Front

TACGRAF®
(T a c r o l i m u s)

ٹیک گراف

COMPOSITION:
TACGRAF Capsule 0.5 mg:
Each capsule contains:
Tacrolimus Monohydrate USP equivalent to
Tacrolimus ..... 0.5 mg.

Product Specs.: CCL Pharmaceuticals

TACGRAF Capsule 1 mg:
Each capsule contains:
Tacrolimus Monohydrate USP equivalent to
Tacrolimus ..... 1 mg.

Product Specs.: CCL Pharmaceuticals

TACGRAF Capsule 5 mg:
Each capsule contains:
Tacrolimus Monohydrate USP equivalent to
Tacrolimus ..... 5 mg.

Product Specs.: CCL Pharmaceuticals

DRUG DESCRIPTION:
Tacrolimus is an immunosuppressive drug whose main use is after allogenic organ transplant to reduce the activity of the patient's immune system and so lower the risk of organ rejection. It reduces T-cell and interleukin-2 (IL-2) activity.

PHARMACOKINETICS:
Tacrolimus inhibits T-lymphocyte activation, although the exact mechanism of action is not known. Tacrolimus bind to cytosolic receptors known as immunophilins (i.e., cyclophilin and FK binding protein-12 [FKBP-12], respectively), forming complexes that inhibit the production of cytokines via the calcineurin pathway. Inhibition of calcineurin activity inhibits early activation of T-cells (i.e. immunosuppresion results).
Absorption: Incomplete and variable. Food decreases both rate and extent of Tacrolimus absorption.
Distribution: 99% bound to plasma protein, mainly to albumin and alpha-1-acid glycoprotein, and has a high level of association with erythrocytes.
Metabolism: Extensively metabolized by cytochrome P-450 system (CYP3A) primarily.
Excretion: It is excreted mainly through feces but small amount is also excreted through urine.

INDICATIONS:
Prophylaxis of graft rejection, in allogenic liver, kidney or heart transplantation.

ADVERSE REACTIONS:
Systemic: Tremor, headache, paraesthesias, nausea and diarrhoea, hypertension, blood dyscrasias, leucocytosis, impaired renal function, serum electrolyte disturbances, infectious complications. Mood changes, sleep disturbances, confusion, dizziness, tinnitus, visual disturbances convulsions, alterations in glucose metabolism, ECG changes, tachycardia, myocardial hypertrophy, constipation, dyspepsia and GI haemorrhage; dyspnoea, asthma, pleural effusions; alopoecia, hirsutism, skin rash and pruritus; myalgia, spasm, leg cramps, peripheral oedema, liver dysfunction and coagulation disorders.
Potentially fatal: Nephrotoxicity, neurotoxicity and anaphylactic reaction.

PRECAUTIONS:
Hypertension is a common adverse effect of Tacrolimus therapy. Mild or moderate hypertension is more frequently reported than severe hypertension. Antihypertensive therapy may be required; the control of blood pressure can be accomplished with any of the common anti hypertensive agents. Since Tacrolimus may cause hyperkalemia, potassium-sparing diuretics should be avoided. While calcium-channel blocking agents can be effective in treating Tacrolimus-associated hypertension, care should be taken since interference with Tacrolimus metabolism may require a dosage reduction.
Special Precautions: Monitoring of blood trough serum concentrations to prevent organ rejection and to reduce drug-related toxicity. Delay use in patients with unknown cause of lymphadenopathy or acute infectious mononucleosis till resolution. Use in patients with Netherton's syndrome is not recommended.

OTHER DRUG INTERACTIONS:
Increased nephrotoxicity with cyclosporine, aminoglycosides, amphotericin B, cisplatin, NSAIDs, vancomycin, co-trimoxazole, aciclovir, ganciclovir. Increased risk of hyperkalemia with potassium-sparing diuretics. Increased plasma concentrations and toxicity with azole antifungals, calcium-channel blockers, cimetidine, danazol, HIV-protease inhibitors, macrolide antibacterials and metoclopramide. Antacids, rifampin, rifabutin, casofungin, phenytoin, phenobarbital and carbamazepine decrease Tacrolimus plasma concentrations. Concurrent administration of sirolimus and Tacrolimus decrease levels of both.
Other interactions:

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Food interaction:
Food decreases rate and extent of absorption. Grapefruit and pomelo juice may increase the serum levels.
DOSAGE:
Prevention of rejection in kidney graft transplant:
Adult: Initially, 0.2-0.3 mg/kg/day in 2 divided doses every 12 hrs. Begin oral dose within 24 hrs. of transplant.
Renal impairment: Dose reduction needed.
Hepatic impairment: Severe impairment (Child-Pugh score of ≥ 10): Use lower dosages and close monitoring of blood concentrations needed.
Prevention of rejection in liver graft transplant:
Adult: Initially, 0.1-0.2 mg/kg/day in 2 divided doses every 12 hrs. Start treatment 12 hrs. after transplantation.
Child: Initially, 0.15-0.20 mg/kg/day in 2 divided doses every 12 hrs. Begin no sooner than 6 hrs after transplant.
Renal impairment: Dose reduction needed.
Hepatic impairment: Severe impairment (Child-Pugh score of ≥ 10): Use lower dosages and close monitoring of blood concentrations needed.
Fistulising Crohn's disease:
Adult: 200 mcg/kg/day in 2 divided doses for 10 weeks.
Renal impairment: Dose reduction needed.
Hepatic impairment: Severe impairment (Child-Pugh score of ≥ 10): Use lower dosages and close monitoring of blood concentrations needed.
Prophylaxis of cardiac graft rejection:
Adult: With or without antibody induction: Starting within 5 days of transplantation but no earlier than 6 hrs after transplantation. 75 mcg/kg daily in 2 divided doses. Oral therapy should start 8-12hrs. after IV infusion discontinued.
Food(before/after): Should be taken on an empty stomach. (Take on an empty stomach at least 1 hr before or 2-3 hrs. after meals.)
Tacrolimus and Pregnancy:
Caution when used during pregnancy.
Category C: Either studies in animals have revealed adverse effects on the foetus (teratogenic or embryocidal or other) and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the foetus.
Tacrolimus and Lactation:
Contraindicated in lactation
Tacrolimus and Children:
Children generally require higher doses to maintain trough Tacrolimus levels similar to adults (oral and IV). Safety and efficacy not established in children younger than 2 years of age.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

TACGRAF Capsule 0.5 mg	:	Pack of 3 x 10 capsules.
TACGRAF Capsule 1 mg	:	Pack of 3 x 10 capsules.
TACGRAF Capsule 5 mg	:	Pack of 1 x 10 capsules.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

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25081-0001-006-0000-0000

CCL
Manufactured by:
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