

RAPAREN[™]

Sirolimus Tablets 1 mg

<u>La Renon</u>°

RAPAREN™ Sirolimus Tablets 1 mg

Class - Immunosuppressant

Indication – Prophylaxis of organ rejection in kidney allograft recipients.

Mechanism of action – Sirolimus is a potent non-calcineurin inhibiting immunosuppressant used for renal transplantation. It inhibits T-lymphocyte activation and proliferation by inhibiting their response to interleukin-2 (IL-2). It also inhibits antibody production. It has been shown to possess antifungal and antineoplastic properties.

Dosage -

Adult:

For low-moderate risk patients: Loading dose: 6 mg on day 1, followed by a maintenance dose of 2 mg once daily, given 4 hr after ciclosporin. Adjust dose to obtain whole blood trough concentrations of 4-12 ng/ml, and reduce doses of ciclosporin and corticosteroids gradually. After 2-3 mth, ciclosporin should be gradually discontinued over 4-8 wk while dose of sirolimus is adjusted to obtain trough concentrations of 12-20 ng/ml.

For patients at high immunological risk: Patients like black Afro-Caribbean and/or repeat renal transplant patients, sirolimus may be continued with ciclosporin and corticosteroids for the 1st yr after transplantation. Recommended loading dose: 15 mg, followed by an initial maintenance dose of 5 mg daily; further adjustments are made based on whole blood trough concentrations.

Child: Used with ciclosporin and corticosteroids: >13 yr and weighing <40 kg: Loading dose of 3 mg/m2 BSA, followed by initial maintenance of 1 mg/m2/day. Adjust dose to obtain whole blood trough concentrations of 4-12 ng/ml, and reduce doses of ciclosporin and corticosteroids gradually. After 2-3 mth, ciclosporin should be gradually discontinued over 4-8 wk while dose of sirolimus adjusted to obtain trough concentrations of 12-20 ng/ml. If ciclosporin withdrawal is unsuccessful, usage of sirolimus should not exceed 3 mth after transplantation. Max: 40 mg/day.

Hepatic impairment: Maintenance dose should be reduced by one-third.

Strength - 1 mg tablets

La Renon Healthcare

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