Royal Free London NHS
NHS Foundation Trust

Shared Care Guideline for Eflornithine 11.5% cream for Polycystic Ovary Syndrome (PCOS) Related Hirsuitism

SHARED CARE CRITERIA

Patients will have been stabilised on eflornithine cream with time allowed for common adverse events and side effects to have occurred before shared care is established. It is proposed that a **minimum period of 4 month stabilisation** is necessary prior to sharing care.

Eflornithine cream will only be initiated in those patients with polycystic ovary syndrome and symptomatic hirsuitism.

RESPONSIBILITIES

Consultant

1. Send a letter to the GP suggesting that shared care is agreed for this patient
2. Initiate treatment in appropriate patients and prescribe until the GP agrees to shared care
3. To assess the patient at 4 months for response
4. To advise the GP regarding continuation of treatment, including the length of treatment
5. Evaluation of any reported adverse effects by GP
6. Ensure that backup advice is available at all times.

General Practitioner

1. To refer appropriate patients to secondary care for assessment
2. To continue to prescribe for patients as advised by the consultant after the 4 month review
3. Monitor patient's overall health and well being
4. Report any adverse events reported by the patient to consultant and Medicines and Healthcare Products Regulatory Agency (MHRA) where appropriate via http://yellowcard.mhra.gov.uk
5. To inform the consultant if the patient discontinues treatment for any reason
6. To seek the advice of the consultant if any concerns with the patient's therapy
7. To return a copy of the standard letter to the Consultant accepting or declining shared care.

If the GP does not agree to shared care, he/she will notify the consultant in writing without undue delay.

Clinical Commissioning Group

1. To support GPs to make the decision whether or not to accept clinical responsibility for prescribing
2. To support trusts in resolving issues that may arise as a result of shared care.

Patient / Carer

1. Share any concerns in relation to their treatment.
2. Ensure they attend for routine monitoring requirements
3. Report any adverse effects to the specialist or GP regarding their treatment.

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FORM

Eflornithine 11.5% cream.

LICENSED INDICATIONS (relevant to this Shared Care Guideline)

Eflornithine 11.5% cream is indicated for the treatment of facial hirsuitism in women. Efficacy has only been demonstrated for affected areas of the face and under the chin.

DOSE AND ADMINISTRATION

A thin layer of cream is applied to clean and dry affected areas twice daily, at least 8 hours apart. The cream should be rubbed in thoroughly and the treated area should not be cleansed within 4 hours of application.

Maximum applied doses in the clinical trials were 30g per month.

MONITORING

Improvement in hirsuitism may be noticed within 8 weeks of starting therapy. Use should be discontinued if no beneficial effects are seen within 4 months of starting therapy.

Continued treatment is necessary to maintain beneficial effects. The condition may return to pre-treatment levels within 8 weeks following discontinuation.

No specific monitoring for toxicity is required. Although long term studies (>12 months) have not been carried out, use is continued in practice beyond 12 months. Duration of treatment will be advised by initiating consultant.

ADVERSE EFFECTS

The common side effects are skin related and include burning, stinging, tingling, rash, erythema and acne.

In clinical trials, acne was reported in both the eflornithine and placebo groups and this may be because hirsuitism and acne commonly coexist.

If skin intolerance or irritation develops and is mild, application should be reduced temporarily to once daily. If irritation continues, treatment should be discontinued.

CAUTIONS

- 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.
- 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.

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CONTRAINDICATIONS

Hypersensitivity to eflornithine or any of the excipients.

CONTACT NUMBERS

Royal Free Hospital		0207 794 0500
Dermatology Consultants:	Dr M Rustin	Ext. 33561
Endocrine Consultants:	Dr Vanderpump	Ext. 38727
	Prof Bouloux	Ext 33175
Dermatology Nurse Specialist	Annie Waite	Bleep 2064
Specialist Pharmacist:	Nisha Patel	Bleep 2958
Pharmacy Drug Information (Mon-Fri - 10.00-5.00)		0207 830 2983

Shared care guideline prepared by Royal Free London NHS Foundation Trust March 2009. Agreed with NHS Camden May 2009.

Reviewed & Updated by RFL February 2014.

Update agreed with lead commissioning CCG: Camden Clinical Commissioning Group: 26 February 2014
Ratified by North Central London Medicines Optimisation Network: 02 December 2014

Date of next review: February 2017