Rolimus®

Tacrolimus

Description: Rolimus® is a preparation of Tacrolimus which works as an immunosuppressant. It is for topical dermatologic use only.

Mode of action: The exact mechanism of action of Tacrolimus is not known. It has been demonstrated that Tacrolimus inhibits 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 inhibited. This effect may prevent the dephosphorylation and translocation of nuclear factor of activated T-cells. Tacrolimus prolongs the survival of the host and transplanted graft in animal transplant models of liver, kidney, heart, bone marrow, small bowel and pancreas, lung and trachea, skin, cornea, and limb.

Composition:
Rolimus® 0.03% Ointment: Each gram ointment contains Tacrolimus Monohydrate USP 0.306 mg equivalent to Tacrolimus 0.3 mg.
Rolimus® 0.1% Ointment: Each gram ointment contains Tacrolimus Monohydrate USP 1.02 mg equivalent to Tacrolimus 1 mg.

Indications: Rolimus® ointment is indicated for short-term and intermittent long-term therapy in the treatment of patients with moderate to severe atopic dermatitis. **Rolimus®** Ointment is also indicated in other skin conditions such as chronic cutaneous graft-vs-host disease, hand and foot eczema, allergic contact dermatitis, psoriasis, lichen planus, facial lichen, vulvar lichen sclerosis, pyoderma gangrenosum, leg ulcers in rheumatoid arthritis, steroid-induced rosacea & alopecia areata, annular erythema, chronic actinic dermatitis and recalcitrant facial erythema.

Dosage & Administration: Apply a thin layer of **Rolimus®** ointment onto the affected skin areas twice daily, rub in gently and completely. Treatment should be continued for one week after clearing of signs and symptoms of atopic dermatitis.

Contraindications: Tacrolimus ointment is contraindicated in patients with a history of hypersensitivity to Tacrolimus.

Side Effects: Transient burning or heat sensation, skin erythema, flu-like symptoms, headache and skin infection. It does not cause skin atrophy despite prolonged application.

Use in Pregnancy & Lactation: There are no adequate and well-controlled studies of topically administered Tacrolimus in pregnant women. It is known that Tacrolimus is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants, decision should be made according to risks benefit ratio.

Precautions: It is recommended for topical use only. The safety of Tacrolimus ointment has not been established in patients with generalized erythroderma.

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.

Overdose: Rolimus® ointment is not for oral use. If oral ingestion occurs, medical advice should be sought.

Storage: Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging:
Rolimus® 0.03% Ointment: Each pack has a tube containing 10 gm.
Rolimus® 0.1% Ointment: Each pack has a tube containing 10 gm.

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Opsonin Pharma
Ideas for healthcare

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