Tacrolimus

FDA approved for dermatologic use only

For Allergic Conjunctivitis

- Tacrolimus 0.03% ointment (Protopic or generic)
    - FDA approved for use on skin only, not approved for use in the eyes
    - Apply BID to the affected eyes for 4 weeks
    - Adverse Effects
        - Foreign body sensation
        - burning sensation
        - blurring of vision
    - Highly effective for allergic conjunctivitis refractory to topical antihistamine treatment
- Tacrolimus 0.1% drops
    - not yet available in the US for human consumption unless compounded
    - available for animals

Black Box Warning

Long-term Safety of Topical Calcineurin Inhibitors Has Not Been Established

Although a causal relationship has not been established, rare cases of malignancy (e.g., skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors, including PROTOPIC Ointment.

Therefore: Continuous long-term use of topical calcineurin inhibitors, including PROTOPIC Ointment, in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis.

PROTOPIC Ointment is not indicated for use in children less than 2 years of age. Only 0.03% PROTOPIC Ointment is indicated for use in children 2-15 years of age.

Resources

- **FDA package insert for Tacrolimus**
- Hazarika AK et al. Efficacy of topical application of 0.03% tacrolimus eye ointment in the management of allergic conjunctivitis. J Natural Science, Biology and Medicine 2015;6(1):S10-12

- Fukushima A et al. Therapeutic effects of 0.1% tacrolimus eye drops for refractory allergic ocular diseases with proliferative lesion or corneal involvement. Br J Ophthalmology 2014;98-1023-1027
- Yazu H et al. Long-term outcomes of 0.1% tacrolimus eye drops in eyes with severe allergic conjunctival diseases. Allergy, Asthma &Clinical Immunology 2021;17(11)

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