

1 **MEDICATION GUIDE**

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3 **PROTOPIC®** [pro-TOP-ik]
4 (tacrolimus)

5
6 Ointment 0.03%

7 Ointment 0.1%

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10 Read the Medication Guide every time you or a family member gets PROTOPIC Ointment. There may
11 be new information. This Medication Guide does not take the place of talking to your doctor about your
12 medical condition or treatment. If you have questions about PROTOPIC Ointment, ask your doctor or
13 pharmacist.

14 **What is the most important information I should know about PROTOPIC Ointment?**

16 The safety of using PROTOPIC Ointment for a long period of time is not known. A very small number
17 of people who have used PROTOPIC Ointment have had cancer (for example, skin or lymphoma).
18 However, a link with PROTOPIC Ointment has not been shown. Because of this concern:

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- 20 • Do not use PROTOPIC Ointment continuously for a long time.
 - 21 • Use PROTOPIC Ointment only on areas of your skin that have eczema.
 - 22 • Do not use PROTOPIC Ointment on a child under 2 years old.

23 **PROTOPIC Ointment comes in two strengths:**

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- 25 • Only PROTOPIC Ointment 0.03% is for use on children aged 2 to 15 years.
 - 26 • Either PROTOPIC Ointment 0.03% or 0.1% can be used by adults and children 16 years and older.

27 Talk to your doctor for more information.

28 **What is PROTOPIC Ointment?**

29 PROTOPIC Ointment is a prescription medicine used on the skin (topical) to treat eczema (atopic
30 dermatitis). PROTOPIC Ointment is in a class of medicines called topical calcineurin inhibitors. It is for
31 adults and children 2 years of age and older who do not have a weakened immune system. PROTOPIC
32 Ointment is used on the skin for short periods, and if needed, treatment may be repeated with breaks in
33 between.

34 PROTOPIC Ointment is for use after other prescription medicines have not worked for you, or if your
35 doctor recommends that other prescription medicines should not be used.

36 **Who should not use PROTOPIC Ointment?**

37 **PROTOPIC Ointment should not be used:**

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- 39 • on children younger than 2 years of age.
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 - 41 • if you are allergic to PROTOPIC Ointment or anything in it. See the end of this Medication
 - 42 Guide for a complete list of ingredients.
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What should I tell my doctor before starting PROTOPIC Ointment?

Before you start using PROTOPIC, you and your doctor should talk about all of your medical conditions, including if you:

- have a skin disease called Netherton’s syndrome (a rare inherited condition).
- have any infection on your skin including chicken pox or herpes.
- have been told you have a weakened immune system.
- are pregnant, breastfeeding, or planning to become pregnant.

Tell your doctor about all the medicines you take and skin products you use including prescription and nonprescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine.

How should I use PROTOPIC Ointment?

- Use PROTOPIC Ointment exactly as prescribed.
- Use PROTOPIC Ointment only on areas of your skin that have eczema.
- Use PROTOPIC Ointment for short periods, and if needed, treatment may be repeated with breaks in between.
- Stop PROTOPIC Ointment when the signs and symptoms of eczema, such as itching, rash, and redness go away, or as directed by your doctor.
- Follow your doctor’s advice if symptoms of eczema return after treatment with PROTOPIC Ointment.
- Call your doctor if :
 - your symptoms get worse with PROTOPIC Ointment.
 - you get an infection on your skin.
 - your symptoms do not improve after 6 weeks of treatment. Sometimes other skin diseases can look like eczema.

To apply PROTOPIC Ointment:

- Wash your hands before applying PROTOPIC.
- Apply a thin layer of PROTOPIC Ointment twice daily to the areas of skin affected by eczema.
- Use the smallest amount of PROTOPIC Ointment needed to control the signs and symptoms of eczema.

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- 2 • If you are a caregiver applying PROTOPIC Ointment to a patient, or if you are a patient who is
3 not treating your hands, wash your hands with soap and water after applying PROTOPIC. This
4 should remove any ointment left on the hands.
 - 5 • Do not bathe, shower, or swim right after applying PROTOPIC. This could wash off the
6 ointment.
 - 7 • You can use moisturizers with PROTOPIC Ointment. Make sure you check with your doctor
8 first about the products that are right for you. Because the skin of patients with eczema can be
9 very dry, it is important to keep up good skin care practices. If you use moisturizers, apply them
10 after PROTOPIC Ointment.
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13 **What should I avoid while using PROTOPIC Ointment?**

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- 15 • Do not use ultraviolet light therapy, sun lamps, or tanning beds during treatment with
16 PROTOPIC Ointment.
 - 17 • Limit sun exposure during treatment with PROTOPIC Ointment even when the medicine is not
18 on your skin. If you need to be outdoors after applying PROTOPIC Ointment, wear loose fitting
19 clothing that protects the treated area from the sun. Ask your doctor what other types of
20 protection from the sun you should use.
 - 21 • Do not cover the skin being treated with bandages, dressings or wraps. You can wear normal
22 clothing.
 - 23 • Avoid getting PROTOPIC Ointment in the eyes or mouth. Do not swallow PROTOPIC
24 Ointment. If you do, call your doctor.
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27 **What are the possible side effects of PROTOPIC Ointment?**

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29 **Please read the first section of this Medication Guide.**

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31 **The most common side effects** of PROTOPIC Ointment at the skin application site are stinging, burning,
32 or itching of the skin treated with PROTOPIC. These side effects are usually mild to moderate, are most
33 common during the first few days of treatment, and usually go away as your skin heals.

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35 **Other side effects** include acne, swollen or infected hair follicles, headache, increased sensitivity of the
36 skin to hot or cold temperatures, or flu-like symptoms such as the common cold and stuffy nose, skin
37 tingling, upset stomach, muscle pain, swollen glands (enlarged lymph nodes), or skin infections including
38 cold sores, chicken pox or shingles.

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40 Talk to your doctor if you have a skin infection or if side effects (for example, swollen glands) continue
41 or bother you.

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

45 These are not all the side effects with PROTOPIC Ointment. Ask your doctor or pharmacist for more
46 information.

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1 **How should I store PROTOPIC Ointment?**

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3 • Store PROTOPIC Ointment at room temperature (59° to 86°F). Do not leave PROTOPIC Ointment
4 in your car in cold or hot weather. Make sure the cap on the tube is tightly closed.

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6 • **Keep PROTOPIC Ointment and all medicines out of the reach of children.**

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9 **General advice about PROTOPIC Ointment**

10 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not
11 use PROTOPIC Ointment for a condition for which it was not prescribed. Do not give PROTOPIC
12 Ointment to other people, even if they have the same symptoms you have. It may not be right for them.

13 This Medication Guide summarizes the most important information about PROTOPIC Ointment. If you
14 would like more information, talk with your doctor.

15 Your doctor or pharmacist can give you information about PROTOPIC Ointment that is written for health
16 care professionals. For more information, you can also visit the PROTOPIC website at
17 www.protopic.com or call 1-800-727-7003.

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20 **What are the ingredients in PROTOPIC Ointment?**

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22 **Active Ingredient:** tacrolimus, either 0.03% or 0.1%

23 **Inactive Ingredients:** mineral oil, paraffin, propylene carbonate, white petrolatum and white wax.

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25 Marketed by:

26 Astellas Pharma US, Inc.

27 Deerfield, IL 60015-2548

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29 Manufactured by:

30 Astellas Pharma Manufacturing, Inc.

31 Grand Island, NY 14072

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33 This Medication Guide has been approved by the U.S. Food and Drug Administration

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35 Revised: January 2006