

National Institute for Clinical Excellence

Tacrolimus and pimecrolimus for atopic eczema

Understanding NICE guidance – information for people with atopic eczema, their families and carers, and the public

August 2004



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To order copies

Copies of this booklet can be ordered from the NHS Response Line (telephone 0870 1555 455 and quote reference number N0687). A version in Welsh and English is also available, reference number N0688. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0688. The NICE technology appraisal on which this information is based, 'Tacrolimus and pimecrolimus for atopic eczema', is available from the NICE website (www.nice.org.uk/TA082guidance). A short version of the guidance (a 'quick reference guide') is available from the website (www.nice.org.uk/TA082quickrefguide), or from the NHS Response Line, reference number N0686.

National Institute for Clinical Excellence

MidCity Place 71 High Holborn London WC1V 6NA

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What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the available evidence on the use of tacrolimus and pimecrolimus for treating atopic eczema. NICE was asked to provide guidance that will help the NHS in England and Wales decide when tacrolimus and pimecrolimus should be used.

What is atopic eczema?

People with atopic eczema (also known as atopic dermatitis) have areas of red, inflamed, itchy skin that is often covered with fluid-filled blisters. Damage to the skin from scratching can cause bleeding, infection and thickening of the skin (also called lichenification).

Atopic eczema is the most common type of eczema. Atopic eczema usually begins in early childhood, and may continue to flare up from time to time throughout life.

Unlike other types of eczema (such as irritant eczema), the causes of atopic eczema are not fully understood. People who inherit a tendency to allergies are most likely to get atopic eczema. Environmental factors such as house dust mites, pollen, tobacco, air pollution and low humidity may cause atopic eczema to start or to flare up. Atopic eczema can be mild, moderate or severe.

What are tacrolimus and pimecrolimus?

Tacrolimus and pimecrolimus are non-steroid products that can be used to treat atopic eczema. They work mainly by reducing inflammation (pain, heat, redness and swelling) by 'switching off' the activities of certain immune system cells that can cause the skin to become red and broken. They are applied directly to the affected areas of the skin (tacrolimus as an ointment and pimecrolimus as a cream) and are usually used alongside creams that help keep the skin moisturised (called emollients).

Flare-ups of atopic eczema are often treated with a type of steroid, called topical corticosteroids (topical means it is applied directly to the skin). Different topical corticosteroids vary in potency (how much they reduce inflammation). They are described as mild, moderately potent, potent or very potent. Different preparations of a steroid may also vary in strength (how much of the steroid they contain).

A possible long-term side effect of topical corticosteroids is that the skin becomes thin and easily bruised (this is called skin atrophy). This is most likely to happen in areas where the skin is already thin, such as the face or inside the bends of the joints, and can be a particular problem in children. The skin may recover gradually when

treatment is stopped, but it may never recover completely. Permanent skin damage is more likely if potent or very potent steroids are used excessively, or for long periods. Tacrolimus and pimecrolimus can be used on all parts of the body and do not cause skin atrophy, although they may have other long-term side effects that are not yet known.

What has NICE recommended on using tacrolimus and pimecrolimus for atopic eczema?

During the appraisal, NICE's Appraisal Committee read and heard evidence from:

- high-quality studies of tacrolimus and pimecrolimus
- doctors with specialist knowledge of atopic eczema and its treatment
- individuals with specialist knowledge of the issues affecting people with atopic eczema
- organisations representing the views of people who will be affected by the guidance (because they have, or care for someone with, the condition or because they work in the NHS and are involved in providing care for people with the condition)

the manufacturers of tacrolimus and pimecrolimus.

The evidence is summarised in the full guidance (see page 10 for details). More information about the studies is provided in the Assessment Report for this appraisal (see page 10 for details).

NICE has made the following recommendations about the use of tacrolimus and pimecrolimus to treat atopic eczema within the NHS in England and Wales.

Tacrolimus and pimecrolimus should not be used to treat mild atopic eczema. When atopic eczema is moderate or severe, tacrolimus and pimecrolimus should not be used as 'first-line' treatments – that is, they should not be used before other treatments have been tried. But, they may be considered in the circumstances below.

 Tacrolimus may be considered to treat moderate or severe atopic eczema for adults, or children aged 2 years or older, if the maximum strength and potency of topical corticosteroid that is appropriate for the patient's age and the area being treated has been adequately tried and hasn't worked, where there is serious risk of important side effects from further use of topical corticosteroids (particularly permanent damage to the skin). Pimecrolimus may be considered to treat moderate atopic eczema on the face and neck for children aged between 2 and 16 years if the maximum strength and potency of topical corticosteroid that is appropriate for the patient's age and the area being treated has been adequately tried and hasn't worked, where there is serious risk of important side effects from further use of topical corticosteroids (particularly permanent damage to the skin).

Treatment with either tacrolimus or pimecrolimus should only be started by doctors with a special interest and experience in skin diseases (this can include your GP), and only after the pros and cons of these and other appropriate treatment options have been discussed.

What should I do next?

If you or someone you care for has atopic eczema, you should discuss this guidance with your doctor or specialist.

Will NICE review its guidance?

Yes. The guidance will be reviewed in August 2007.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on the use of tacrolimus and pimecrolimus for atopic eczema that has been issued to the NHS. The Assessment Report, which contains details of the studies that were looked at, is also available from the NICE website. A short version of the guidance (a 'quick reference guide') is available on the website and from the NHS Response Line (reference number N0686).

NICE has published guidance on topical corticosteroids for treating atopic eczema. 'Information for the public' is available from www.nice.org.uk/TA081publicinfo or from the NHS Response Line, quote reference N0617 for a version in English, or N0618 for a version in English and Welsh.

If you have access to the Internet, you can find more information about atopic eczema on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 0845 46 47.



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