

# ATOLIMUS<sup>®</sup> 0.03% & 0.1%

Tacrolimus Ointment

## MECHANISM OF ACTION:

Tacrolimus ointment suppresses the immune system and the inflammation by inhibiting an enzyme (calcineurin) crucial for the multiplication of T-cells which are required for activation of the immune system. By inhibiting T-cell activation and cytokine production, topically applied tacrolimus modulates inflammatory responses in the skin.

Tacrolimus prevents the dephosphorylation of NF-AT (nuclear factor of activated T-cells). Tacrolimus inhibits T-lymphocyte activation by first binding to an intracellular protein, FKBP-12 (FK Binding Protein). A complex of tacrolimus-FKBP-12, calcium, calmodulin, and calcineurin is then formed and the phosphatase activity of calcineurin is inhibited. This effect has been shown to prevent the dephosphorylation and translocation of NF-AT, a nuclear component thought to initiate gene transcription for the formation of lymphokines (such as interleukin-2, gamma interferon).

## INDICATION:

Atolimus is a topical immunomodulator that acts at the site of the immune imbalance to stop the redness & itching of skin inflammation.

- Tacrolimus ointment 0.1% and 0.03% ointment can be used for the treatment of moderate to severe **Atopic eczema** that is unresponsive to conventional therapy.
- Topical tacrolimus is safe therapeutic option for **Psoriasis**; especially on facial, intertriginous and genital areas.
- Effective for the **Vitiligo** treatment; successful treatment is possible when combined with other therapy like narrow-band UVB, microtherapy.

## DOSAGE AND ADMINISTRATION:

Children aged 2-15 are prescribed 0.03% concentration while those 16 and above may use the 0.1% formulation.

This topical prescription therapy should be applied twice a day or as prescribed by physician.

- **ADULT** over 16 years initially apply 0.1% ointment thinly twice daily until lesion clears (consider other treatment if eczema worsens or no improvement after 2 weeks); reduce to once daily or switch to 0.03% ointment if condition allows; **CHILD** 2-16 years, initially apply 0.03% ointment thinly twice daily for up to 3 weeks then reduce to once daily until lesion clears

## Direction for use:

- Hands should be washed before applying ATOLIMUS.
- Apply a thin layer of ATOLIMUS Ointment twice daily or as prescribed by physician.
- While applying the ointment rub gently and effectively to the affected area.
- ATOLIMUS Ointment should be used exactly as prescribed.
- ATOLIMUS Ointment should be used only on areas of skin that have been affected.

## SIDE EFFECTS:

Redness, burning, itching, allergic reactions, headache may occur.

## PRECAUTION:

### Pregnancy:

Pregnancy Category C. Should only be used during pregnancy if the potential benefit to mother justifies a potential risk to the fetus.

### Nursing Mothers:

Tacrolimus is excreted in mother milk. Because of the potential for serious adverse reactions in nursing infants from tacrolimus, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### Pediatric Use:

ATOLIMUS Ointment is not indicated for children less than 2 years of age.

## CONTRAINDICATION:

ATOLIMUS Ointment is contraindicated in patients with a history of hypersensitivity to tacrolimus.

## FINDINGS:

- Topical tacrolimus is a promising tool which is expected as a useful and safe therapeutic option for psoriasis, especially on the facial, intertriginous and genital areas (Toshiyuki Yamamoto; Topical Tacrolimus for Psoriasis; The Open Allergy Journal, 2009, 2, 51-55 Department of Dermatology, Fukushima Medical University, Fukushima, Japan).

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- Topical tacrolimus ointment is an effective alternative therapy for childhood vitiligo, particularly involving the head and neck. (J Am Acad Dermatol 2004;51 :760-6.)
- Tacrolimus ointment is a safe therapy for the treatment of adult patients with atopic dermatitis on the face, neck, or other body regions. (J Am Acad Dermatol 2001;44: S39-46.)

## PRESENTATION:

15 gram tube

Manufactured by:

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