

# Brightside Specialty Pharmacy

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## Patient Education for TACROLIMUS 0.1% OINTMENT

Do not apply occlusive bandage unless directed. May cause photosensitive reactions Use sunscreen Apply a thin layer and rub in Not recommended when breast feeding Wash hands before and after using Not recommended for use in children < 2 yrs, unless directed Reduce or avoid alcohol consumption Dispense Medication Guide and explain to patient before use

Do not bandage unless told by doctor. Skin may be more prone to sunburn; Use sunscreen Apply a thin layer and rub in Not recommended when breast feeding Wash hands before and after using Unless MD directs, do not use in kids less than 2 Reduce or avoid drinking alcohol Before use, important to read the Medication Guide

### .....Education Section.....

#### **IMPORTANT:**

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

TACROLIMUS - TOPICAL

(tack-row-LEE-muss)

#### **COMMON BRAND NAME(S):**

Protopic

#### **WARNING:**

Patients have benefited from tacrolimus when it is used

correctly. Long-term safety for this drug is not known at this time. There have been rare reports of cancers (such as skin cancer, lymphoma) in patients using tacrolimus. It is not known whether tacrolimus caused these cancers when used on the skin. Further studies to determine the long-term safety of this product are ongoing. In the unlikely event that unusual lumps, swollen glands, or growths (especially on the skin) occur, contact your doctor right away.

The US Food and Drug Administration recommends the following: This drug should be used only if other drugs have failed or if other medications are not considered appropriate by your doctor. Tacrolimus should be used on the skin for short treatment periods only. If needed, treatment may be repeated with breaks in between. Use the smallest amount that will treat your condition properly, and apply only on the affected skin. Also, this medication should not be used by children younger than 2 years. As with all medications, discuss the risks, benefits, and proper use of this medication with your doctor.

#### **USES:**

This form of tacrolimus is used on the skin to treat a

skin condition called eczema (atopic dermatitis) in patients who

have not responded well to (or should not use) other eczema medications.

Eczema is an allergic-type condition that causes red, irritated, and itchy skin. This drug works by weakening the skin's defense (immune) system, thereby decreasing the allergic reaction and relieving the eczema. Tacrolimus belongs to a class of drugs known as topical calcineurin inhibitors (TCIs).

This medication is not recommended if you have a history of a certain rare genetic disorder (Netherton's syndrome). Also, this medication should not be used by anyone who has a weakened immune system (for example, following an organ transplant).

#### **OTHER USES:**

This section contains uses of this drug that are not

listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This medication may also be used for a certain skin condition that causes patchy loss of skin coloring (vitiligo).

#### **HOW TO USE:**

Read the Medication Guide provided by your

pharmacist before you start using tacrolimus and each time you get a refill. If you have any questions, consult your doctor or pharmacist.

Wash your hands with soap and water before using this medication. Apply a thin layer to the affected areas of skin, usually twice daily or as directed by your doctor. Rub the medication into the skin gently and completely. Wash your hands after using this product unless your hands are being treated. If your doctor recommends a moisturizer, apply it after this medication.

This product is for use on the skin only. Avoid getting this medication in your eyes or on the inside of your nose or mouth. If you do get the medication in those areas, flush with plenty of water. Do not apply this medication to open wounds or infected areas. Do not cover the treated area with plastic or waterproof bandages unless directed to do so by your doctor. Do not bathe, shower, or swim right after applying this medication. This could

wash it off the treated area.

Use this medication exactly as directed. Your doctor may instruct you to stop using it once your eczema has cleared and to start using it again if symptoms reappear. Consult your doctor for details.

Inform your doctor if your condition does not improve after 6 weeks of using this medication or if your condition worsens at any time.

Only the weakest product should be used by children 2 to 15 years old.

**SIDE EFFECTS:**

Stinging, burning, soreness, or itching in the

area of treated skin may occur during the first few days of treatment. Headache, acne, "hair bumps" (folliculitis), stomach upset, flu-like symptoms (such as fever, chills, runny nose, sore throat, muscle aches), or increased sensitivity of the skin to hot/cold/pain/touch may also occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: unusual tiredness, back/joint/muscle pain, appearance of any skin infections or sores (such as chicken pox, shingles, lip sores, tumors, warts), chest pain.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

**PRECAUTIONS:**

Before using tacrolimus, tell your doctor or

pharmacist if you are allergic to it; or to other macrolide medications (such as sirolimus); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: swollen lymph nodes (for example, due to lymphadenopathy, mononucleosis), use of light therapy (such as UVA or UVB), skin or other cancers, skin infections (such as herpes, shingles), other skin conditions, kidney disease.

This drug may make you more sensitive to the effects of

alcohol. Your face or skin may flush red and feel hot. Limit alcoholic beverages.

This medication may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors. Tell your doctor right away if you get sunburned or have skin blisters/redness.

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

It is unknown if this medication passes into breast milk.

Consult your doctor before breast-feeding.

**DRUG INTERACTIONS:**

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

**OVERDOSE:**

This medicine may be harmful if swallowed. If someone

has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center.

**NOTES:**

Do not share this medication with others. This drug

should be used as directed for treating your current condition only. Do not use it later for another condition unless told to do so by your doctor. A different medication may be necessary in that case.

Talk with your doctor about other ways to manage your eczema, such as using moisturizers and taking shorter baths/showers.

**MISSED DOSE:**

If you miss a dose, use it as soon as you remember.

If it is near the time of the next dose, skip the missed dose.

Use your next dose at the regular time. Do not double the dose to catch up.

**STORAGE:**

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Information last revised April 2022.

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