EMA/457275/2011
EMEA/H/C/000374

EPAR summary for the public

Protopic

tacrolimus

This is a summary of the European public assessment report (EPAR) for Protopic. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Protopic.

What is Protopic?

Protopic is an ointment that contains the active substance tacrolimus (0.1% and 0.03%).

What is Protopic used for?

Protopic is used to treat 'flare-ups' (recurrence or worsening) of moderate to severe atopic dermatitis (eczema, an itchy red rash of the skin). 'Atopic' means that the dermatitis is linked to an allergy. Protopic is used in patients aged two years and above who do not respond well to or do not tolerate conventional treatments such as locally applied corticosteroids.

Protopic can also be used to prevent flare-ups of the disease or prolong the time that patients are free from flare-ups. In maintenance treatment, it is used in patients who usually have four or more flare-ups per year and who have had a response to an initial course of Protopic used twice a day for up to six weeks.

While Protopic 0.03% can be used in all patients over two years of age, Protopic 0.1% is only used in adults and adolescents over 16 years of age.

The medicine can only be obtained with a prescription.

How is Protopic used?

Protopic should be prescribed by a doctor with experience in the diagnosis and treatment of atopic dermatitis. The ointment should be applied as a thin layer to the skin.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

When used for flare-ups, Protopic can be used for short-term and intermittent long-term treatment, but it should not be used continuously on a long-term basis. Protopic treatment should begin as soon as symptoms appear. Each affected area is treated twice a day with Protopic until the skin is clear. Generally, improvement is seen within one week of starting treatment. If there is no improvement after two weeks, the doctor should consider other treatment options. Children should use Protopic 0.03% twice a day for up to three weeks before reducing the frequency to once a day. Adults should start treatment with Protopic 0.1% twice a day but should switch to less frequent application or use of the lower strength (0.03%) as the condition improves.

When used as maintenance treatment, Protopic should be applied twice a week to areas of the skin commonly affected by the disease. If there are signs of a flare-up, treatment should revert to twice a day as above. The doctor should review the need to continue maintenance treatment after a year. In children, this should include suspension of treatment to allow the doctor to assess whether continued treatment for the disease is necessary.

How does Protopic work?

The way in which Protopic works in atopic dermatitis is not fully understood. The active substance in Protopic, tacrolimus, is an immunomodulator. This means that it works on the immune system (the body's natural defences). Tacrolimus has been used since the mid-1990s to help prevent rejection in transplant patients (when the immune system attacks the transplanted organ). In atopic dermatitis, an over-reaction of the skin's immune system causes skin inflammation (itchiness, redness and dryness). Tacrolimus reduces the activity of the immune system, helping to relieve the skin inflammation and the itching.

How has Protopic been studied?

The use of Protopic in the treatment of flare-ups has been studied in six main studies involving 1,202 patients over the age of 16 years, and 1,535 aged from two to 16 years. Protopic was compared either with placebo (a dummy treatment) or with hydrocortisone (a corticosteroid often used for eczema). The main measure of effectiveness was the improvement in the eczema seen at the end of the studies, after three or 12 weeks, using a scoring system that looks at all of the symptoms of atopic dermatitis. Another study looked at the repeated use of Protopic for up to four years in about 800 patients.

Maintenance treatment with Protopic has been studied in two main studies involving 224 patients aged 16 years or over, and 250 aged from two to 15 years. All of the patients had atopic dermatitis that had responded to a maximum of six weeks of previous treatment with Protopic. The studies compared twice-weekly Protopic with placebo, although both groups of patients could use Protopic whenever they had a flare-up of the disease. The main measure of effectiveness was the number of flare-ups the patients had over a year.

What benefit has Protopic shown during the studies?

In the treatment of flare-ups of atopic dermatitis, Protopic was more effective than hydrocortisone at producing improvements in symptoms, although it also produced more burning than hydrocortisone. In the longer study, Protopic could be used repeatedly without losing its effectiveness.

In maintenance treatment, Protopic was more effective than placebo at reducing the number of flare-ups. In both studies, the patients with moderate to severe disease who were using Protopic had an average of one flare-up over a year, compared with three in those using placebo.

What is the risk associated with Protopic?

The most common side effects with Protopic (seen in more than 1 patient in 10) are a burning sensation and itching at the application site. For the full list of all the side effects reported with Protopic, see the package leaflet.

Protopic should not be used in people who may be hypersensitive (allergic) to tacrolimus, any of the other ingredients or macrolides.

Why has Protopic been approved?

The CHMP decided that Protopic's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Protopic

The European Commission granted a marketing authorisation valid throughout the European Union for Protopic on 28 February 2002.

The full EPAR for Protopic can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Protopic, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2011.