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2. Protopic

# Protopic Ointment do

Generic name: tacrolimus topical [ ta-KROE-li-mus ]

Brand name: Protopic

Drug class: Miscellaneous topical agents

Medically reviewed by Melisa Puckey, BPharm. Last updated on Mar 1, 2024.

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### What is Protopic?

Protopic (tacrolimus) is a topical macrolide immunosuppressant that belongs to a class of medications called topical calcineurin inhibitors. Tacrolimus works by decreasing cell activity in the body's immune system which helps to slow down the growth of atopic dermatitis (eczema) on your skin.

Protopic ointment is used to treat the symptoms of moderate to severe eczema in adults and children at least 2 years old, who cannot use other medications for their condition or whose eczema has not responded to another medication. Eczema (atopic dermatitis) is a skin disease that causes the skin to be dry and itchy and to sometimes develop red, scaly rashes).

Protopic ointment is not for use in people who have a weak immune system.

## **Warnings**

Protopic ointment is not for long-term use. A small number of people using Protopic ointment, or another similar medication have developed skin cancer or lymphoma. However, it is not known if tacrolimus causes cancer.

Only use Protopic on skin that is affected by eczema. Avoid applying to an area that may be affected with skin cancer.

Before using this medicine, tell your doctor if you have skin cancer or a skin infection (including herpes or chickenpox), any genetic skin disorder (such as Netherton's syndrome), a weak immune system, kidney disease, or swelling, redness, or irritation of large areas of your skin.

Protopic can lower the blood cells that help your body fight infections. This can make it easier for you to get sick from a virus such as chicken pox or herpes (cold sores or shingles). Tell your doctor if you have been exposed to any illness.

Avoid sunlight, sun lamps, tanning beds, and phototherapy treatments with UVA or UVB light. If you must be outdoors, wear loose clothing over the skin areas treated with Protopic ointment. Do not use sunscreen on treated skin unless your doctor has told you to.

Talk to your doctor if your skin condition does not improve after using Protopic for 6 weeks.

Do not use this medication on a child younger than 2 years old. Some people have developed skin cancer or lymphoma after using Protopic or pimecrolimus (Elidel). However, it is not known if either of these medicines causes skin cancer or lymphoma. Talk to your doctor about your individual risk.

### Before taking this medicine

You should not use Protopic ointment if you are allergic to tacrolimus.

Protopic ointment in 0.03% or 0.1% strengths may be used by adults and children 16 years and older. Only the 0.03% strength should be used on a child 2 to 15 years old.

To make sure Protopic is safe for you, tell your doctor if you have ever had:

- skin cancer (melanoma);
- a bacterial or viral skin infection (including herpes or chickenpox);
- Netherton's syndrome (a genetic skin disorder); or
- a weak immune system (caused by disease or by using certain medicines).

A small number of people using Protopic ointment, or another similar medication have developed skin cancer or lymphoma. However, it is not known if tacrolimus causes cancer. Ask your doctor about your risk.

Tell your doctor if you are pregnant, plan to get pregnant, or breastfeeding before starting this medicine.

1 Protopic pregnancy and breastfeeding warnings (more detail)

### How should I use Protopic ointment?

Use Protopic ointment exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets.

Use this medicine only on skin that is affected by eczema. Avoid applying to an area that may be affected with skin cancer.

Do not take by mouth. Topical medicine is for use only on the skin.

Wash your hands before and after applying Protopic, unless you are using it to treat a hand condition.

Use only a small amount of medicine. Apply a thin layer and rub in gently.

Right after applying Protopic ointment, you may need to use a moisturizing cream or lotion to keep your skin from getting too dry. Ask your doctor about which cream or lotion to use.

Do not cover treated skin with a bandage unless your doctor tells you to.

Do not bathe, shower, or swim right after applying Protopic ointment. Water may wash off the medicine.

Protopic is not for long-term use. Stop using this medicine when symptoms of eczema clear up, unless your doctor has told you otherwise. You may need to take a short break from using Protopic if you need to repeat this treatment.

Call your doctor if:

- your symptoms get worse or do not improve after 6 weeks;
- you get viral infections more easily, such as chickenpox or herpes (cold sores or shingles); or
- your symptoms return after treatment with Protopic ointment.

Store tightly closed at room temperature, away from moisture and heat.

