Remus®

Tacrolimus Ointment

COMPOSITION
Remus® 0.03% Ointment: Each gram ointment contains Tacrolimus USP 0.3 mg.
Remus® 0.1% Ointment: Each gram ointment contains Tacrolimus USP 1 mg.

PHARMACOLOGY
The mechanism of action of Tacrolimus in atopic dermatitis is not known. It has been demonstrated that Tacrolimus inhibitis T-lymphocyte activation by binding to an intracellular protein, FKBP-12. 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 nuclear factor of activated T-cells. Tacrolimus also inhibits the transmission for genes which encode IL-3, IL-4, IL-5, GM-CSF and TNF-alfa, all of which are involved in the early stages of T-cell activation. Additionally Tacrolimus has been shown to inhibit the release of preformed mediators from skin mast cells and basophils, and to downregulate the expression of FeeRI on Langerhans cells.

INDICATION
Remus® (Tacrolimus USP) ointment, both 0.03% and 0.1% for adults, and only 0.03% for children aged 2 to 15 years, is indicated for short-term and intermittent long-term therapy in the treatment of patients with moderate to severe atopic dermatitis / vitiligo.

DOSAGE AND ADMINISTRATION
Short-term treatment: for ADULT & CHILD 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. For CHILD 2-16 years, initially apply 0.03% ointment thinly twice daily for up to 3 weeks (consider other treatment if eczema worsens or if no improvement after 2 weeks) then reduce to once daily untill lesion clears.
Prevention of flares: for ADULT & CHILD over 16 years, apply 0.1% ointment thinly twice weekly; use short-term treatment regimen during an acutre flare; review need for preventive therapy after 1 year. For CHILD 2-16 years, apply 0.03% ointment thinly twice weekly; use short-term treatment regimen during an acutre flare; interrupt preventive therapy after 1 year to reassess condition.

CONTRAINDICATION AND PRECAUTION
Tacrolimus ointment is contraindicated in patients with a history of hypersensitivity to Tacrolimus or any other components of the preparation.
The use of Tacrolimus ointment in patients with Netherton's Syndroms is not recommended due to the potential for increased systemic absorption of Tacrolimus. The safety of Tacrolimus ointment has not been established in patients with generalized erythroderma.

SIDE EFFECT
No phototoxicity and no photoallergenicity are detected in the patient using Tacrolimus. However, Skin Burning, Pruritus, allergic reaction may occur in the patient of Tacrolimus. Other adverse events are anaphylactoid reaction, angioedema, anorexia, anxiety.

DRUG INTERACTION
Formal topical drug interaction studies with Tacrolimus ointment have not been conducted. Based on its minimal extent of absorption, interactions of Tacrolimus ointment with systemically administered drugs are unlikely to occur but cannot be ruled out. The concomitant administration of known CYP3A4 inhibitors in patients with widespread and/or erythrodermic disease should be done with caution. Some examples of such drugs are erythromycin, itraconazole, ketoconazole, fleoconazole, calcium channel blockers and cimetidine.

WARNING
Long-term safety of topical calcineurin inhibitors has not been established (beyond 1 year of non-continuous use). 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 Tacrolimus. Therefore, continuous long-term use of topical calcineurin inhibitors, including Tacrolimus, in any age group should be avoided and application limited to areas of involvement with atopic dermatitis. The diagnosis of atopic dermatitis should be confirmed if signs and symptoms do not improve within 6 weeks.

USE IN PREGNANCY AND LACTATION
There are no adequate and well-controlled studies of topically administered Tacrolimus in pregnant women. The experience with Tacrolimus ointment when used by pregnant women is too limited to permit assessment of the safety of its use during pregnancy.

Although systemic absorption of Tacrolimus following topical applications of Tacrolimus ointment is minimal relative to systemic administration, it is known that Tacrolimus is excreted to human 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 the drug to the mother.

STORAGE CONDITION
Store below 25°C in dry place. Keep away from light.
Keep out of reach of children.

HOW SUPPLIED
Remus® 0.03% Ointment: Each pack has a tube containing 5/10 gm ointment.
Remus® 0.1% Ointment: Each pack has a tube containing 5/10 gm ointment.

SQUARE