

## Summary of prescribing information for MEPRESSO I injection

**Active Ingredient:** each vial of MEPRESSO I contains: methylprednisolone succinate USP equivalent to methylprednisolone 40mg, 125mg, 500mg, 1g; 2ml vial. **Indication:** Corticosteroid responsive conditions such as severe allergic rhinitis, asthma, rheumatoid arthritis, osteoarthritis, collagen disease, dermatoses. **Dosage:** Injection is indicated for intramuscular (IM) and intravenous (IV) use. Preferred method for initial emergency use being intravenous injection. Following the initial emergency period, consideration should be given to employing a longer acting injectable preparation or an oral preparation. When high dose therapy is desired, the recommended dose is 30 mg/kg administered intravenously over at least 30 minutes. This dose may be repeated every 4 to 6 hours for 48 hours. High dose corticosteroid therapy should be continued only until the patient's condition has stabilized; usually not beyond 48 to 72 hours. In other indications, initial dosage will vary from 10 to 40 mg of methylprednisolone depending on the specific disease entity being treated. In 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. **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. **Overdose:** No experience related to overdose.

Prepared on 25<sup>th</sup> Feb 2020.

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](mailto:productqueries@intaspharma.com)