Remus®

Tacrolimus INN

COMPOSITION

Remus® 0.03% Ointment: Each gram ointment contains Tacrolimus INN 0.3 mg.
Remus® 0.1% Ointment: Each gram ointment contains Tacrolimus INN 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.

INDICATION

Remus® (Tacrolimus INN) 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.

DOSAGE AND ADMINISTRATION

For both adults & children, apply a thin layer of ointment to the affected skin twice daily. The minimum amount should be rubbed gently and completely to control signs and symptoms of atopic dermatitis. Stop using when signs and symptoms of atopic dermatitis resolve.

The safety of Tacrolimus ointment under occlusion, which may promote systemic exposure, has not been evaluated. Tacrolimus ointment should not be used with occlusive dressings.

CONTRAINDICATION

Tacrolimus ointment is contraindicated in patients with a history of hypersensitivity to the preparation.

PRECAUTION

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.

ADVERSE 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

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, fluconazole, calcium channel blockers and cimetidine.

USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies of topically administered Tacrolimus in pregnant women. It is known that Tacrolimus may be 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

Store in a cool & dry place, protected from light & moisture. Do not freeze. Keep all medicines out of the reach of children.

HOW SUPPLIED

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

Manufactured by :
SQUARE
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