

TACROTOR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for Tacrotor [Tacrolimus Ointment]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The mechanism of action of tacrolimus in atopic dermatitis is not fully understood. While the following have been observed, the clinical significance of these observations in atopic dermatitis is not known. Via its binding to a specific cytoplasmic immunophilin (FKBP12), tacrolimus inhibits calcium-dependent signal transduction pathways in T cells, thereby preventing the transcription and synthesis of IL-2, IL-3, IL-4, IL-5 and other cytokines such as GM-CSF, TNF- α and IFN- γ .

INDICATIONS: For treatment of patients with moderate to severe atopic dermatitis in whom the use of alternative conventional therapy is advisable..

DOSAGE AND ADMINISTRATION: Tacrotor Ointment should be applied as a thin layer to affected or commonly affected areas of the skin. Tacrotor Ointment may be used on any part of the body, including face, neck and flexure areas, except on mucous membranes. Tacrotor Ointment should not be applied under occlusion because this method of administration has not been studied in patients

CONTRAINDICATION: Hypersensitivity to the active substance, macrolides in general, or to any of the excipients

WARNINGS & PRECAUTIONS: Patients with atopic dermatitis treated with tacrolimus have not been found to have significant systemic tacrolimus levels and the role of local immunosuppression is unknown. The use of tacrolimus ointment is not recommended in patients with a skin barrier defect, such as Netherton's syndrome, lamellar ichthyosis, generalized erythroderma, pyoderma gangrenosum, or cutaneous Graft Versus Host Disease

DRUG INTERACTIONS:: Tacrolimus is not metabolised in human skin, indicating that there is no potential for percutaneous interactions that could affect the metabolism of tacrolimus

ADVERSE REACTIONS: Local skin infection regardless of specific, aetiology including but not limited to: Eczema herpeticum, Folliculitis, Herpes simplex, Herpes virus infection, Kaposi's varicelliform eruption, Ophthalmic Herpes Infection, Alcohol intolerance (facial flushing or skin irritation after consumption of an alcoholic beverage, Paraesthesias and dysaesthesias (hyperaesthesia, burning sensation), pruritus, acne, rosacea lentigo, application site burning, warmth, erythema, pain, irritation, parathesia, rash, oedema, drug level increased.

MARKETED BY:

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(Additional information is available on request)