Depomed-500
Injection

Composition : Depomed 500mg IV/IM Injection : Each vial contains sterile powder of Methylprednisolone 500mg as Methylprednisolone Sodium Succinate USP IV/IM Injection.

Indications : It is indicated for the treatment of **1. Endocrine Disorders:** Primary or secondary adrenocortical insufficiency, congenital adrenal hyperplasia, nonsuppurative thyroiditis, hypercalcemia associated with cancer **2. Rheumatic Disorders:** Rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis, acute and subacute bursitis, synovitis of osteoarthritis, acute non-specific tenosynovitis, post-traumatic osteoarthritis, psoriatic arthritis, epicondylitis, acute gouty arthritis **3. Collagen Diseases:** Systemic lupus erythematosus systemic dermatomyositis, acute rheumatic carditis **4. Dermatologic Diseases:** Bullous dermatitis herpetiformis, severe erythema multiforme, severe seborrheic dermatitis, exfoliative dermatitis, mycosis fungoides, pemphigus, severe psoriasis **5. Allergic States:** Seasonal or perennial allergic rhinitis, drug hypersensitivity reactions, serum sickness, contact dermatitis, bronchial asthma, atopic dermatitis **6. Ophthalmic Diseases:** Allergic corneal marginal ulcers, herpes zoster ophthalmicus, anterior segment inflammation, sympathetic ophthalmia, keratitis, optic neuritis, allergic conjunctivitis chorioretinitis, iritis and iridocyclitis **7. Respiratory Diseases:** Symptomatic sarcoidosis, berylliosis, loeffler's syndrome not manageable by other means, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, aspiration pneumonitis **8. Hematologic Disorders:** Idiopathic thrombocytopenic purpura in adults, secondary thrombocytopenia in adults, acquired (autoimmune) hemolytic anemia, erythroblastopenia (RBC anemia), congenital (erythroid) hypoplastic anemia **9. Neoplastic Diseases:** For palliative management of: Leukemias and lymphomas in adults, acute leukemia of childhood **10. Edematous States:** To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the indiopathic type or that due to lupus erythematosus **11. Gastrointestinal Diseases:** Ulcerative colitis, regional enteritis **12. Nervous System:** Acute exacerbations of multiple sclerosis, etc. It is also indicated for the treatment of terminal cancer, organ transplantation, cardiovascular condition etc.

Dosage and administration : It is depending on the specefic disease entity being treated in the following conditions :

Indications	Dosage
Adjunctive therapy in life-threatening conditions	Administer 30 mg/kg IV over a period of at least 30 minutes. Dose may be repeated every 4 to 6 hours for up to 48 hours.
Acute respiratory distress syndrome (ARDS)	Initially 2-3mg/kg/day IV, decreasing after 7 days.
Rheumatic disorders unresponsive to standard therapy (or during exacerbation episodes).	Administer either regimen as IV pulse dosing over at least 30 minutes. The regimen may be repeated if improvement has not occurred within a week after therapy. 1 g/day for 1 to 4 days, or 1 g/month for 6 months.
Systemic Lupus Erythematosus (SLE) unresponsive to standard therapy (or during exacerbation episodes).	Administer 1 g/day for 3 days as IV pulse dosing over at least 30 minutes. The regimen may be repeated if improvement has not occurred within a week after therapy, or as the patient's condition dictates.
Multiple sclerosis unresponsive to standard therapy (or during exacerbation episodes).	Administer 1 g/day for 3 or 5 days as IV pulse dosing over at least 30 minutes. The regimen may be repeated if improvement has not occurred within a week after therapy, or as the patient's condition dictates.
Acute spinal cord injury	Treatment should begin within 8 hours of injury. Within 3 hours of injury : Bolus 30 mg/kg in 50ml IV fluid over 15 minutes, wait 45 minutes, then continuous infusion of 5.4 mg/kg/hour for 23 hours. 3-8 hours after injury : Bolus 30mg/kg in 50ml IV fluid over 15 minutes, wait 45 minutes, then continuous infusion of 5.4 mg/kg/hour for 47 hours. There should be a separate intravenous site for the infusion pump.
Edematous states, such as glomeulonephritis or lupus nephritis, unresponsive to standard therapy (Or during exacerbation episodes).	Administer either regimen as IV pulse dosing over at least 30 minutes. The regimen may be repeated if improvement has not occurred within 1 week after therapy, or as the patient's condition dictates. 30 mg/kg every other day for 4 days or 1 g/day for 3, 5 or 7 days.
Pemphigus & Bullous Pemphigoid	20-30 mg/kg IV as pulse therapy depending on patient's conditions.
In other indications	Initial dosage will vary from 10 to 500 mg depending on the clinical problem being treated. The larger dosage may be required for short-term management of severe, acute conditions. The initial dose should be given intravenously over a period of at least 5 minutes (e.g up to 250mg) to at least 30 minutes (e.g doses exceeding 250mg). Subsequent doses may be given intravenously or intramuscularly at intervals dictated by the patients response and clinical conditions.

Dosage may be reduced for infants and children but should be governed more by the severity of the condition and response of the patient than by age or size. It should not be less than 0.5mg/kg every 24 hours. Dosage must be decreased or discontinued gradually when the drug has been administered for more than a few days. Or, as directed by the registered physicians.

N:B: Before use, Methylprednisolone of the vial should be mixed well 8ml WFI of provided solution. Use only freshly prepared solution. After mixing, the solution will be used within 48 hrs.

Side effects : Most common side effects are GI disturbances, musculoskeletal, endocrine, neuropsychiatric, opthalmic, fluid & electrolyte disturbances, hypersensitivity etc.

Contraindication : It is contraindicated in patients with known hypersensitivity to any of the ingredients. They are also contraindicated in patients with systemic infections.

Use in Pregnancy & Lactation : Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether this medicine is excreted in human milk. Caution should be exercised when this medicine is administered to a nursing woman.

Drug Interaction : Methylprednisolone sodium succinate should be used with caution when it is administered concomitant with hepatic enzyme inducers (eg. phenobarbitone, phenytoin, rifampicin etc), hyperglycemia, hypokalemia, non-steroidal anti-Inflammatory drug, antidiabetics, anticogulants etc.

Precautions : Methylprednisolone should be used with caution in peptic ulceration, renal insufficiency, hypertension, osteoporosis, myasthenia gravis etc.

Overdose : There is no clinical syndrome of acute overdosage with methylprednisolone sodium succinate. Chronic overdosage induces typical cushing symptoms. Methylprednisolone is dialysable.

Storage : Store at controlled room temperature between 20° C to 25° C in a dry place.

Packing : Depomed 500mg IV/IM Injection : Each Combipack contains 1 vial of Methylprednisolone 500mg as Methylprednisolone Sodium Succinate USP sterile powder with 1 ampoule of 10 ml water for injection USP.