SHARED CARE GUIDELINES FOR PRESCRIBING PIMECROLIMUS (ELIDEL®) FOR TREATMENT OF MODERATE ATOPIC ECZEMA ON THE FACE & NECK IN CHILDREN

INDICATION

Pimecrolimus is recommended for the treatment of patients aged 2 years and over with mild or moderate atopic dermatitis where treatment with topical corticosteroids is either inadvisable or not possible. This may include:

- Intolerance to topical corticosteroids
- Lack of effect of topical corticosteroids
- Use on the face and neck where prolonged intermittent treatment with topical corticosteroids may be inappropriate

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AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of pimecrolimus can be shared between the specialist and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

REFERRAL AND INITIATION

Shared Care is only appropriate if it provides the optimum solution for the patient.

Patients will only be referred to the GP once the GP has agreed in each individual case.

Guidance regarding the use of pimecrolimus has been included in the NICE technology appraisal 'Tacrolimus and pimecrolimus for atopic eczema' (**TA82**). The specific guidance regarding pimecrolimus is:

Pimecrolimus is recommended, within its licensed indications, as an option for the second-line treatment of moderate atopic eczema on the face and neck in children aged 2 to 16 years that has not been controlled by topical corticosteroids, where there is a serous risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy.

Atopic eczema that has not been controlled by topical corticosteroid refers to disease that has not shown a satisfactory clinical response to adequate use of the maximum strength and potency that is appropriate for the patient's age and the area being treated.

N.B. TA 82 does not recommend the use of pimecrolimus in adults, due to its weaker evidence base compared to tacrolimus, and only to the face and neck in children aged 2-16 years.

The NICE Clinical Guideline 'Atopic eczema in children', (CG57), also states:

Topical tacrolimus and pimecrolimus are not recommended for the treatment of mild atopic eczema or as first-line treatments for atopic eczema of any severity. It is recommended that treatment with tacrolimus or pimecrolimus be initiated only by physicians (including general practitioners) with a special interest and experience in dermatology, and only after careful

discussion with the patient about the potential risks and benefits of all appropriate second line treatment options.

Healthcare professionals should explain to children with atopic eczema and their parents or carers that they should only apply topical calcineurin inhibitors to areas of active atopic eczema, which may include areas of broken skin.

Specialist Responsibilities	
1	To assess the patient and establish the diagnosis, determine a management strategy and ensure appropriate follow-up in conjunction with the GP.
2	Where appropriate: o to initiate treatment; o assess initial response to treatment and discontinue after 6 weeks if there is no benefit from pimecrolimus; o obtain consent from the patient's GP to continue prescribing once treatment has been stabilised (usually after 6-8 weeks); o monitor the patient and their therapy at six monthly intervals.
3	Ensure that the child/adolescent or carer understands the management of the condition. In the long-term management of atopic eczema, treatment should begin at first appearance of signs and symptoms of atopic dermatitis to prevent flares of the disease and should be stopped when those signs and symptoms have resolved.
4	To provide the GP with appropriate prescribing information and any additional information requested.
5	To be available for advice if the patient's condition changes.
6	To ensure that procedures are in place for the rapid re-referral of the patient by the GP.
7	To ensure the patient has given informed consent to their treatment.
8	To liaise with the GP on any suggested changes in prescribed therapy.

General Practitioner Responsibilities	
1	Initially, to refer the patient for specialist advice.
2	Where appropriate, to continue to prescribe pimecrolimus as part of a shared care arrangement (usually after 6-8 weeks).
4	To deal with general health issues of the patient.
5	To advise the patient/carer of appropriate sun protection measures, such as minimisation of the time in the sun, use of sunscreen product and covering the skin with appropriate clothing.
6	To monitor concordance with therapy

Responsibility of community pharmacies	
1	To provide support and advice to the patient and/or family regarding concordance, adverse effects and over the counter therapies.
2	To advise the patient/carer about appropriate sunscreen products.
3	To monitor concordance with therapy and refer the patient to their GP if any concern arises.

Patient's role (or that of carer)	
1	Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2	Attend appropriate GP and other follow up appointments
3	Share any concerns in relation to treatment with pimecrolimus
4	Use written and other information on the medication.
5	Seek help urgently if side effects are suspected, or if otherwise unwell.

SUPPORTING INFORMATION

Dosage and Administration

Children and adolescents (2-16 years)

A thin layer of cream should be applied to the affected skin twice daily and rubbed in gently. The cream should be used until clearance of the skin occurs, and treatment of the skin with pimecrolimus should then be discontinued.

