

Mepcort[®] Tablet

Methylprednisolone USP

Presentation

Mepcort 4 Tablet: Each film-coated tablet contains Methylprednisolone USP 4 mg.
Mepcort 8 Tablet: Each film-coated tablet contains Methylprednisolone USP 8 mg.
Mepcort 16 Tablet: Each film-coated tablet contains Methylprednisolone USP 16 mg.

Description

Mepcort tablet contains Methylprednisolone, is a potent anti-inflammatory steroid and it has greater anti-inflammatory potency than prednisolone, even less tendency than prednisolone to induce sodium and water retention. Mepcort tablet can be used to treat a wide variety of diseases and conditions that required either reduction of inflammation or suppression of the immune system. Methylprednisolone is rapidly absorbed and the maximum plasma concentration is achieved around 1.5 to 2.3 hours following oral administration in normal healthy adults. The absolute bioavailability of Methylprednisolone in normal healthy subjects is generally high (82% to 89%) following oral administration and is widely distributed throughout the body.

Indication

Endocrine Disorders: Primary or Secondary Adrenocortical Insufficiency, Congenital Adrenal Hyperplasia, Nonsuppurative Thyroiditis, Hypercalcemia associated with Cancer. **Rheumatic Disorders:** Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Ankylosing Spondylitis, Acute and Sub-acute Bursitis, Synovitis of Osteoarthritis, Acute nonspecific Tenosynovitis, Post-traumatic Osteoarthritis, Psoriatic Arthritis, Epicondylitis, Acute Gouty Arthritis. **Collagen Diseases:** Systemic Lupus Erythematosus, Systemic Dermatomyositis and Acute Rheumatic Carditis, **Dermatologic Diseases:** Bullous Dermatitis Herpetiformis, Severe Erythema Multiforme (Stevens-Johnson syndrome), Severe Seborrheic Dermatitis, Exfoliative Dermatitis, Mycosis Fungoides, Pemphigus, Severe Psoriasis, **Allergy:** Seasonal or Perennial Allergic Rhinitis, Drug Hypersensitivity Reactions, Serum Sickness, Contact Dermatitis, Bronchial Asthma and Atopic Dermatitis. **Ophthalmic Diseases:** Allergic Corneal Ulcers, Herpes Zoster Ophthalmicus, Anterior segment inflammation, Sympathetic Ophthalmia, Keratitis, Optic Neuritis, Allergic Conjunctivitis, Chorioretinitis, Iritis and Iridocyclitis. **Respiratory Diseases:** Symptomatic Sarcoidosis, Loeffler's syndrome not manageable by other means, berylliosis, Aspiration Pneumonitis. **Hematological Disorders:** Idiopathic Thrombocytopenic Purpura in adults, Secondary Thrombocytopenia in adults, Acquired (Autoimmune) Hemolytic Anemia, Erythroblastopenia, Congenital Hypoplastic Anemia. **Neoplastic Diseases:** For palliative management of Leukemias and Lymphomas in adults, Acute Leukemia of childhood. **Gastrointestinal Disease:** Ulcerative Colitis & Regional Enteritis. **CNS Disease:** Acute Exacerbations of Multiple Sclerosis.

Dosage and Administration

The usual range is 2-48 mg daily in divided doses, depending on the specific disease being treated. The initial dosage of Methylprednisolone tablet may vary from 4- 48 mg per day depending on the specific disease entity being treated. In situations of less severity lower doses will generally suffice while in selected patients higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, Methylprednisolone should be discontinued and the patient transferred to other appropriate therapy. It should be emphasized that dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient. It should be kept in mind that constant monitoring is needed in regard to drug dosage. If after long term therapy the drug is to be stopped. It is recommended that it should be withdrawn gradually rather than abruptly.

