TACROTOR®

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
Abbreviated Prescribing information for TACROTOR® (Tacrolimus Ointment 0.1% and 0.03%)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: It is an Immunosuppressant agent.

INDICATION: 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 not indicated because of potential risks, or in the treatment of patients who are not adequately responsive to or are intolerant of alternative, conventional therapies. Either strength (0.03% and 0.1%) of Tacrotor® can be used in adults, but only the 0.03% strength is indicated in children aged 2 to 15 years.

DOSAGE AND ADMINISTRATION: Adults: Apply a thin layer of Tacrotor® 0.03% or 0.1% to the affected skin areas twice daily. Treatment should be continued for one week after clearing of signs and symptoms of atopic dermatitis. Children: Apply a thin layer of Tacrotor® 0.03% to the affected skin areas twice daily and rub in gently and completely. Treatment should be continued for one week after clearing of signs and symptoms of atopic dermatitis. Tacrotor® 0.03% and 0.1% should not be used with occlusive dressings.

CONTRAINDICATION: History of hypersensitivity to tacrolimus or any other component of the preparation.

WARNINGS & PRECAUTIONS: Not for ophthalmic, oral or intravaginal use. In patients with atopic dermatitis predisposed to superficial skin infections including eczema herpeticum (Kaposi's varicelliform eruption), treatment with Tacrotor® may be associated with an increased risk of varicella zoster virus infection (chicken pox or shingles), herpes simplex virus infection, or eczema herpeticum. It is not recommended in patients with Netherton's Syndrome. Vaccination failure: vaccination should be administered prior to commencement of treatment, or during a treatment-free interval with a period of 14 days between the last application of Tacrotor® and the vaccination.

Drug Interactions: 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.)

ADVERSE REACTIONS: Skin burning, pruritus, flu-like symptoms, allergic reaction, skin erythema, headache, skin infection, fever, infection, cough increased, asthma, herpes simplex, eczema herpeticum, pharyngitis, folliculitis, sinusitis, rash, acne, dyspepsia, vesiculobullous rash, skin tingling, dyspepsia, Hyperesthesia, Back Pain, Myalgia, cyst, bronchitis, insomnia, gastroenteritis, lymphadenopathy, anaphylactoid reaction, angina pectoris, cerebrovascular accident, arrhythmia and dysmenorrhea.

MARKETED BY:

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IN/ TACROTOR® 0.03%, 0.1%/FEB 2015/01/AbPI
(Additional information is available on request)