Guidelines for the use of eflornithine cream in the treatment of facial hirsutism in women

Background
Hirsutism may be clinically diagnosed when there is an average hair density of at least 5 coarse hairs/cm² on both the chin and upper lip, and the woman needs to remove facial hair at least twice weekly. It affects 5-15% of women and there are several causes:
- Polycystic ovary syndrome (50-60% of cases)
- It can be drug induced (e.g. ciclosporin, steroids, danazol, sodium valproate and phenytoin)
- Very rarely, an androgen – secreting tumour (suspect if rapid onset and severe hirsutism)
- No underlying cause (up to 40% of women)

There are two licensed pharmaceutical preparations for the treatment of female facial hirsutism:
Co-cyprindiol tablets (Proprietary: Dianette® and generic) and Eflornithine cream (Proprietary: Vaniqa®).

Recommended course of action
Address the underlying cause when this has been identified:

Polycystic ovary syndrome (PCOS) As well as hirsutism, the patient may be suffering from acne, menstrual disorders, glucose intolerance, and have cardiovascular risk factors. The priority is to treat this condition adequately with lifestyle advice and hormonal treatment, if tolerated.

Drug – induced If the condition is distressing the patient, consider an alternative treatment

Sudden, severe onset The patient should be referred for further investigation, particularly if there are other symptoms such as alopecia or clitoromegaly, as an androgen-secreting tumour (adrenal or ovarian) may be responsible.

Options for patients with a clinical diagnosis and who have requested treatment

Co-cyprindiol is a combination of cyproterone acetate (2mg) and ethinylestradiol (35 micrograms). Cyproterone acetate reduces hair growth through androgen suppression, but can cause feminisation of a male fetus if the woman becomes pregnant. It is for this reason, ethinylestradiol is added.

Co-cyprindiol acts in a similar way to the combined oral contraceptive pill preparations, but due to its higher risk of venous thromboembolism, the Committee for Safety of Medicines (CSM) advise against its use solely as a contraceptive.

Eflornithine cream has been shown to be more effective than placebo, but there have been no comparative studies on eflornithine versus co-cyprindiol. It slows down hair growth, but does not provide permanent hair removal. It needs to be applied twice a day and therefore requires commitment. Since growth is slowed rather than prevented, treatment is not recommended unless hair removal is required more than twice weekly.

Electrolysis and laser treatments tend to last longer than other methods, but are expensive and not available on the NHS.

Costs
The monthly costs of each preparation is:
Co-cyprindiol tablets x 21 (generic) £1.87
Co-cyprindiol tablets x 21 (Dianette®) £3.11
Eflornithine 11.5% cream (30g) £26.04

Treatment should only be initiated in those women where traditional cosmetic means are not controlling hair growth and it is having a moderate to severe impact on daily life.

First line treatment:
Generic co-cyprindiol tablets.

Where co-cyprindiol is contra-indicated (see prescribing exceptions below):
Eflornithine cream, apply thinly twice daily.
It must not be used in patients where co-cyprindiol has failed as there is no evidence to support superior efficacy. Patients should be advised that regular, twice daily application is essential, that treatment is only successful in a proportion of patients and hair re-growth returns to pre-treatment levels when therapy is discontinued.

If treatment has been initiated in secondary care: Assess patient after 3-4 months following initiation of therapy. If there is demonstrable improvement, eflornithine can be continued by primary care provided there is no other reason why the patient cannot be discharged from the consultant clinic. Secondary care to prescribe initial prescription and assess patient.

If treatment is initiated in primary care: Assess patient after 3-4 months following initiation of therapy. Eflornithine should only be continued if there is demonstrable improvement.

Prescribing exceptions:
Eflornithine is only to be used as first line treatment if the patient has:

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<thead>
<tr>
<th>Any one of the following:</th>
<th>Or any two of the following:</th>
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<tbody>
<tr>
<td>past history of venous thromboembolism</td>
<td>body mass index &gt; 30Kg/m²</td>
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<tr>
<td>known thrombophilia</td>
<td>family history of venous thromboembolism</td>
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<tr>
<td>hypertension</td>
<td>varicose veins</td>
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<td>smoking (&gt;40/day)</td>
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<td>migraine</td>
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<td>severe diabetes mellitus</td>
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<td>breast / genital tract carcinoma</td>
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Summary
Eflornithine should be reserved for a small group of patients who satisfy the following criteria:
- PCOS is already being treated appropriately
- The patient has considered all other physical methods of hair removal, such as shaving, waxing, electrolysis and laser therapy
- The patient finds their condition distressing and co-cyprindiol is contra-indicated.
- The patient is able to comply with therapy and has shown a demonstrable response to eflornithine when reviewed after 3-4 months

References:
1 British National Formulary March 2007
3 DTB Volume 45 No 8 August 2007

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