Summary of prescribing information for MEPRESSO D injection

Active Ingredient: each vial of MEPRESSO D contains: methylprednisolone acetate USP equivalent to methylprednisolone 40mg/ml; 2ml vial. **Indication:** Corticosteroid responsive conditions such as severe allergic rhinitis, asthma, rheumatoid arthritis, osteoarthritis, collagen disease, dermatoses. **Dosage:** for intramuscular, intra-articular, soft tissue or intralesional injection. Not for intravenous use. Dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient. The initial dosage of may vary from 4 to 120 mg depending on the specific disease entity being treated. However, in certain overwhelming, acute, life-threatening situations, administrations in dosages exceeding the usual dosages may be justified. After a favorable response is noted, the proper maintenance dose should be determined by decreasing the initial drug dosage in small increments at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. Dose should be regulated in accordance with severity of condition; intra-articular: large joints- 20 to 80 mg; medium joints- 10 to 40 mg; small joints- 4 to 10 mg; intralesional: 20-60mg directly in bursae. **Contraindications:** Systemic fungal infection (unless specific antimicrobial therapy given); herpes keratitis; avoid live virus vaccines in those receiving immunosuppressive doses (serum antibody response diminished); hypersensitivity; premature infants. **Warning and precautions:** unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated. Mask some signs of infection which may be mild, severe or may be fatal. Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves. Can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. Active tuberculosis. Drug-induced secondary adrenocortical insufficiency. Enhanced effect in patients with hypothyroidism and liver cirrhosis. Patients with systemic sclerosis, ocular herpes simplex, nonspecific ulcerative colitis. Psychic derangements. **Pregnancy & Lactation:** adequate human reproduction studies have not been done with corticosteroids. **Interaction:** vaccines: response to killed vaccines may be diminished. Cyclosporine: Mutual inhibition of metabolism, Convulsions have been reported; hepatic enzymes inducer such as phenobarbital, phenytoin and rifampin: may increase the clearance; troleandomycin & ketoconazole: may inhibit the metabolism; Methylprednisolone may increase the clearance of chronic high dose aspirin, cautiously used in patients with hypoprothrombinemia; oral anticoagulants: variable effect. **Adverse reactions:** Fluid and Electrolyte Disturbances: Sodium retention, Congestive heart failure in susceptible patients, Hypertension, Fluid retention, Potassium loss, Hypokalemic alkalosis. Musculoskeletal: Muscle weakness, Loss of muscle mass, Steroid myopathy, Osteoporosis, Tendon rupture, particularly of the Achilles tendon, Vertebral compression fractures, Aseptic necrosis of femoral and humeral heads, Pathologic fracture of long bones. Gastrointestinal: Peptic ulcer with possible perforation and hemorrhage, Pancreatitis, Abdominal distention, Ulcerative esophagitis. Increases in alanine transaminase (ALT, SGPT), aspartate transaminase (AST, SGOT), and alkaline phosphatase. Dermatologic: impaired wound healing, Petechiae and ecchymoses, May suppress reactions to skin tests, Thin fragile skin, Facial erythema, Increased sweating. Neurological: Increased intracranial pressure with papilledema (pseudo-tumor cerebri), Convulsions, Vertigo, Headache. Endocrine: Development of Cushingoid state, Suppression of growth in children, Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness, Menstrual irregularities, Decreased carbohydrate tolerance, Manifestations of latent diabetes mellitus, Increased requirements of insulin or oral hypoglycemic agents in diabetics. Ophthalmic: Posterior subcapsular cataracts, increased intraocular pressure, Glaucoma, Exophthalmos. Metabolic: Negative nitrogen balance due to protein catabolism. Injection site reactions. **Overdose:** No experience related to overdose.

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com