

## PART III: CONSUMER INFORMATION

**Pr**PROTOPIC®  
tacrolimus ointment

This leaflet is part III of a three-part "Product Monograph" published when Protopic was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Protopic.

Read this important information before you start using Protopic and each time you refill your prescription. This summary is not meant to take the place of your doctor's instructions. If you have any questions or want more information about Protopic, talk with your doctor or pharmacist.

### ABOUT THIS MEDICATION

#### What the medication is used for:

Protopic, a non-steroid prescription medicine, is in the class of medicines called topical calcineurin inhibitors. Protopic is used to treat eczema (atopic dermatitis) in adults and children age 2 years and older who do not have a weakened immune system. Protopic is for use on the skin only and should be used only after other therapies have been shown to be ineffective or unsuitable. Protopic should be used for short or intermittent long periods of treatment, as directed by your doctor. If you have a high frequency of flares (5 or more times per year) your doctor may advise you to use Protopic to prevent flares of your eczema from coming back or to prolong the time you are free from flares, once the affected areas of your skin have cleared.

Protopic can be applied to all affected areas of the skin including the face, neck and eyelids.

Protopic should be used only to treat eczema (atopic dermatitis) that has been diagnosed by a doctor. Do not use Protopic to treat any other skin condition for which it was not prescribed.

#### What it does:

The exact mechanism by which Protopic works is not known. However, tacrolimus applied topically has been shown to control inflammation, itch or redness associated with atopic dermatitis.

#### When it should not be used:

Do not use Protopic if you:

- are breast-feeding or pregnant, unless your doctor determines it is necessary to use Protopic.
- are allergic to any medicines including tacrolimus or any of the ingredients of Protopic (See "What the nonmedicinal ingredients are"). Speak with your doctor if you have had allergic reactions in the past.
- Have any skin infections at the site to be treated; or have a viral infection of your skin, such as chickenpox or herpes. If your skin becomes infected, see your doctor.
- Have been told you have a weakened immune system.

Contact your doctor or pharmacist if you have any questions.

#### What the medicinal ingredient is:

tacrolimus

#### What the nonmedicinal ingredients are:

mineral oil, paraffin, propylene carbonate, white petrolatum, and white wax

#### What dosage forms it comes in:

Protopic is a white to slightly yellowish ointment for topical use and comes in two strengths 0.03% and 0.1% (w/w).

### WARNINGS AND PRECAUTIONS

**Long-term safety of topical calcineurin inhibitors (a new class of eczema medication that includes Protopic) has not been established. Although a link has not been established, rare cases of skin cancer and lymphomas (cancer of certain white blood cells) have been reported in patients treated with topical calcineurin inhibitors, including Protopic ointment 0.1% and 0.03%.**

#### **Therefore:**

- **Continuous long-term use of Protopic ointment 0.1% and 0.03% should be avoided, and application limited to areas that have eczema.**
- **Protopic ointment is not indicated in children less than 2 years of age. Only 0.03% Protopic ointment is indicated for use in children 2-15 years of age.**

#### **BEFORE you start using Protopic be sure to tell your doctor if you:**

- are using **any** other prescription medicines.
- are receiving any form of light therapy (phototherapy or UV) to your skin.
- are using any over-the-counter medicines or any natural/herbal remedies.
- are using any other type of skin product.
- are pregnant or planning to become pregnant or breast-feeding.
- are suffering from any kidney problems or disease
- have an inherited skin barrier disease such as Netherton's syndrome, lamellar ichthyosis, or if you suffer from generalized erythroderma (inflammatory reddening and scaling of the entire skin).
- have a cutaneous Graft Versus Host Disease (a immune reaction of the skin which is a common complication in patients who have undergone a bone marrow transplant).

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, you should ask your doctor what other type of protection from the sun you should use.

## INTERACTIONS WITH THIS MEDICATION

No drug interaction studies have been done with Protopic. Be sure to check with your doctor or pharmacist before you start taking any new medicines while using Protopic. Also, before you use any other ointments, lotions, or creams on your skin, discuss it with your doctor or pharmacist.

## PROPER USE OF THIS MEDICATION

- Wash your hands before applying Protopic.
- If your hands **are not** being treated, wash your hands with soap and water after applying Protopic. This should remove any ointment left on the hands.
- Apply a thin layer of Protopic to all skin areas that your doctor has diagnosed as eczema. Try to cover the affected areas completely. Most people find that a pea-sized amount squeezed from the tube covers an area about the size of a 5 centimeter (two-inch) circle.
- Protopic should be applied twice a day, about 12 hours apart for treating flares.
- Protopic should be applied once a day twice a week for preventing flares from coming back if you have a high frequency of flares (5 or more times per year).
- 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.
- Before applying Protopic after a bath or shower, be sure your skin is completely dry.
- Protopic must be used **only** on your skin. Protopic can also be safely used on your eyelids but it is recommended that you avoid direct contact with the eyes. Do not swallow Protopic.

### Usual dose:

Protopic comes in two strengths (0.03% or 0.1%). The 0.1% strength is for use in patients age 16 and over. The 0.03% strength is for patients age 2 and over. 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.

**Treating eczema (atopic dermatitis):** Protopic 0.03% or 0.1% should be applied topically morning and evening twice daily as a thin layer to affected areas of skin.

Protopic usually begins to provide relief from the symptoms of eczema within a few weeks. It is important to use Protopic as instructed by your doctor.

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 (atopic dermatitis) from coming back:**

You may be told by your doctor to continue using Protopic once your eczema has cleared. Protopic 0.03% or 0.1% should be applied once a day twice per week (e.g., Monday and Thursday) to the areas normally affected by eczema. Between applications there

should be 2 to 3 days without Protopic treatment. If your eczema comes back, you should call your doctor.

After 12 months of treatment you should see your doctor so that he or she can assess your atopic dermatitis 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 application 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.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, Protopic can cause side effects. The most common side effects of Protopic are stinging, a burning feeling or itching of the skin that is being treated with Protopic. These side effects are usually mild to moderate and usually go away after the first few days of using Protopic.

Less common side effects include acne, allergic reaction, fever, diarrhea, swollen or infected hair follicles, headache, increased sensitivity of the skin to hot or cold temperature, or flu-like symptoms (common cold, congestion, upper respiratory infection). While you are using Protopic, drinking alcohol may cause the skin or face to become flushed or red and feel hot. Some people may develop skin tingling, upset stomach, herpes zoster (chickenpox or shingles), muscle pain, cyst, an infection on the skin where Protopic was applied or a bacterial infection of the skin called impetigo. Call your doctor if side effects persist or become bothersome.

Although a link has not been established, rare cases of skin cancer and lymphomas (cancer of certain white blood cells) have also been reported in postmarketing reports (reporting of adverse events by health care professionals and consumers after the launch of the product) for patients treated with topical calcineurin inhibitors, including Protopic ointment 0.1% and 0.03%.

Rare cases of renal (kidney) problems have also been reported in postmarketing use.

***For any unexpected effects while taking Protopic, contact your doctor or pharmacist.***

**HOW TO STORE IT**

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

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701C  
Ottawa, ON K1A 0K9

Postage paid labels, the Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

**NOTE:** Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at: [www.leo-pharma.ca](http://www.leo-pharma.ca) or by contacting the sponsor, LEO Pharma Inc., at: 1-800-668-7234.

This leaflet was prepared by LEO Pharma Inc.

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