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**Rapolax**<sup>®</sup>  
Sirolimus 0.5 mg, 1mg,  
2mg Tablets

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Sirolimus 0.5 mg, 1mg,  
2mg Tablets

**For Newly transplanted kidney !**

#### **Indications and Usage**

RAPOLAX (sirolimus) is indicated for the prevention of organ rejection in kidney transplant patients aged 13 years or older.

**Blood levels of sirolimus should be checked in all patients taking RAPOLAX (sirolimus).**

In patients at low to moderate risk of acute rejection, it is recommended that RAPOLAX (sirolimus) be used initially in combination with cyclosporine and corticosteroids; cyclosporine should be withdrawn approximately 3 months after transplantation. Cyclosporine withdrawal has not been studied in patients who have had severe acute rejection prior to cyclosporine withdrawal, those who require dialysis or have a high serum creatinine, Black patients, patients receiving a repeat kidney transplant, patients receiving other transplanted organs besides the kidney transplant, or patients with antibodies that may be directed against the kidney transplant. In patients at high risk of acute rejection (defined as Black patients and/or patients receiving a repeat kidney transplant who lost a previous **kidney transplant from rejection and/or patients with high levels of antibodies** that may be directed against the kidney transplant), it is recommended that RAPOLAX (sirolimus) be used in combination with cyclosporine and corticosteroids for the first year following transplantation. The safety and efficacy of this combination in high-risk patients have not been studied beyond one year; therefore, after the first year, adjustments to the immunosuppressive regimen may be considered by your doctor.

In pediatric patients, the safety and efficacy of RAPOLAX (sirolimus) have not been established in kidney transplant patients less than 13 years old, or in patients less than 18 years old who are considered at high risk of acute rejection.

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