Presentation

Tacroderm Ointment: Each gram ointment contains Tacrolimus Monohydrate USP equivalent to 1 mg Tacrolimus.

Pharmacology

Tacrolimus is a macrolide immunomodulator produced by Streptomyces tsukubaensis. It has been demonstrated that Tacrolimus inhibits T-lymphocyte activation by first 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 leads to a general decrease in the entire inflammatory cascade.

Indications

Tacroderm ointment is indicated for short-term and intermittent long-term therapy in the treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative, conventional therapies are deemed inadvisable because of potential risks, or in the treatment of patients who are not adequately responsive to or are intolerant of alternative, conventional therapies. Tacroderm ointment is also indicated in other skin conditions such as vitiligo, chronic cutaneous graft-vs-host disease, hand and foot eczema, allergic contact dermatitis, psoriasis, lichen planus, facial lichen, vulvar lichen sclerosus, pyoderma gangrenosum, leg ulcers in rheumatoid arthritis, steroid-induced rosacea & alopecia areata, annular erythema, chronic actinic dermatitis and recalcitrant facial erythema.

Dosage and Administration

Apply a thin layer of Tacroderm ointment onto the affected skin areas twice daily and rub gently and completely. Treatment should be continued for one week after clearing of signs and symptoms of atopic dermatitis. 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.

Side Effects

Transient burning or heat sensation at the site of application is frequently observed. It tends to decrease after repeated applications. Other side-effects include skin erythema, flu-like symptoms, headache and skin infection. It does not cause skin atrophy despite prolonged application.

Contraindications

Tacrolimus should not be applied to eczema that is infected, or to skin affected by viral infections such as Herpes simplex (cold sores) or Herpes zoster (chicken pox), because it may make these infections worse. Tacrolimus should not be used by pregnant women. It is not recommended for breast feeding women, and should be used with caution in people who have liver failure.

Drug Interactions

Formal topical drug interaction studies with Tacrolimus ointment have not been conducted. The concomitant administration of known CYP3A4 inhibitors in patients with wide spread and erythrodermic

disease should be done with caution. Some examples of such drugs are Erythromycin, Itraconazole, Ketoconazole, Fluconazole, Calcium Channel Blockers and Cimetidine.

Precautions

It should not be used by people allergic to macrolide-type medicines, which include the antibiotics Erythromycin, Clarithromycin and Azithromycin.

Over dosage

Tacrolimus ointment is not for oral use. Accidental oral ingestion of Tacrolimus ointment may lead to adverse effects associated with systemic administration of Tacrolimus. If oral ingestion occurs, medical advice should be sought.

Use in Pregnancy and Lactation

There is 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 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.

Pharmaceutical Precautions

Store at below 30^{o}C in a dry place protected from light. Keep out of reach of children.

Commercial Pack

Tacroderm Ointment: Each pack has a laminated tube containing 5 g ointment.