Indications	Recommended initial daily dosage
Rheumatoid arthritis	severe 12 - 16 mg
	moderately severe 8 - 12 mg
	moderate 4 - 8 mg
	children 4 - 8 mg
Systemic dermatomyositis	48 mg
Systemic lupus erythematosus	20 - 100 mg
Acute rheumatic fever	48 mg until ESR normal for one week.
Allergic diseases	12 - 40 mg
Bronchial asthma	Up to 64 mg single dose/alternate day up to 100 mg maximum.
Ophthalmic diseases	12 - 40 mg
Haematological disorders and leukaemias	16 - 100 mg
Malignant lymphoma	16 - 100 mg
Ulcerative colitis	16 - 60 mg
Crohn's disease	Up to 48 mg per day in acute episodes.
Organ transplantation	up to 3.6 mg/kg/day
Pulmonary sarcoid	32 - 48 mg on alternate days.
Giant cell arteritis/polymyalgia rheumatica	64 mg
Pemphigus vulgaris	80 - 360 mg

Methylprednisolone tablet can be used to treat and to control severe allergy and dermatitis following the guidelines listed below to minimize the steroid withdrawal syndromes:

Day 1: 8 mg before breakfast + 4 mg after lunch + 4 mg after dinner + 8 mg at bedtime
Day 2: 4 mg before breakfast + 4 mg after lunch + 4 mg after dinner + 8 mg at bedtime
Day 3: 4 mg before breakfast + 4 mg after lunch + 4 mg after dinner + 4 mg at bedtime
Day 4: 4 mg before breakfast + 4 mg after lunch + 4 mg at bedtime
Day 5: 4 mg before breakfast + 4 mg at bedtime
Day 6: 4 mg before breakfast

Contraindication

Systemic fungal infections and known hypersensitivity to components methylprednisolone tablet.

Precaution

Drug-induced secondary adrenocortical insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstated. Since mineralocorticoid secretion may be impaired, salt and a mineralocorticoid should be administered concurrently.

There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis. Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed.

Use in Pregnancy and Lactation

The possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus.

Drug Interaction

Erythromycin, Clarithromycin, Phenobarbital, Phenytoin, Rifampin and Ketoconazole inhibit the metabolism of Methylprednisolone. Cyclosporin reduces the metabolism of Methylprednisolone while Methylprednisolone reduces the metabolism of Cyclosporin. Methylprednisolone may increase or decrease the effect of blood thinners (e.g. Warfarin). For all these interactions, the dose of Methylprednisolone may need to be lowered.

Side Effect

Side effects of Methylprednisolone depend on dose, duration and frequency of administration. Short courses of Methylprednisolone are usually well-tolerated with few, mild side effects. Long term, high doses of Methylprednisolone may produce predictable and potentially serious side effects. Whenever possible, the lowest effective doses of Methylprednisolone should be used for the shortest length of time to minimize side effects. Alternate day dosing also can help reduce side effects. Side effects of Methylprednisolone and other corticosteroids range from mild annoyances to serious irreversible bodily damage. Side effects include fluid retention, weight gain, high blood pressure, potassium loss, headache, muscle weakness, hair growth on the face, glaucoma, cataracts, peptic ulceration, growth retardation in children, convulsions, and psychic disturbances including depression, euphoria, insomnia etc. Prolonged use of Methylprednisolone can depress the ability of the body's adrenal glands to produce corticosteroids. Abruptly stopping Methylprednisolone in these individuals can cause symptoms of corticosteroid insufficiency, with accompanying nausea, vomiting, and even shock.

Over Dosage

Report of acute toxicity or death following overdose of glucocorticoids are rare. No specific antidote is available; treatment is supportive and symptomatic. Serum electrolytes should be monitored.

Storage

Store in a cool and dry place, away from light. Keep out of reach of the children.

Commercial Pack

Mepcort 4 Tablet: Each box contains 3x10 tablets in Alu-Alu strips.
Mepcort 8 Tablet: Each box contains 3x10 tablets in Alu-Alu strips.
Mepcort 16 Tablet: Each box contains 2x10 tablets in Alu-Alu strips.

Manufactured by



GLOBE PHARMACEUTICALS LTD.
Noakhali, Bangladesh