European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PROTOPY

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Protopy?

Protopy is a white to slightly yellowish ointment that contains either 0.1% or 0.03% of the active ingredient tacrolimus.

What is Protopy used for?

Protopy is used for the treatment of moderate to severe atopic dermatitis (eczema, an itchy red rash of the skin- atopic means that is linked to an allergy) in adults who do not respond well or do not tolerate usual treatments. The lower strength of Protopy (0.03%) may also be used for this condition in children (2 years of age and above) who do not respond well to, or do not tolerate usual treatments.
The medicine can only be obtained with a prescription.

How is Protopy used?

Protopy should be prescribed by a doctor with experience in the diagnosis and treatment of atopic dermatitis.
Protopy should not be used continuously. The ointment should be applied as a thin layer to affected areas of the skin. Each affected area is treated with Protopy until the skin is clear and then treatment should be stopped. Generally, improvement is seen within one week of starting treatment, and if there is no improvement after 2 weeks, the doctor needs to look at more treatment options.
In children, only the lowest strength Protopy 0.03% should be used. Treatment should be started as twice a day for up to three weeks. Afterwards, application should be reduced to once a day until the skin is clear. Protopy should not be used in children under 2 years of age.
In adults, treatment should be started with Protopy 0.1% twice a day and treatment should be continued until the skin is clear. If possible, patients should use less frequent applications, or the lower strength as their condition improves.

How does Protopy work?

The exact way that Protopy works in atopic dermatitis is not yet fully understood. Tacrolimus, the active substance in Protopy, is an immunomodulator, this means that it works on the immune system (the body's natural defences). Tacrolimus has been used since the mid-1990's 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, dryness). Tacrolimus calms down the immune system, and this helps relieve the skin inflammation and the itch.

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How has Protopy been studied?
The safety and effectiveness of Protopy has been studied in more than 13,500 patients treated with tacrolimus ointment in clinical trials. The six main clinical studies involved 1,202 adults (over the age of 16) and 1,535 children (aged 2 to 16 years of age), and Protopy was compared either with placebo (a dummy treatment, the ointment base) or with a topical corticosteroid often used for eczema (hydrocortisone butyrate in adults, hydrocortisone acetate in children). The main measure of effectiveness was the improvement in the eczema seen at the end of the study (3 or 12 weeks) using a scoring system (the modified Eczema Area and Severity Index) that looks at all the symptoms of atopic dermatitis. Another study has also looked at the use of Protopy for up to 4 years in about 800 patients.

What benefit has Protopy shown during the studies?
Protopy was significantly more effective than either of the 2 hydrocortisone preparations at producing improvements in the modified Eczema Area and Severity Index, although it also produced more burning than hydrocortisone. In the longer study, Protopy could be used repeatedly without losing its effectiveness.

What is the risk associated with Protopy?
The most common side effects (seen in more than 1 patient in 10) are burning sensation and itching at the application site. For the full list of all the side effects reported with Protopy, please see the Package Leaflet.
Protopy should not be used in people who may be hypersensitive (allergic) to tacrolimus or to any of the other ingredients.
Doctors must be aware that a very small number of patients using the medicine have developed cancer (skin cancer, lymphoma). A link to Protopy has not been shown. However, doctors must ensure that the medicine is used appropriately.

Why has Protopy been approved?
The Committee for Medicinal products for Human Use (CHMP) decided that Protopy's benefits are greater than its risks for the treatment of moderate to severe atopic dermatitis in adults and children over the age of 2 who are not adequately responsive to or are intolerant of conventional therapies. They recommended that Protopy be given marketing authorisation.

Other information about Protopy:
The European Commission granted a marketing authorisation valid throughout the European Union, for Protopy to Astellas Pharma GmbH on 28 February 2002. The marketing authorisation was renewed on 11-2006.

The full EPAR for Protopy is available here.

This summary was last updated in 09-2007