GUIDELINE FOR PRESCRIBING EFLORNITHINE (VANIQA®) FOR FACIAL HIRSUTISM

INDICATION

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

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.

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.

REFERRAL AND INITIATION

Eflornithine is categorised as a "green" on the Dorset Formulary meaning 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.

SUPPORTING INFORMATION

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.

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.

Cautions

Hepatic / renal impairment: the safety and efficacy of Vaniqa in women with hepatic or renal impairment have not been established. As the safety of Vaniqa has not been studied in patients with severe renal impairment, caution should be used when prescribing Vaniqa for these patients. No data are available.

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.

Interactions

No interaction studies have been performed.

This list is not exhaustive. 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 contra-indications, warnings, side-effects and drug interactions.

Drug Cost

Current price of Vaniqa® 11.5% Cream 60g tube £56.87 (2 months' treatment at maximum application)

Medical comparator: Co-cyprindiol 2000microgram/35microgram tablets (combined cyproterone acetate and ethinylestradiol) (generic of Dianette®) £5.70 x 63 tablets

References

Dictionary of Medicines and Devices accessed via http://dmd.medicines.org.uk/DesktopDefault.aspx?AMPP=14946011000001108&toc=nofloat Pricing correct as of 12th February 2018

Vaniqa®11.5% Cream (Almirall Ltd) Summary of Product Characteristics last updated 10/08/2017, assessed via https://www.medicines.org.uk/emc/product/6398 on 12th February 2018

Scottish Medicines Consortium: Eflornithine 11.5% cream (Vaniqa®) submission 12th September 2005 accessed 12th February 2018 via:
https://www.scottishmedicines.org.uk/SMC_Advice/Advice/Eflornithine_11.5__cream__Vaniqa__174___for_the_treatment_of_facial_hirsutism_in_women/Eflornithine_11.5__cream__Vaniqa___

For current Formulary Status: accessed 12th February 2018
http://www.dorsetformulary.nhs.uk/chaptersSubDetails.asp?FormularySectionID=13&SubSectionRef=13.09&SubSectionID=B100&drugmatch=1270#1270

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Written By	The Dermatology Working Group	March 2014
Approved By	Dorset Medicines Advisory Group	May 2014
Reviewed By	The Dermatology Working Group	February 2018
Review Date	Dorset Medicines Advisory Group	September 2018
Date of next review	Sept 2020 or before, in light of new evidence or information.	