- Eflornithine cream is accepted for restricted use within NHS Scotland for the treatment of facial hirsutism in women.
- It is restricted to use in women for whom alternative drug therapy is ineffective, contraindicated or considered inappropriate. Eflornithine 11.5% cream, as a topical treatment, may offer advantages over existing therapy for some women as it avoids the risks associated with systemic therapies.

Two-thirds of women will discontinue treatment with eflornithine due to lack of effectiveness or adverse effects.

Dosage and Administration

A thin layer of the cream should be applied to clean and dry affected areas. The cream should be rubbed in thoroughly twice daily, at least 8 hours apart. Efficacy has only been demonstrated for affected areas of the face and under the chin therefore application should be limited to these areas. Maximal applied doses used safely in clinical trials were up to 30 grams per month.

No residual product should remain on the treated areas after rubbing-in. 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.

Improvement in the condition may be noticed within eight weeks of starting treatment. Continued treatment may result in further improvement and is necessary to maintain beneficial effects. The condition may return to pre-treatment levels within eight weeks following discontinuation of treatment.
Patients may need to continue to use a hair removal method (e.g. shaving or plucking) in conjunction with eflornithine. In that case, the cream should be applied no sooner than five minutes after shaving or use of other hair removal methods, as increased stinging or burning may otherwise occur.

**Assessment of benefit**

Beneficial effects should be apparent after 2-4 months consistent use of eflornithine. If no benefits are apparent within 4 months of commencing therapy, eflornithine should be discontinued. Ongoing need for therapy should be reviewed at least annually.

**Patient counselling**

Advise the patient/carer that appropriate sun protection measures should be taken, such as minimisation of the time in the sun, use of sunscreen product and covering the skin with appropriate sunscreen.

**Contraindications**

Eflornithine cream is contraindicated where there is known hypersensitivity to eflornithine or to any of the excipients (refer to summary of product characteristics for a full list of excipients).

The potential risk of eflornithine use during pregnancy is unknown. Therefore, women who are pregnant or planning pregnancy should use an alternative means to manage facial hair. It is not known if eflornithine is excreted in human milk therefore women should not use eflornithine whilst breastfeeding.

Eflornithine is known to be eliminated primarily in the urine. As the safety of eflornithine has not been studied in patients with severe renal impairment, caution should be used when prescribing eflornithine for these patients.

**Special Warnings**

Excessive hair growth 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). These factors should be considered in the overall medical treatment of patients who might be prescribed eflornithine.

Eflornithine is for cutaneous use only. Contact with eyes or mucous membranes (e.g. nose or mouth) should be avoided. Transient stinging or burning may occur when the cream is applied to abraded or broken skin.

This medicinal product contains cetostearyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) as well as methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).
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.

**Side Effects**

The mostly skin related adverse reactions reported were primarily mild in intensity and resolved without discontinuation of eflornithine or initiation of medical treatment. The most frequently reported undesirable effect was acne, which was generally mild. Other reactions seen commonly in clinical trials were: Pseudofolliculitis barbae, alopecia, stinging skin, burning skin, dry skin, pruritus, erythema, tingling skin, irritated skin, rash, folliculitis.

The manufacturer’s summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contraindications, warnings, side-effects and drug interactions.

**References**

Vaniqa® (Almirall Ltd) Summary of Product Characteristics (last updated 01/05/2013).

**References**

Current price of Vaniqa® 60g tube (2 months treatment at maximum application): £56.87 (Drug Tariff, March 2014)

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<th>Dermatology Working Group</th>
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