Remus®

Tacrolimus

COMPOSITION

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

PHARMACOLOGY

The mechanism of action of Tacrolimus 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) 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 and vitiligo.

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. Stop using when signs and symptoms resolve.
The safety of Tacrolimus ointment under occlusion, which may promote systemic exposure, has not
been evaluated. So, this 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 using Tacrolimus.
Other adverse events are anaphylactic 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 discontinue the drug to the mother.

STORAGE

Store below 250
C temperature, protected from light & moisture. Do not freeze. Keep all
medicines out of the reach of children.

HOW SUPPLIED

Remus® 0.03% Ointment (10 gm): Each pack has a tube containing 10 gm ointment.
Remus® 0.1% Ointment (10 gm): Each pack has a tube containing 10 gm ointment. Remus® 0.1%.
Remus® 0.1% Ointment (30 gm): Each pack has a alu tube containing 30 gm ointment.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH