

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Protopic 0.03% Ointment Tacrolimus monohydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Protopic is and what it is used for
2. What you need to know before you use Protopic
3. How to use Protopic
4. Possible side effects
5. How to store Protopic
6. Contents of the pack and other information

1. What Protopic is and what it is used for

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

Protopic 0.03% ointment 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 and in children (2 years of age and older) who failed to respond adequately to conventional therapies such as topical corticosteroids.

Once moderate to severe atopic dermatitis is cleared or almost cleared after up to 6 weeks treatment of a flare, and if you are experiencing frequent flares (i.e. 4 or more per year), it may be possible to prevent flares coming back or prolong the time you are free from flares by using Protopic 0.03% ointment twice weekly.

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.

2. What you need to know before you use Protopic

Do not use Protopic

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

Warnings and precautions

Talk to your doctor if you:

- have **liver failure**.
- have any **skin malignancies** (tumours) or if you have a **weakened immune system** (immuno-compromised) whatever the cause.
- 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).

- have a cutaneous Graft Versus Host Disease (an immune reaction of the skin which is a common complication in patients who have undergone a bone marrow transplant).
 - have **swollen lymph nodes** at initiation of treatment. If your lymph nodes become swollen during treatment with Protopic, consult your doctor.
 - have **infected lesions**. Do not apply the ointment to infected lesions.
 - notice any **change to the appearance of your skin**, please inform your physician.
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- The safety of using Protopic for a long time is not known. A very small number of people who have used Protopic ointment have had malignancies (for example, skin or lymphoma). However, a link to Protopic ointment treatment has not been shown.
 - 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.

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

Other medicines, cosmetics and Protopic

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.

Protopic with alcohol

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

Pregnancy and breast-feeding

Don't use Protopic if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

3. How to use Protopic

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

- 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.
- Before applying Protopic after a bath or shower, be sure your skin is completely dry.

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 patients (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.

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.

You may be told by your doctor to use Protopic ointment twice weekly once your atopic dermatitis has cleared or almost cleared (Protopic 0.03% for children and Protopic 0.1% for adults). Protopic ointment should be applied once a day twice weekly (e.g. Monday and Thursday) to areas of your body commonly affected by atopic dermatitis. There should be 2–3 days without Protopic treatment between applications.

If symptoms reappear you should use Protopic twice daily as outlined above and arrange to see your doctor to review your treatment.

If you accidentally swallow some ointment

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

If you forget to use Protopic

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

4. Possible side effects

Like all medicines, Protopic 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 (especially to hot and cold)

- skin tingling
- rash
- local skin infection regardless of specific cause 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

Following twice-weekly treatment application site infections have been reported in children and adults. Impetigo, a superficial bacterial skin infection that usually produces blisters or sores on skin, has been reported in children.

Rosacea (facial redness), rosacea-like dermatitis, lentigo (presence of flat brown spots on the skin), oedema at the application site and herpes 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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Protopic

Keep out of the sight and reach of children.

Do not use Protopic 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.

Do not store above 25°C.

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 to protect the environment.

6. Contents of the pack and other information

What Protopic contains

- The active substance is tacrolimus monohydrate.
One gram of Protopic 0.03% ointment contains 0.3 mg tacrolimus (as tacrolimus monohydrate).
- The other ingredients are white soft paraffin, liquid paraffin, propylene carbonate, white beeswax and hard paraffin.

What Protopic looks like and contents of the pack

Protopic is a white to slightly yellowish ointment. It is supplied in tubes containing 10, 30 or 60 grams of ointment. Not all pack sizes may be marketed. Protopic is available in two strengths (Protopic 0.03% and Protopic 0.1% ointment).

Marketing Authorisation Holder:

LEO Pharma A/S, Industriparken 55, 2750 Ballerup, Denmark.

Manufacturer: Astellas Ireland Co. Ltd., Killorglin, County Kerry, Ireland.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu/>.