

## **TACROTOR**

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory Only**  
**Abbreviated Prescribing information for Tacrotor (Tacrolimus Capsule USP 0.5 mg/1.0 mg)** [Please refer the complete prescribing information for details]

**PHARMACOLOGICAL PROPERTIES:** Tacrolimus is the active ingredient in Tacrotor. Tacrolimus is a macrolide immunosuppressant produced by *Streptomyces tsukubaensis*. It inhibits T-lymphocyte activation, although the exact mechanism of action is not known.

**INDICATIONS:** It is indicated for organ rejection and lupus nephritis (in a case where the effect of steroids is insufficient or administration of steroids is difficult because of their adverse reactions).

**DOSAGE AND ADMINISTRATION:** The initial recommended dose (in two divided doses) for patient of *acute kidney transplant*: 0.2 mg/kg/day (In combination with azathioprine) and 0.1 mg/kg/day (In combination with mycophenolate mofetil (MMF)/IL-2 receptor antagonist), *Liver transplant*: 0.10-0.15 mg/kg/day (adult) and 0.15-0.20 mg/kg/day (Pediatric), *Adult Heart transplant*: 0.075 mg/kg/day. Careful and frequent monitoring of tacrolimus trough concentrations is recommended.

**CONTRAINDICATIONS:** Hypersensitivity to tacrolimus or to any of the inactive ingredients.

**WARNINGS AND PRECAUTIONS:** Tacrolimus can increase the risk of lymphoma and other malignancies, serious infections, polyoma virus infections, cytomegalovirus (CMV) infections, new onset diabetes after transplant, nephrotoxicity, neurotoxicity, hyperkalemia, hypertension, QT prolongation, myocardial hypertrophy, pure red cell aplasia and gastrointestinal perforation. Precaution should be taken while managing immunosuppression, when use with sirolimus and on immunization.

**DRUG INTERACTION:** Mycophenolic acid products, grapefruit juice, CYP3A Inhibitors and CYP3A4 Inducers.

**ADVERSE REACTIONS:** The most common adverse reactions with kidney transplant are infection, tremor, hypertension, abnormal renal function, constipation, diarrhea, headache, abdominal pain, insomnia, nausea, hypomagnesemia, urinary tract infection, hypophosphatemia, peripheral edema, asthenia, pain, hyperlipidemia, hyperkalemia, anemia. The most common adverse reactions with liver transplant are tremor, headache, diarrhea, nausea, abnormal renal function, abdominal pain, insomnia, paresthesia, anemia, pain, fever, asthenia, hyperkalemia, hypomagnesemia, and hyperglycemia. The most common adverse reactions with heart transplant are abnormal renal function, hypertension, diabetes mellitus, CMV infection, tremor, hyperglycemia, leukopenia, infection, anemia, bronchitis, pericardial effusion, urinary tract infection and hyperlipemia. Other reactions mentioned in warning and precaution section.