

Package leaflet: information for the user

Protopic 0.03% ointment
Tacrolimus monohydrate

Read the entire 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.
- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- If you experience any side effects listed in section 4, or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

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1. What is Protopic and what is it used for?

The active substance of Protopic, tacrolimus monohydrate, is an immunomodulator.

Protopic 0.03% ointment is used for the treatment of moderate to severe atopic dermatitis (eczema) in adults who do not respond adequately to conventional treatments, such as topical corticosteroids, or cannot tolerate them, and in children (from the age of 2 years) who do not respond adequately to conventional treatments, such as topical corticosteroids.

Once the moderate to severe atopic dermatitis has cleared or almost cleared after treating a flare for up to 6 weeks, and if you experience frequent flares (i.e., 4 or more per year), Protopic 0.03% can be applied twice a week in an attempt to extend the period without a flare or to prevent the flares from returning.

In atopic dermatitis, the skin's immune system overreacts, causing skin inflammation (itching, redness, dryness). Protopic modifies the abnormal immune response and alleviates the skin inflammation and itching.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to tacrolimus or any of the ingredients in this medicine. These ingredients can be found in section 6.

You are allergic to antibiotics of the macrolide group (e.g., azithromycin, clarithromycin, erythromycin).

When should you be extra careful with this medicine?

Contact your doctor before using this medicine.

If you suffer from liver failure

If you have malignant skin conditions (tumors) or if you have a weakened immune system (suppressed immunity), regardless of the cause (immunosuppressed) has, regardless of the cause

If you have a cutaneous graft-versus-host disease (an immune reaction of the skin that is a common complication in patients who have undergone a bone marrow transplant)

If you have swollen lymph nodes at the start of treatment. If your lymph nodes swell during treatment with Protopic, you should consult your doctor.

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

If you notice a change in the appearance of your skin, inform your doctor.

Long-term study results and experience have not confirmed a link between treatment with this medicine and the development of malignancies, but definitive conclusions cannot be drawn.

Avoid exposing the skin to sunlight or artificial sunlight such as tanning beds for long periods. If you go outside after applying Protopic, you should apply a protective sunscreen and wear loose-fitting clothing that protects the skin from sunlight. Also, ask your doctor for advice on other effective sun protection. If you are prescribed light therapy, inform your doctor that you are using Protopic. It is not advisable to use Protopic in conjunction with light therapy.

If your doctor has prescribed Protopic twice a week to keep you free from eczema, your condition should be reviewed by your doctor at least every 12 months, even if the condition remains under control. In children, maintenance treatment should be interrupted after 12 months to assess whether it is still necessary to continue treatment.

It is recommended to use Protopic ointment with the lowest possible strength, at the lowest frequency, and for the shortest possible time needed. This decision should be based on your doctor's assessment of how your eczema responds to the Protopic treatment.

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Children

Protopic ointment is not approved for children under 2 years of age. Therefore, it should not be used in this age group. Please contact your doctor.

The effect of treatment with Protopic on the developing immune system in children, particularly in young children, has not been studied.

Are you using any other medicines and cosmetics?

Are you using any other medicines besides Protopic, have you recently done so, or is there a possibility that you will use other medicines soon? Then tell your doctor or pharmacist.

You may use moisturizing creams and lotions during treatment with Protopic. However, these products should not be applied within two hours before or after applying Protopic ointment.

The simultaneous use of Protopic with other topical agents or with oral corticosteroids (e.g., cortisone) or medicines that affect the immune system has not been studied.

What should you be aware of with alcohol?

If you use Protopic, drinking alcohol may cause the skin or face to flush, turn red, and feel warm.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Protopic contains butylhydroxytoluene (E321)

Protopic contains butylhydroxytoluene (E321), which may cause local skin reactions (e.g., contact dermatitis), or irritation to the eyes and mucous membranes.

3. How do you use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Apply Protopic in a thin layer to the affected areas of your skin.

Protopic can be applied to most areas of the body, including the face and neck and in the hollows of the elbows and knees.

Avoid using the ointment in the nose, mouth, or eyes. If the ointment does get on these areas, you should thoroughly wipe it off and/or rinse with water.

The treated skin must not be bandaged or wrapped.

Wash your hands after applying Protopic unless the hands themselves are to be treated.

After taking a bath or shower, the skin must be completely dry before applying Protopic.

Children (from the age of 2 years)

Apply Protopic 0.03% ointment twice daily for up to 3 weeks, once in the morning and once in the evening. Thereafter, the ointment should be applied once daily to all affected areas of the skin until the eczema has completely disappeared.

Adults (from the age of 16 years)

There are two strengths of Protopic (Protopic 0.03% and Protopic 0.1% ointment) available for adult patients (from the age of 16 years). Your doctor will decide which strength is most appropriate for you.

Usually, treatment is started with Protopic 0.1% ointment, twice daily, once in the morning and once in the evening, until the symptoms have disappeared. Depending on the result of the ointment on your eczema, the doctor may decide whether the frequency of application can be reduced, or whether the lower strength, namely Protopic 0.03%, can be used.

Treat each affected area of the skin until the eczema has disappeared. Improvement is usually seen within a week. If no improvement occurs after two weeks of treatment, you should consult your doctor about other possible treatments.

Your doctor may have told you to use Protopic ointment twice a week once the eczema has disappeared or almost disappeared (Protopic 0.03% for children and Protopic 0.1% for adults). Protopic ointment should be applied once daily twice a week (for example, on Monday and Thursday) to areas of your body that are often affected by eczema. There should be 2-3 treatment-free days between applications of Protopic ointment. If symptoms return, you should use Protopic twice daily again as described above, and make a follow-up appointment with your doctor to assess the treatment.

Have you accidentally swallowed some ointment?

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

Have you forgotten to use this medicine?

If you have forgotten to apply the ointment at the scheduled time, do so as soon as you remember and continue the treatment as normal.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone 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 disappear within a week after starting treatment with Protopic.

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

- redness
- feeling of warmth
- pain
- increased skin sensitivity (especially to heat and cold)
- skin tingling
- rash
- local skin infection without specific cause including, but not limited to: inflamed or infected hair follicles, cold sores, generalized herpes simplex infections
- flushing or skin irritation after drinking alcohol is also common

Sometimes (may affect less than 1 in 100 people):
acne

After twice-weekly treatment, infections at the application site have been reported in children and adults. In children, impetigo, a superficial bacterial skin infection that usually causes blisters or painful skin lesions, was identified.

Rosacea (red face), rosacea-like dermatitis, lentigo (presence of flat, brown spots on the skin), application site edema, and herpes eye infections have been reported after this product was marketed.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the tube and the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store below 25°C.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is tacrolimus monohydrate.

One gram of Protopic 0.03% ointment contains 0.3 mg tacrolimus (as tacrolimus monohydrate).

The other substances in this medicine are white soft paraffin, liquid paraffin, propylene carbonate, white beeswax, hard paraffin, butylhydroxytoluene (E321), and all-rac- α -tocopherol.

What does Protopic look like and what is in a package?

Protopic is a white to light yellow ointment. It is available in tubes of 10 g, 30 g, or 60 g ointment. Not all mentioned pack sizes may be marketed. Protopic is available in two strengths (Protopic 0.03% and Protopic 0.1% ointment).

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This leaflet was last approved in

More information about this medicine is available on the website of the European Medicines Agency: <http://www.ema.europa.eu>.