### **Dosing information**

#### **Usual Adult Dose for Atopic Dermatitis:**

Apply a thin layer to the affected areas 2 times a day and rub in gently and completely; discontinue use when symptoms resolve

#### **Usual Pediatric Dose for Atopic Dermatitis:**

Less than 2 years: Safety and efficacy have not been established

#### 2 to 15 years:

0.03% ointment: Apply a thin layer to the affected areas 2 times a day and rub in gently and completely; discontinue use when symptoms resolve

0.1% ointment: Safety and efficacy have not been established

#### 16 years and older:

0.03 or 0.1% ointment: Apply a thin layer to the affected areas 2 times a day and rub in gently and completely; discontinue use when symptoms resolve

#### Comments:

-If itch, rash, and redness do not improve within 6 weeks, patients should be re-examined by their healthcare provider to confirm the diagnosis of atopic dermatitis. -Children aged 2 to 15 years should only receive the 0.03% formulation of this drug.

Use: As second-line therapy for the short-term and noncontinuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised patients who have failed to respond adequately to other topical treatments, or when those treatments are not advisable

Detailed Protopic dosage information

### What happens if I miss a dose?

Apply the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not apply two doses at one time.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222 if anyone has accidentally swallowed the medicine.

### What should I avoid while using Protopic?

Avoid getting this medicine in your eyes or mouth. Rinse with water if this medicine gets in your eyes or mouth.

Avoid sunlight, tanning beds, and phototherapy treatments with ultraviolet light. Wear loose clothing over treated skin. Ask your doctor before using sunscreen on treated skin.

Do not share this medicine with another person, even if they have the same symptoms you have.

Avoid using other medications on the areas you treat with Protopic unless your doctor tells you to.

Drinking alcohol while using this medicine can cause flushing (sudden warmth, redness, or tingly feeling) on your skin or face.

### **Protopic side effects**

Get emergency medical help if you have **signs of an allergic reaction to Protopic**: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

#### Protopic may cause serious side effects. Call your doctor at once if you have:

- severe pain, burning, itching, or stinging;
- new or worsened skin symptoms (warts, unusual rash or skin lesions, blistering or oozing);
- a mole that has changed in size or color; or
- symptoms of a viral skin infection cold sores around your mouth, skin sores or blisters, scabs, itching, tingling.

#### Common Protopic side effects may include:

- burning, stinging, itching, or tingling of treated skin (especially during the first few days of treatment);
- · viral skin infection;
- your skin being more sensitive to hot or cold temperatures;
- acne, redness or crusting around your hair follicles;
- · upset stomach;
- headache, muscle pain;
- · runny or stuffy nose; or
- fever, chills, body aches, sore throat, cough, swollen glands.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

i Protopic side effects (more detail)

### Related/similar drugs

#### Rinvoq

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## What other drugs will affect Protopic?

Other drugs may interact with tacrolimus, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all other medicines you use.

Protopic drug interactions (more detail)

## Does Protopic interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Protopic
+
Enter a drug name
Add

## Ingredients

Active ingredient: tacrolimus, either 0.03% or 0.1%

**Inactive ingredients:** mineral oil, paraffin, propylene carbonate, white petrolatum, white wax, all-rac-a-tocopherol and butylhydroxytoluene.

### **Manufacturer**

LEO Laboratories Ltd., 285 Cashel Road, Dublin 12, Ireland

Distributed by LEO Pharma Inc., Seven Giralda Farms, Madison, NJ 07940, USA.

#### References

1. Protopic Product Label

## More about Protopic (tacrolimus topical)

- Check interactions
- · Compare alternatives
- Reviews (95)
- · Side effects
- Dosage information
- During pregnancy
- · Generic availability
- Drug class: miscellaneous topical agents
- Breastfeeding
- En español

#### **Professional resources**

- Protopic prescribing information
- Tacrolimus (Topical) (AHFS Monograph)

### Related treatment guides

• Atopic Dermatitis

### **Further information**

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Protopic ointment only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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#### **DRUG STATUS**

#### **Availability**

Rx Prescription only

#### **Pregnancy & Lactation**

ন্য Risk data available

### **CSA Schedule\***

N/A Not a controlled drug

#### **Approval History**

The Drug history at FDA

#### **User Reviews & Ratings**

7.1 / 10

95 Reviews

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