

PROTOPIC® OINTMENT

Tacrolimus (0.03% w/w, 0.1% w/w)

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What Protopic® is used for

Protopic® is used to treat moderate to severe atopic dermatitis (eczema) in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids.

Only Protopic® 0.03% is used to treat children (2 years of age and older) who failed to respond adequately to conventional therapies such as topical corticosteroids.

Protopic® is also used to treat moderate to severe atopic dermatitis (eczema) for the prevention of flares and prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to maximum 6 weeks treatment of twice daily Protopic® ointment.

How Protopic® works

The active substance of Protopic®, tacrolimus monohydrate, is an immunomodulating agent.

In atopic dermatitis, an over-reaction of the skin's immune system causes skin inflammation (itchiness, redness, dryness).

Protopic® alters the abnormal immune response and relieves the skin inflammation and the itch.

Before you use Protopic®

- When you must not use it

If you are allergic to tacrolimus or any of the other ingredients of this medicine or to macrolide antibiotics (e.g. azithromycin, clarithromycin, erythromycin).

- Before you start to use it

Talk to your doctor

- If you have liver failure.
- If you have any skin malignancies (tumours) or if you have a weakened immune system (immuno-compromised) whatever the cause.
- If you have an inherited skin barrier disease such as Netherton's syndrome, lamellar ichthyosis (extensive scaling of the skin due to a thickening of the outer layer of the skin), or if you suffer from generalised erythroderma (inflammatory reddening and scaling of the entire skin).
- If you have a cutaneous Graft Versus Host Disease (an immune reaction of the skin which is a common complication after

undergoing a bone marrow transplant). If you have swollen lymph nodes at initiation of treatment. If your lymph nodes become swollen during treatment with Protopic®, consult your doctor.

- If you have infected lesions. Do not apply the ointment to infected lesions.

- If you notice any change to the appearance of your skin, please inform your physician.

- Based on the results of long-term studies and experience, a link between Protopic ointment treatment and the development of malignancies has not been confirmed, but definitive conclusions cannot be drawn.

- Avoid exposing the skin to long periods of sunlight or artificial sunlight such as tanning beds. If you spend time outdoors after applying Protopic®, use a sunscreen and wear loose fitting clothing that protects the skin from the sun. In addition, ask your doctor for advice on other appropriate sun protection methods. If you are prescribed light therapy, inform your doctor that you are using Protopic® as it is not recommended to use Protopic® and light therapy at the same time.

- If your doctor tells you to use Protopic twice weekly to keep your atopic dermatitis cleared, your condition should be reviewed by your doctor at least every 12 months, even if it remains under control. In children, maintenance treatment should be suspended after 12 months, to assess whether the need for continued treatment still exists.

- It is recommended to use Protopic

ointment at the lowest possible strength, at the lowest frequency and for the shortest possible duration necessary. This decision should be based on your doctor's assessment of how your eczema responds to Protopic ointment.

Children

•Protopic® ointment is not approved for children younger than 2 years of age. Therefore it should not be used in this age group. Please consult your doctor.

•Protopic® 0.1 % ointment is not approved for children younger than 16 years of age. Therefore it should not be used in this age group. Please consult your doctor.

•The effect of treatment with Protopic® on the developing immune system in children, especially the young, has not been established.

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Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines especially:

- erythromycin (antibiotic)
 - itraconazole, ketoconazole (antifungal)
 - diltiazem (used to treat high blood pressure or heart problems).
- You may use moisturising creams and lotions during treatment with Protopic® but these products should not be used within two hours of applying Protopic®.

The use of Protopic® at the same time as other preparations to be used on the skin or while taking oral corticosteroids (e.g. cortisone) or

medicines which affect the immune system has not been studied.

How to use Protopic®

- How much to use

- Apply Protopic® as a thin layer to affected areas of your skin.
- Protopic® may be used on most parts of the body, including the face and neck and in the creases of your elbows and knees.
- Avoid using the ointment inside your nose or mouth or in your eyes. If the ointment gets on any of these areas, it should be thoroughly wiped off and/or rinsed off with water.
- Do not cover the skin being treated with bandages or wraps.
- Wash your hands after applying Protopic® unless your hands are also being treated.
- After a bath or shower, be sure your skin is completely dry before applying Protopic®.

- When to use it

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How long to use it

Children (2 years of age and older)

Apply Protopic® 0.03 % ointment twice a day for up to three weeks, once in the morning and once in the evening. Afterwards the ointment should be used once a day on each affected region of the skin until the eczema has gone away.

Adults (16 years of age and older)

Two strengths of Protopic® (Protopic® 0.03% and Protopic® 0.1% ointment) are available for adult (16 years of age and older). Your doctor will decide which strength is best for you.

Usually, treatment is started with Protopic® 0.1% ointment twice a day, once in the morning and once in the evening, until the eczema has cleared. Depending on the response of your eczema your doctor will decide if the frequency of application can be reduced or the lower strength, Protopic® 0.03% ointment, can be used.

•PROTOPIC® treatment should begin at the first appearance of signs and symptoms. Treat each affected region of your skin until the eczema has gone away. Improvement is usually seen within one week. If you do not see any improvement after two weeks, see your doctor about other possible treatments.

- If you forget to use it

If you forget to apply the ointment at the scheduled time, do it as soon as you remember and then continue as before.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

If you accidentally swallow the ointment, consult your doctor or pharmacist as soon as possible. Do not try to induce vomiting.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things you must not do

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

Protopic® with alcohol

While using Protopic®, drinking alcohol may cause the skin or face to become flushed or red and feel hot.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people):

- burning sensation and itching
- These symptoms are usually mild to moderate and generally go away within one week of using Protopic®.

Common (may affect up to 1 in 10 people):

- redness
- feeling of warmth
- pain
- increased skin sensitivity
- skin tingling
- rash
- local skin infection including but not limited to: inflamed or infected hair follicles, cold sores, generalised herpes simplex infections
- facial flushing or skin irritation after drinking alcohol is also common

Uncommon (may affect fewer than 1 in 100 people):

- acne

Rosacea (facial redness), lentigo

(presence of flat brown spots on the skin), swelling at the application site and herpes virus eye infections have been reported during post-marketing experience.

~~Since commercial availability a very small number of people who have used Protopic® ointment have had malignancies (for example lymphoma, including skin lymphoma, and other skin tumours). However, a link to Protopic® ointment treatment has not been confirmed or refuted on the available evidence so far.~~

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Protopic®

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.

Store at 30°C or below.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

White to slightly yellowish ointment

- Ingredients

- Active ingredient(s) Tacrolimus monohydrate
- Inactive ingredients
White soft paraffin, liquid paraffin, propylene carbonate, white beeswax, hard paraffin

- MAL number:

MAL20051359AZ (0.03% w/w)
MAL20051358AZ (0.1% w/w)

Manufacturer

LEO Laboratories Limited
285 Cashel Road, Crumlin, Dublin 12, Ireland

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm No.1, Jalan SS7/26A, Kelana Jaya 47301 Petaling Jaya, Malaysia.

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