1.6.3 PATIENT INFORMATION LEAFLET (PIL)

TACROVATE FORTE OINTMENT (Tacrolimus Ointment 0.1% w/w)

Read all of this leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you only.
Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
If you get any side effects, talk to your doctor or pharmacist.
This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

1. WHAT IS TACROVATE FORTE OINTMENT AND WHAT IT IS USED FOR

Tacrolimus forte Ointment is indicated in adults, adolescents and children from the age of 2 years.
Adults and adolescents (16 years of age and above)
Treatment of moderate to severe atopic dermatitis in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids.
Children (2 years of age and above)
Treatment of moderate to severe atopic dermatitis in children who failed to respond adequately to conventional therapies such as topical corticosteroids.
Maintenance treatment
Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily TACROVATE FORTE OINTMENT (lesions cleared, almost cleared or mildly affected).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TACROVATE FORTE OINTMENT

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

Warnings and precautions

Exposure of the skin to sunlight should be minimised and the use of ultraviolet (UV) light from a solarium, therapy with UVB or UVA in combination with psoralens (PUVA) should be avoided

during use of Tacrolimus ointment. Physicians should advise patients on appropriate sun protection methods, such as minimisation of the time in the sun, use of a sunscreen product and covering of the skin with appropriate clothing. TACROVATE FORTE OINTMENT should not be applied to lesions that are considered to be potentially malignant or pre-malignant.
The development of any new change different from previous eczema within a treated area should be reviewed by the physician.
The use of TACROVATE FORTE OINTMENT is not recommended in patients with a skin barrier defect, such as Netherton's syndrome, lamellar ichthyosis, generalized erythroderma or cutaneous Graft Versus Host Disease. These skin conditions may increase systemic absorption of tacrolimus. Oral use of tacrolimus is also not recommended to treat these skin conditions. Post-marketing cases of increased tacrolimus blood level have been reported in these conditions.
Care should be exercised if applying TACROVATE FORTE OINTMENT to patients with extensive skin involvement over an extended period of time, especially in children. Patients, particularly paediatric patients should be continuously evaluated during treatment with TACROVATE FORTE OINTMENT with respect to the response to treatment and the continuing need for treatment. After 12 months this evaluation should include suspension of TACROVATE FORTE OINTMENT treatment in paediatric patients.
The potential for local immunosuppression (possibly resulting in infections or cutaneous malignancies) in the long term (i.e. over a period of years) is unknown.
TACROVATE FORTE OINTMENT contains the active substance tacrolimus, a calcineurin inhibitor. In transplant patients, prolonged systemic exposure to intense immunosuppression following systemic administration of calcineurin inhibitors has been associated with an increased risk of developing lymphomas and skin malignancies. In patients using tacrolimus ointment, cases of malignancies, including cutaneous (i.e. cutaneous T Cell lymphomas) and other types of lymphoma, and skin cancers have been reported Tacrolimus forte Ointment should not be used in patients with congenital or acquired immune deficiencies or in patients on therapy that cause immunosuppression.
Patients with atopic dermatitis treated with TACROVATE FORTE OINTMENT have not been found to have significant systemic tacrolimus levels.
Lymphadenopathy was uncommonly (0.8%) reported in clinical trials. The majority of these cases were related to infections (skin, respiratory tract, and tooth) and resolved with appropriate antibiotic therapy. Transplant patients receiving immunosuppressive regimens (e.g. systemic tacrolimus) are at increased risk for developing lymphoma; therefore patients who receive TACROVATE FORTE OINTMENT and who develop lymphadenopathy should be monitored to ensure that the lymphadenopathy resolves. Lymphadenopathy present at initiation of therapy should be investigated and kept under review. In case of persistent lymphadenopathy, the aetiology of the lymphadenopathy should be investigated. In the absence of a clear aetiology for the lymphadenopathy or in the presence of acute infectious mononucleosis, discontinuation of TACROVATE FORTE OINTMENT should be considered.
The effect of treatment with TACROVATE FORTE OINTMENT on the developing immune system of children aged below 2 years has not been established.
TACROVATE FORTE OINTMENT has not been evaluated for its efficacy and safety in the treatment of clinically infected atopic dermatitis. Before commencing treatment with Tacrolimus ointment, clinical infections at treatment sites should be cleared. Patients with atopic dermatitis are predisposed to superficial skin infections. Treatment with TACROVATE FORTE OINTMENT may be associated with an increased risk of folliculitis and herpes viral infections