Pimecrolimus cream may be used on all areas of skin on the head, face and neck (including intertriginous areas), **except** on mucous membranes.

Emollients can be applied immediately after using pimecrolimus cream.

If there is no response to the pimecrolimus after 6 weeks, or there is a worsening of the eczema during treatment, the pimecrolimus should be discontinued.

The use of pimecrolimus cream in adults, or in children on skin other than the face and neck, is not covered by this guideline.

Contraindications

Pimecrolimus cream is contraindicated:

- in patients with a known hypersensitivity to the drug, other macrolactams or any of the excipients
- in pregnancy

Special Warnings

Pimecrolimus cream should not be used in:

- congenital or acquired immunodeficiencies
- patients on therapies that cause immunosuppression.
- potentially malignant or pre-malignant skin lesions.
- acute cutaneous viral infections (herpes simplex, chicken pox).
- clinical infections at treatment sites
- patients with Netherton's syndrome
- patients requiring occlusive dressings.

Patients with severe atopic dermatitis may have an increased risk of skin bacterial infections (e.g. impetigo) during treatment with pimecrolimus cream.

Use of pimecrolimus cream may cause mild and transient reactions at the site of application, such as a feeling of warmth and/or burning sensation. If the application site reaction is severe, the risk-benefit of treatment should be re-evaluated.

Topical pimecrolimus should **not** be used under occlusion (bandages and dressings) for treating atopic eczema in children without specialist dermatological advice.

Care should be taken to avoid contact with eyes and mucous membranes. If accidentally applied to these areas, the cream should be thoroughly wiped off and/or rinsed off with water.

Physicians should advise patients on appropriate sun protection measures, such as minimisation of the time in the sun, use of sunscreen product and covering the skin with appropriate clothing.

Pimecrolimus cream contains cetyl alcohol and stearyl alcohol which may cause local skin reactions. It also contains propylene glycol, which may cause skin irritation.

Cases of malignancies, including cutaneous and other types of lymphoma, and skin cancers have been reported in patients using pimecrolimus cream. However, patients with atopic dermatitis treated with pimecrolimus cream have not been found to have significant systemic pimecrolimus levels.

Lymphadenopathy present at initiation should be investigated and kept under review. Patients who receive tacrolimus ointment and who develop lymphadenopathy should be monitored to ensure that it resolves. In case of persistent lymphadenopathy, aetiology needs to be investigated. In the absence of a clear aetiology or in the presence of acute infectious mononucleosis, discontinuation of Tacrolimus ointment should be considered.

If no improvement occurs after 6 weeks, or in case of disease exacerbation, pimecrolimus cream should be stopped. The diagnosis of atopic dermatitis should be re-evaluated and further therapeutic options considered.

Side Effects

The most common adverse effects are: burning sensation, pruritus, erythema, skin infections (including folliculitis and less commonly impetigo, herpes simplex and zoster, molluscum contagiosum); rarely papilloma, skin discoloration, local reactions including pain, paraesthesia, peeling, dryness, oedema, and worsening of eczema. Post marketing cases of malignancy, including cutaneous and other types of lymphoma and skin cancers have been reported in patients using pimecrolimus cream.

The summary of product characteristics should be consulted for full information with respect to adverse effects and drug interactions.

Drug Interactions

Pimecrolimus is exclusively metabolised by CYP 450 3A4. Based on its minimal extent of absorption, interactions of pimecrolimus cream with systemically administered medicinal products are unlikely to occur.

The present data indicate that pimecrolimus cream can be used simultaneously with antibiotics, antihistamines and corticosteroids (oral/nasal/inhaled).

Based on the minimal extent of absorption, a potential systemic interaction with vaccination is unlikely to occur. However, this interaction has not been studied. Therefore, in patients with extensive disease, it is recommended to administer vaccinations during treatment-free intervals.

There is no experience with concomitant use of immunosuppressive therapies given for atopic eczema such as UVB, UVA, PUVA, azathioprine and cyclosporin. Pimecrolimus cream has no photocarcinogenic potential in animals. However, since the relevance to man is unknown excessive exposure of the skin to ultraviolet light including light from a solarium, or therapy with PUVA, UVA or UVB should be avoided during treatment with pimecrolimus cream.

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.

References

1. Elidel® (Meda Pharmaceuticals) Summary of Product Characteristics (January 2012).
2. BNF 64 (September 2012)

Current prices of Elidel ® (pimecrolimus cream):

- 30g - £19.69
- 60g - £37.41
- 100g - £59.07

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