Depodrol®

Methylprednisolone USP

Description: Methylprednisolone is a potent anti-inflammatory steroid. It has greater anti-inflammatory potency than Prednisolone, even less tendency than Prednisolone to induce sodium and water retention. The relative Potency of Methylprednisolone to Hydrocortisone is at least four to one.

Mode of action: Methylprednisolone is thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. These proteins control the biosynthesis of potent mediators of inflammation such as prostaglandin and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from cell membrane phospholipids by phospholipase A2 enzyme.

Pharmacokinetics: Methylprednisolone is hydrolyzed to its active form by serum cholinesterases. Pharmacological activity persists after measurable plasma levels have disappeared. The absolute bioavailability of Methylprednisolone is generally high (82%-89%) following oral administration & rapidly absorbed. The maximum plasma concentration is achieved around 1.5-2.3 hours across doses following oral administration in healty adults.

Composition: Depodrol® 2 mg Tablet: Each tablet contains Methylprednisolone USP 2 mg.
Depodrol® 4 mg Tablet: Each tablet contains Methylprednisolone USP 4 mg.
Depodrol® 8 mg Tablet: Each tablet contains Methylprednisolone USP 8 mg.
Depodrol® 16 mg Tablet: Each tablet contains Methylprednisolone USP 16 mg.

Indications: 1. Endocrine Disorders: Primary or secondary adrenocortical insufficiency congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis. 2. Rheumatic Disorders: Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Ankylosing Spondylitis and Subacute Bursitis Osteoarthritis, Psoriatic Arthritis etc. 3. Dermatologic Diseases: Bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens - Johnson syndrome). 4. Respiratory Diseases: Symptomatic sarcoidosis, Berylliosis, Aspiration Pneumonitis. 5. Gastrointestinal diseases: Regional enteritis and ulcerative colitis. 6. Hematologic Disorders: Acquired (autoimmune) hemolytic anemia, idiopathic thrombocytopenic purpura in adults, secondary thrombocytopenia in adults, congenital hypoplastic anemia.

Dosage & administration: The usual range is 2-48 mg daily in divided doses, depending on the specific disease being treated.
As anti-inflammatory/immunosuppressive initial dosage: The initial dosage of Methylprednisolone tablets 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 sufficient; 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 should be 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.
As anti-inflammatory/immunosuppressive maintenance dosage: After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage. 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.
Multiple Sclerosis: In the treatment of acute exacerbations of multiple sclerosis, daily doses of 160 mg of Methylprednisolone for a week followed by 64 mg every other day for 1 month have been shown to be effective.
Methylprednisolone 4 mg tablet can be used to treat and to control severe allergy and dermatitis following the guideline listed below to minimize the steroid withdrawal syndromes:
Day 1: 2 tablets before breakfast + 1 tablet after lunch + 1 tablet after dinner + 2 tablets at bedtime
Day 2: 1 tablet before breakfast + 1 tablet after lunch + 1 tablet after dinner + 2 tablets at bedtime
Day 3: 1 tablet before breakfast + 1 tablet after lunch + 1 tablet after dinner + 1 tablet at bedtime
Day 4: 1 tablet before breakfast + 1 tablet after lunch + 1 tablet at bedtime
Day 5: 1 tablet before breakfast + 1 tablet at bedtime
Day 6: 1 tablet before breakfast

Contraindications: Methylprednisolone is contraindicated in patients with known hypersensitivity to the product and its constituents.

Side effects: Allergic or hypersensitivity reactions, cardiac arrhythmias, acne, allergic dermatitis decreased carbohydrate and glucose tolerance, development of cushingoid state, abdominal distention, bowel/bladder dysfunction & convulsions.

Use in pregnancy & lactation: Pregnancy: Pregnancy Category C. It should be given only if the potential benefit justifies the potential risk to the fetus.
Lactation: Methylprednisolone has not been adequately evaluated in nursing mothers.

Precautions: Adrenocortical insufficiency may persist for months after discontinuation of therapy. Therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

Drug interactions: Erythromycin, Clarithromycin, Phenobarbital, Phenytoin, Rifampin and Ketoconazole inhibit the metabolism of Methylprednisolone. Estrogens, including birth control pills, can increase the effect of corticosteroids by 50%. 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.

Over dosage: There is no clinical syndrome of acute over dosage with methylprednisolone. Repeated frequent doses over a protracted period may result in a Cushingoid state.

Storage: Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging: Depodrol® 2 mg Tablet: Each carton contains 14X4 tablets in blister pack.
Depodrol® 4 mg Tablet: Each carton contains 14X4 tablets in blister pack.
Depodrol® 8 mg Tablet: Each carton contains 10X3 tablets in blister pack.
Depodrol® 16 mg Tablet: Each carton contains 10X2 tablets in blister pack.