(herpes simplex dermatitis [eczema herpeticum], herpes simplex [cold sores], Kaposi's varicelliform eruption). In the presence of these infections, the balance of risks and benefits associated with TACROVATE FORTE OINTMENT use should be evaluated.
Emollients should not be applied to the same area within 2 hours of applying Tacrolimus Ointment. Concomitant use of other topical preparations has not been assessed. There is no experience with concomitant use of systemic steroids or immunosuppressive agents.
Care should be taken to avoid contact with eyes and mucous membranes. If accidentally applied to these areas, the ointment should be thoroughly wiped off and/or rinsed off with water.
The use of TACROVATE FORTE OINTMENT under occlusion has not been studied in patients. Occlusive dressings are not recommended.
As with any topical medicinal product, patients should wash their hands after application if the hands are not intended for treatment.
Tacrolimus is extensively metabolised in the liver and although blood concentrations are low following topical therapy, the ointment should be used with caution in patients with hepatic failure.

3. HOW TO USE TACROVATE FORTE OINTMENT

Always use this medicine exactly as your doctor has told you.
Check with your doctor or pharmacist if you are not sure.

The recommended dose is:
A pea-sized amount of TACROVATE FORTE OINTMENT should be applied once daily at bedtime.

Method of administration
Wash your face gently with mild soap and warm water and pat your skin dry with a towel. Squeeze a pea-sized amount of Ointment onto the fingertip. Dab the Ointment on your forehead, chin, nose and both cheeks, and then gently spread it evenly over your whole face.
Do not use more than the amount that has been suggested by your doctor, or apply the product more frequently than instructed. Too much medication may irritate the skin, and will not give faster or better results.

Duration of treatment
To get the best results with TACROVATE FORTE OINTMENT, it is necessary to use it properly and not stop using it as soon as your acne starts to get better. Typically, it may take several weeks to have an optimal effect. In some cases, it may take up to 12 weeks. Please contact your doctor if symptoms persist for more than 12 weeks, as your doctor will need to re-evaluate your treatment.

4. POSSIBLE SIDE EFFECTS

Skin burning. Pruritus. Skin erythema (approximately 50% in trials though there is a marked decrease within several days with continued use) Skin tingling. Folliculitis. Herpes simplex (herpes, cold sores, eczemaherpeticum [Kaposi's varicelliform eruption]). Hyperaesthesia (increased skin sensitivity, especially to hot and cold).Alcohol intolerance (facial flushing or skin

irritation after consumption of alcohol). Acne. Rosacea. Lymphadenopathy has been reported rarely Pimecrolimus Application site reactions - irritation, pruritus and erythema. Skin infections - folliculitis.Alcohol intolerance (facial flushing or skin irritation after consumption of alcohol). Furuncle. Impetigo.Herpes simplex, herpes zoster, herpes simplex dermatitis (eczema herpeticum). Molluscum contagiosum. Skin papilloma. Application site disorders (rash, pain, paraesthesia, desquamation, dryness, oedema, aggravated eczema)

5. HOW TO STORE TACROVATE FORTE OINTMENT

Keep this medicine out of the sight and reach of children.
Store below 30^0 C. Protect from Light.
Keep the tube tightly closed.
Do not use this medicine after the expiry date which is stated on the carton and tube after "EXP". The expiry date refers to the last day of that month.
Once opened use within 3 months.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

6. FURTHER INFORMATION

What TACROVATE FORTE OINTMENT contains
• The active substances are Tacrolimus USP. Each gm. ointment contains 1.0 mg Tacrolimus USP.
• The other ingredients are Cetostearyl Alcohol BP, Cetomacrogol 1000 IHS, Light liquid paraffin BP, Butylated Hydroxytoluene BP & White soft paraffin BP.

7. What TACROVATE FORTE OINTMENT looks like and contents of the pack.

TACROVATE FORTE OINTMENT is a white to off white ointment, free from grittiness TACROVATE FORTE OINTMENT is available in Lami Tube containing 10g.

8. Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Ochoa Laboratories
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8 Date of Revision of PIL