

Tacrolimus ointment

This information sheet is a short guide to tacrolimus ointment (also known as Protopic®). It contains information, which will help in understanding what tacrolimus ointment does, how it works, how it is used and what the possible side effects might be.

What is it?

Tacrolimus ointment is an ointment applied to the skin. It is not a steroid. Tacrolimus ointment is an immunomodulatory drug, which means it modulates or 'changes' the immune system in some way. Tacrolimus has been used for a few years as a drug taken by mouth to suppress the immune system to prevent rejection of kidney transplants. The skin's immune system is normally responsible for protection against things such as infection, but in atopic eczema, it is overactive to some degree. Tacrolimus helps to suppress this over-activity.

When can tacrolimus ointment be used

Tacrolimus ointment 0.1% and 0.03% ointment can be used for the treatment of moderate to severe atopic eczema that is unresponsive to conventional therapy. The ointment is available on prescription only.

How does it work?

Atopic eczema is a skin condition where the body reacts to things in the environment, which would normally do it no harm. This means that the immune system may be fighting things such as the house-dust mite and pollen allergens, which in turn cause the skin to become red, itchy and inflamed.

Tacrolimus ointment acts on the cells in the body and the skin to dampen down the immune system. This will help to reduce inflammation and make the skin less itchy and red.

How is it used?

Tacrolimus ointment is used for people with atopic eczema and is available in two different strengths, 0.03% and 0.1%. It is applied thinly to the skin, twice a day, in the same way in which a topical steroid may be applied. It should only be applied to areas of the skin where there is atopic eczema. The patient information leaflet enclosed in the packaging will explain this in more detail. Please discuss the application of this ointment with your doctor.

The manufacturers, Fujisawa, indicate its use in the UK is for children over the age of two and adults who have not responded adequately to conventional treatments, for example, if in your prescribing doctor's opinion, topical steroids fail to work on your eczema.

Topical tacrolimus will be prescribed by dermatologists and doctors who have experience in the treatment of atopic dermatitis.

Topical tacrolimus can be used on the skin on any part of the body, including the face, except mucosa (inside the nose, mouth and internal genital area)

Can it be used in combination with other treatments?

It is important to always use plenty of emollient as often as possible to keep the skin smooth, supple and well moisturised. Emollients can be used alongside tacrolimus ointment. As topical tacrolimus works by damping down the immune system, it could worsen skin infections by reducing the skin's natural resistance. It should not therefore be applied to skin that is infected either with bacteria (e.g. impetigo) or viruses (e.g. chickenpox, cold sores or warts). Tacrolimus is not suitable for use under wet wraps.

As yet no trials have been undertaken to assess the impact of using tacrolimus at the same time as other treatments such as topical steroids and antibiotics. Practice will be developed in the light of better understanding as more research is undertaken and the results become available. It is likely that doctors *will* use topical tacrolimus alongside topical steroids but on different parts of the body and it is more than likely that oral antibiotics will be used alongside topical tacrolimus for infected atopic eczema. Other treatments for severe atopic eczema such as oral steroids or ultraviolet light treatment will probably be stopped before a course of tacrolimus ointment is started, or tailed off soon after starting the tacrolimus ointment,

Does it work?

There have now been a number of trials using tacrolimus ointment to treat atopic eczema; it has been compared to placebo and to 1% hydrocortisone (a very weak topical steroid available over the counter) and the results look very good when compared against these. More recently it has been compared to hydrocortisone butyrate, which is a potent topical steroid. The results of this study suggest that stronger strength of tacrolimus (0.1%) is as effective at treating atopic eczema as hydrocortisone butyrate. Hydrocortisone butyrate was more effective than the 0.03% tacrolimus in that study. Even though tacrolimus is being developed for those for whom conventional treatment hasn't worked, none of the trials to date have tested tacrolimus with this particular group of people, so it is difficult to say how well it will work in such people

The skin begins to improve in about the first week of using the ointment, with an improvement in itching and redness, and this continues whilst treatment carries on. It is important to understand that topical tacrolimus is not a cure for atopic eczema; it is a new way of controlling the eruption of atopic eczema.

What are the side effects?

The trials that have been carried out involving tacrolimus ointment have looked into side effects and potential side effects and trials are on-going to assess the long-term side effects of this new treatment. The main short-term side effects identified are a burning feeling on the skin – this occurs in around one third to half of all people using it; some itching and some infected hair follicles (folliculitis). As a patient you should be warned by your doctor about this burning sensation and be prepared to put up with it for a day or two as these symptoms seem to disappear within the first few days of using the ointment.

Tests have also been performed to see whether tacrolimus ointment can pass through into the blood stream. It can pass through into the bloodstream, but the risk of this happening to a significant degree appears to be small. Tests have also been conducted to see whether tacrolimus ointment can cause the skin to become thinner. These tests show that this does not happen. Rarely, skin thinning can occur in people using strong topical steroids for long periods on delicate sites such as the face without a break.

It must be stressed that it is impossible to know what the long term side effects of using tacrolimus ointment might be as this treatment has not been available for very long. Studies have begun to monitor the long-term use of tacrolimus ointment. When drugs similar to tacrolimus are taken by mouth over very many years there is an increased risk of skin cancer occurring, although there is no evidence of this happening in any patients using tacrolimus as an ointment. Patients using long-term tacrolimus ointment on sun-exposed areas should avoid excessive strong sun exposure until such time as the safety of sun exposure with this ointment has been established.

Can anyone use it?

Trials have included children from the age of two upwards. Tacrolimus ointment is available for adults and children aged two years and over.

It is available on prescription only, to patients with moderate to severe atopic eczema, under the guidance and advice of the patient's doctor or specialist.

Can it be used for other types of eczema?

At present tacrolimus ointment has only been licensed to treat people with atopic eczema.

So in summary:

- Tacrolimus ointment has been developed from a treatment used to prevent transplant rejections
- A number of short term studies suggest that it is effective when compared against placebo for children and adults with atopic eczema
- It seems to be better than 1% hydrocortisone ointment (a weak topical steroid)
- The stronger preparation (0.1%) appears to be as good as a strong topical steroid. Both were more effective than the 0.03% strength of tacrolimus
- Although it is to be used for people in whom conventional treatment might have failed, it has not been tested in such people
- A burning sensation commonly occurs after applying tacrolimus to the skin. This normally settles after a few days
- Tacrolimus does not appear to cause skin thinning which can sometimes occur with strong (potent) topical steroids when used incorrectly
- Short term studies suggest that tacrolimus is a safe drug, but far less is known about its long term effects on the immune system

Further information

For further information please contact the information department at the National Eczema Society.

These details are provided only as a general guide. Individual circumstances differ and the National Eczema Society does not prescribe, give medical advice or endorse products or treatments. We hope you will find the notes helpful but they do not replace and should not replace the essential guidance, which can be given by your doctor.

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