

IMMUNOSUPPRESSANTS

SIGMASPORIN MICRORAL

Presentation

Soft gelatin capsules: Pack of 50 capsules.

Oral solution: Bottle of 50mL.

Composition

Each capsule contains: Cyclosporine USP 25mg, 50mg, and 100mg.

Each 1mL contains: Cyclosporine USP 100mg

Indications

- Prevention of graft rejection following bone marrow, kidney, liver, pancreas, heart, and heart-lung transplantation.
- Treatment of chronic transplant rejection in patients previously treated with other immunosuppressants.
- Prophylaxis and treatment of graft-versus-host disease after bone marrow transplantation.
- Short-term treatment of severe atopic dermatitis where conventional therapy is ineffective or inappropriate.
- Treatment of severe, recalcitrant, plaque-type psoriasis failing to respond to at least one systemic therapy or in patients unable to tolerate other systemic therapy.
- Treatment of severe, active rheumatoid arthritis when conventional second-line therapy inappropriate or ineffective.
- Treatment of nephrotic syndrome; to induce and maintain remissions of steroid-dependent and steroid-resistant nephrotic syndrome due to glomerular diseases.

Dosage and Administration

Organ transplantation

The usual initial dose of **Sigmatasporin Microral** when

used alone is 10 - 15mg/kg 4 - 12 hours before transplantation, followed postoperatively by 10 - 15mg/kg daily for 1 - 2 weeks, then dosage may subsequently be reduced gradually to a daily maintenance dose of 2 - 6mg/kg. Dosage should be adjusted by regular monitoring of blood concentrations and renal function. Lower initial doses may be given for patients concomitantly receiving other immunosuppressant therapy (e.g. corticosteroids).

Prevention of graft rejection in bone marrow transplantation and prevention and treatment of graft-versus-host disease

An initial dose of 12.5 - 15mg/kg daily is usually recommended from the day before transplantation to 2 weeks postoperatively, then a maintenance dose of 12.5mg/kg daily for 3 - 6 months can be instituted. Then, the maintenance dose can be reduced gradually until it is withdrawn altogether; this may take up to a year after transplantation.



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Severe atopic dermatitis

Adults over 16 years: Initially, 2.5mg/kg daily (5mg/kg daily in very severe cases) in 2 divided doses, if good initial response is not achieved within 2 weeks, increase the dose rapidly to a maximum of 5mg/kg daily. Treatment should be continued for a maximum of 8 weeks.

Children under 16 years: Use is not recommended.

Severe psoriasis

Adults over 16 years: Initially, 2.5mg/kg daily in 2 divided doses, increased gradually to a maximum of 5mg/kg daily if no improvement within 1 month; if the response is still insufficient after 6 weeks, treatment should then be discontinued.

When the condition requires rapid improvement, an initial dose of 5mg/kg daily is usually justified.

Children under 16 years: Use is not recommended.

Severe active rheumatoid arthritis

Adults above 18 years: Initially, 2.5mg/kg daily in 2 divided doses; if the clinical effect is insufficient dosage may then be increased gradually after 6 weeks to a maximum of 4mg/kg daily; if the response is insufficient after 3 months, treatment should then be discontinued. Maintenance dose should be adjusted according to the response and treatment should be reviewed after 6 months; continue the treatment only if the benefits outweigh the risks.

Children and patients under 18 years: Use is not recommended.

Nephrotic syndrome

The recommended dosage depends on the age and renal function. To induce remission in patients with normal renal function 5mg/kg daily may be given to adults and 6mg/kg daily to children, in 2 divided doses by month. In patients with renal impairment the initial dose should not exceed 2.5mg/kg daily; maintenance treatment should be gradually reduced to the lowest effective dose according to proteinuria and serum creatinine measurements.

Treatment may be discontinued after 3 months if there is no improvement in glomerulonephritis or glomerulosclerosis (or 6 months in membranous glomerulonephritis).



• **Julphar** produces also **Betasone** and **Gupisone** which are oral corticosteroids (See page 46-47)