

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr**PROTOPIC**[®]
tacrolimus ointment

Read this carefully before you start taking **Protopic**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Protopic**[®].

What is Protopic[®] used for?

Only use Protopic[®] on your skin. Do NOT use in the eyes.

Acute (Flare) Treatment: Protopic[®] is used to treat eczema flares in adults and children age 2 years and older. These patients must not have a weakened immune system.

Prevention (Maintenance Therapy): If you have a high frequency of eczema flares (5 or more times per year), Protopic[®] can be used to prevent these flares from coming back. It may also be used to increase the length of time between flares.

Only use Protopic[®] to treat eczema that has been diagnosed by a doctor. Do not use Protopic[®] to treat any other skin condition for which it was not prescribed.

How does Protopic[®] work?

The exact way that Protopic[®] works is not known. When the active ingredient in Protopic[®], tacrolimus, is applied on the skin, it has been shown to control inflammation, itch or redness associated with eczema.

What are the ingredients in Protopic[®]?

Medicinal ingredient: tacrolimus

Non-medicinal ingredients: mineral oil (contains all-*rac*- α -tocopherol), paraffin, propylene carbonate, white petrolatum (contains butylhydroxytoluene) and white wax.

Protopic[®] comes in the following dosage forms:

Ointment, 0.03% and 0.1% (w/w).

Do not use Protopic[®] if you:

- are allergic to tacrolimus, or any of the other ingredients in this medicine (See “What the nonmedicinal ingredients are”). Speak with your healthcare professional if you have had allergic reactions in the past.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Protopic[®]. Talk about any health conditions or problems you may have, including if you:

- Have a weakened immune system
- Are using any other type of skin product
- Have any skin infections that have not healed on the areas to be treated with Protopic[®]

- Are pregnant or planning to become pregnant or breast-feeding
- Have kidney problems
- Have an inherited skin barrier disease such as:
 - Netherton's syndrome,
 - lamellar ichthyosis, or
 - generalized erythroderma, this is a condition that causes inflammatory reddening and scaling of the entire skin
- Have an immune system reaction of the skin such as a cutaneous Graft Versus Host Disease. This is a common problem in patients who have had a bone marrow transplant.

Other warnings you should know about:

Lymphadenopathy: Patients treated with Protopic® may develop lymphadenopathy. This is when the lymph nodes (located on the sides of the neck, in the armpits and groin area) become enlarged. If you find that your lymph nodes are swollen while using Protopic®, talk to your healthcare professional.

Skin infections: Patients treated with Protopic® may experience skin infections. These patients may also be more likely to develop chicken pox, shingles, or cold sores. If your skin becomes infected, see your doctor.

Sunlight: Avoid sunlight and sun lamps, tanning salons, and treatment with UVA or UVB light. If you need to be outdoors after applying Protopic®, wear clothing that protects the treated area from the sun. In addition, ask your doctor what other type of protection from the sun you should use.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Be sure to check with your doctor or pharmacist before you:

- Take any new medicines.
- Use any other ointments, lotions, or creams on your skin.

How to take Protopic®:

- Wash your hands before applying Protopic®.
- If you are not treating your hands, wash your hands with soap and water after applying Protopic®. This should remove any ointment left on the hands.
- If you apply Protopic® after a bath or shower, be sure your skin is completely dry.
- Protopic® must ONLY be used on your skin. It can be applied to all affected areas including on the face, neck and eyelids.
- Avoid getting Protopic® in your eyes.
- Do not swallow Protopic®.
- Apply a thin layer of Protopic® to all areas on the skin that your doctor has diagnosed as eczema. The layer should completely cover the affected areas.
- Do not cover the skin being treated with bandages, dressings, or wraps. However, you can wear normal clothing.
- Do not bathe, shower or swim right after applying Protopic®. This could wash off the ointment.

Usual dose:

Your doctor will tell you how to use Protopic® based on your medical condition and response to the drug. Do not use any more or any less of the drug than your doctor says.

Most people find that a pea-sized amount squeezed from the tube covers an area about the size of a 5-centimeter circle.

Treating eczema:

Apply Protopic® to the affected areas of the skin twice a day, in the morning and evening (about 12 hours apart).

Protopic® usually begins to provide relief from the symptoms of eczema within a few weeks. If you do not notice an improvement in your eczema within the first 6 weeks of treatment or if your eczema gets worse, tell your doctor.

Preventing eczema flares from coming back:

This is only for patients who experience eczema flares 5 or more times per year. Apply Protopic® to the affected areas once a day, two times a week. Between applications, there should be 2 to 3 days without treatment (e.g., apply Monday and Thursday). If your eczema comes back (flares), talk to your doctor.

After 12 months of treatment, see your doctor so that they can assess your eczema and determine if you should keep using Protopic®.

Overdose:

Do not swallow Protopic®. If you do, call your doctor immediately. Oral ingestion of Protopic® may lead to adverse effects not associated with the use of tacrolimus on the skin.

In case of drug overdose, particularly accidental oral ingestion, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use Protopic® as directed, apply it as soon as possible, then go back to your regular schedule. If you forget to use Protopic®, do not apply twice as much Protopic® the next time you use it.

What are possible side effects from using Protopic®?

These are not all the possible side effects you may feel when taking Protopic®. If you experience any side effects not listed here, contact your healthcare professional.

- Reactions at the application site (stinging, a burning feeling, or itching) for the first few days of application, which typically resolve as the skin heals
- Increased sensitivity of the skin to hot or cold temperatures
- Skin tingling
- Fever, headache, or muscle pain
- Flu-like symptoms (common cold, congestion, upper respiratory infection)
- Acne
- Swollen or infected hair follicles

- Upset stomach
- Diarrhea

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Allergic Reaction: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			✓
Herpes Zoster (Chickenpox or Shingles): a painful skin rash of fluid-filled blisters, blisters appear along a strip of skin, itching			✓
Cyst			✓
Impetigo (bacterial infection of the skin): red fluid-filled blisters that break			✓
UNKNOWN			
Renal Problems (kidney problems): nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, abnormal blood test results, mental status changes (drowsiness, confusion, coma)			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C and 30°C. Keep out of the reach and sight of children. Do not use after the expiry date.

If you want more information about Protopic®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.leo-pharma.ca, or by contacting the sponsor, LEO Pharma Inc., calling 1-800-263-4218.

This leaflet was prepared by LEO Pharma Inc.

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