***Amber with Guidance**= To be initiated and titrated to a stable dose by a specialist prescriber with follow up prescribing and monitoring by primary care where deemed appropriate.*

Pimecrolimus (Elidel®) cream

It is recommended that treatment with 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[2].

Background Information	Pimecrolimus cream is a topical immunomodulator and belongs to the class of immunosuppressant drugs known as calcineurin inhibitors. They work by reducing inflammation through the suppression of T-lymphocyte responses (different mechanism of action from topical corticosteroids)[1].
BNF therapeutic class	13.05.03
Indication	**NICE Recommendations** Pimecrolimus (Elidel®) is available as 1% cream and 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 2-16 years that has not been controlled by topical corticosteroids and where there is a serious risk of important adverse effects from further topical corticosteroid use, particularly irreversible skin atrophy[2,3]. **Licensed Indications** The licensed indication for pimecrolimus (Elidel®) 1% cream differs from the NICE recommendations. It is licensed for the treatment of Adults and children aged 2 years and over with mild or moderate atopic dermatitis for short-term treatment of signs and symptoms and intermittent long-term treatment to prevent flare-ups where treatment with topical corticosteroids is either inadvisable or not possible.[3] *(Please note: secondary care may advise the application of Pimecrolimus cream on mucous membranes (oral/genital e.g. for erosive oral lichen planus) in exceptional circumstances. This indication is NOT licensed and hence NOT covered by this guidance. For this indication pimecrolimus cream would be classified as a red drug.)*
Administration	**Pimecrolimus (Elidel®) cream.** Pimecrolimus cream should be applied as a thin layer to the affected skin and rubbed in gently and completely. Pimecrolimus cream may be used on all skin areas, including the head and face, neck and intertriginous areas (except on mucous membranes). Each affected region of the skin should be treated until clearance occurs and then treatment should be discontinued[3].

	In the long-term management of atopic dermatitis, pimecrolimus treatment should begin at the first appearance of signs and symptoms of atopic dermatitis to prevent flares of the disease. Pimecrolimus should be used for as short period as possible during flares of disease. The patient or caregiver should stop using Pimecrolimus when signs and symptoms resolve. Treatment should be intermittent, short-term and not continuous[3].
Dosage	**Pimecrolimus (Elidel®) cream** **Adults:** Apply a thin layer of pimecrolimus cream to the affected skin twice daily and rub in gently and completely. Each affected region of the skin should be treated with pimecrolimus cream until clearance occurs and then treatment should be discontinued. Apply twice daily until symptoms resolve (stop treatment if eczema worsens or no response after 6 weeks)[3]. **Children and adolescents 2-17years:** Apply a thin layer of pimecrolimus cream to the affected skin twice daily and rub in gently and completely. Each affected region of the skin should be treated with pimecrolimus cream until clearance occurs and then treatment should be discontinued. Apply twice daily until symptoms resolve (stop treatment if eczema worsens or no response after 6 weeks)[3]. *(Please note: secondary care may advise the application of Pimecrolimus cream on 'clear skin' to maintain control of eczema. This indication is NOT covered by the guidance and for this indication Pimecrolimus cream would be classified as a red drug.)*
Cautions	**Pimecrolimus (Elidel®) cream** Pimecrolimus cream should not be used in patients with congenital or acquired immunodeficiencies or in patients on therapy that causes immunosuppression[3]. Avoid application to malignant or potentially malignant skin lesions and areas affected by acute cutaneous viral infections (herpes simplex, chicken pox)[1,3]. Also use with caution in eczema patients prone to herpes simplex virus infection – as application may precipitate eczema herpeticum. Exposure of the skin to sunlight should be minimised and the use of UV light from solarium therapy with UVB or UVA should be avoided during the use of pimecrolimus cream. Physicians should advise patients on appropriate sun protection methods, such as minimisation of the time in the sun, use of a sunscreen product and covering of the skin with appropriate clothing (high SPF cream over 30)[1,3.] Pimecrolimus cream contains alcohol and patients should be advised of this prior to treatment being commenced.[3] Pimecrolimus cream does not contain animal products.[3]
Contraindications	**Pimecrolimus (Elidel®) cream** Hypersensitivity to pimecrolimus, other macrolactams or to any of the excipients[1,3].

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Adverse Drug Reactions & Interactions	**Pimecrolimus (Elidel®) cream** **Adverse drug Reactions –** application-site reactions -site burning, stinging (very common), irritation, pruritus and erythema; application site infections -folliculitis. **Interactions -** Pimecrolimus interacts with alcohol- alcohol increases the risk of facial flushing and skin irritation when given with topical pimecrolimus (rare)[1,3].
Monitoring	Initiation by specialist dermatology service under which patient should be given a patient specific treatment plan. Review: Primary care should review the patient 6 weeks after treatment commenced to ensure treatment is effective and then every 12 months. This review should include a discussion around: • Use of all treatments (including concomitant emollients) and when to discontinue treatment. • Liaising with dermatology regarding side effects, increase in skin infections or changes in patients' condition which may have an impact on treatment.

Contact names and details

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References

1. *BNF- https://bnf.nice.org.uk/drug/pimecrolimus.htm*
2. *NICE- https://www.nice.org.uk/guidance/ta82*
3. *Summary of Product Characteristics (SmPC)Pimecrolimus1% cream- https://www.medicines.org.uk/emc/product/4966/smpc*

Development Process

This guidance has been produced following an AMBER-G classification status of Pimecrolimus by the Barnsley Area Prescribing Committee. This guideline has been subject to consultation and endorsement by the Area Prescribing Committee on 14th August 2019.