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

Abbreviated prescribing information for TORAFT (Sirolimus Tablets). [Please refer the complete prescribing information for details]

PHARMACOLOGICAL PROPERTIES: Sirolimus is an immunosuppressant drug which significantly reduced the incidence of organ rejection in low-to moderate-immunologic risk renal transplant patients.

INDICATION: Immunosuppressant.

DOSAGE AND ADMINISTRATION: Sirolimus is to be administered orally once daily. The maximum sirolimus dose administered on any day should not exceed 40 mg. *Patients at Low-to Moderate-Immunologic Risk*: A loading dose of sirolimus equivalent to 3 times the maintenance dose should be given. i.e. a daily maintenance dose of 2 mg should be preceded with a loading dose of 6 mg. *Patients at High-Immunologic Risk:* It is recommended that sirolimus be used in combination with cyclosporine and corticosteroids for the first 12 months following transplantation. For patients receiving sirolimus with cyclosporine, sirolimus therapy should be initiated with a loading dose of up to 15 mg on day 1 post-transplantation. *Patients with Low Body Weight:* The initial dosage in patients ≥ 13 years who weigh less than 40 kg should be adjusted, based on body surface area, to 1 mg/m2/day. *Patients with Hepatic Impairment:* The maintenance dose should be reduced by approximately one third in patients with mild or moderate hepatic impairment and by approximately one half in patients with severe hepatic impairment. *Patients with Renal Impairment:* Dosage adjustment is not needed.

CONTRAINDICATION: It is contraindicated in patients with a hypersensitivity to Sirolimus.

WARNINGS & PRECAUTIONS: Precaution should be taken for increased susceptibility to infection and the possible development of lymphoma, (in liver transplantation) – excess mortality, graft loss, and hepatic artery thrombosis (HAT), (in lung transplantation)– bronchial anastomotic dehiscence, hypersensitivity reactions, angioedema, fluid accumulation and wound healing delayed, hyperlipidemia, deterioration of renal function, proteinuria, latent viral infections, interstitial lung disease, increased risk of calcineurin inhibitor-induced hemolytic uremic syndrome/thrombotic thrombocytopenic purpura/thrombotic microangiopathy (HUS/TTP/TMA), antimicrobial prophylaxis, skin cancer events.

DRUG INTERACTION: Use with Cyclosporine, strong inducers and strong inhibitors of CYP3A4 and P-gp, grapefruit juice, inducers or inhibitors of CYP3A4 and P-gp, vaccination.

ADVERSE REACTIONS: Increased susceptibility to infection, lymphoma, and malignancy, Excess mortality, graft loss, hepatic artery thrombosis, bronchial anastomotic dehiscence in lung transplant patients, hypersensitivity reactions, exfoliative dermatitis, peripheral edema, hypertriglyceridemia, hypertension, hypercholesterolemia, creatinine increased, constipation, abdominal pain, diarrhea, headache, fever, urinary tract infection, anemia, nausea, arthralgia, pain, thrombocytopenia, pericardial effusion, ascites, hepatotoxicity, tuberculosis, nephrotic syndrome and reactions mentioned in warning and precaution section.