

Prednol-L



Prednol-L freeze-dried for injection 20-40-250 mg, 1 freeze-dried ampoule + 1 diluent ampoule

COMPOSITION: Each freeze-dried ampoule contains methylprednisolone sodium succinate equivalent to 20-40 mg methylprednisolone.

Each freeze-dried ampoule contains 250 mg methylprednisolone sodium succinate.

PHARMACOLOGICAL PROPERTIES:

- A non-fluorinated synthetic corticosteroid.
- Can be administered by IM or IV route.
- Suitable for emergency treatment in cases requiring rapid and high blood corticosteroid levels.
- More potent antiinflammatory effect compared to hydrocortisone and prednisolone.
- Minimum mineralocorticoid activity.
- Readily and easily soluble in water because it is freeze-dried.

INDICATIONS: Rheumatoid arthritis (including juvenile rheumatoid arthritis), psoriatic arthritis, ankylosing spondylitis, acute gout arthritis, post-traumatic osteoarthritis, acute non-specific tenosynovitis, acute/subacute bursitis and epicondylitis, systemic lupus erythematosus, systemic dermatomyositis and acute rheumatoid carditis, pemphigus, erythema multiforme (Stevens Johnson syndrome), exfoliative dermatitis, bullous dermatitis herpetiformis, severe psoriasis, seborrheic dermatitis and mucositis fungoides, herpes zoster ophthalmicus, iritis, iridocyclitis chorioretinitis, common posterior uveitis and choroiditis, optic neuritis, sympathetic ophthalmia, front segment inflammation, allergic conjunctivitis, allergic corneal marginal ulcers and keratitis, bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness, seasonal or prolonged allergic rhinitis, drug hypersensitivity, urticaria-like transfusion reactions and acute non-infectious larynx edema, symptomatic sarcoidosis, berilliosis, untreatable Löffler syndrome, aspiration pneumonia and fulminant or disseminated tuberculosis with the necessary anti-tuberculosis therapy, autoimmune hemolytic anemia, secondary thrombocytopenia in adults, erythroblastopenia, congenital hypoplastic anemia, multiple sclerosis, ulcerative colitis and regional enteritis, cardiogenic shock, septic shock, anaphylactic shock, hypovolemic shock, trauma, burns, late shocks with due to various etiologies.

CONTRAINDICATIONS: Methylprednisolone is contraindicated in patients with systemic fungal infections and known hypersensitivity to methylprednisolone.

WARNINGS AND PRECAUTIONS: Corticosteroids may mask some signs of infections, and new infections may appear during their use. Prolonged use of corticosteroids may produce posterior sub capsular cataracts and glaucoma with possible damage to the optic nerves and also may enhance the establishment of secondary ocular infections due to fungi or viruses. Because rare instances of anaphylactic reactions have occurred in patients receiving parenteral corticosteroid therapy, appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of allergy to any drug. Steroids should be used with caution in nonspecific ulcerative colitis, diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis and myasthenia gravis. Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids; killed or inactivated vaccines may be administered to patients receiving immunosuppressive doses of corticosteroids. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. **Pregnancy category is C.**

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SIDE EFFECTS / ADVERSE EFFECTS: Musculo-skeletal system, water and electrolyte balance, digestive system, nervous system, endocrine system, dermatologic, ophthalmologic. In addition, due to protein catabolism, negative nitrogen balance, allergic reactions and rarely, anaphylactoid reactions, urticaria and hyperpigmentation can occur.

DRUG INTERACTIONS: Since drugs that stimulate enzyme secretion such as rifampin, phenobarbital and phenytoin increase the hepatic binding and biliary excretion of corticosteroids, they decrease the active methylprednisolone levels; response to anticoagulants can be decreased.

DOSAGE AND ADMINISTRATION: It is injected within the muscle and between deep muscles. It can also be given by adding into perfusion liquids. It should be given slowly into a muscle and muscle injections should be deep. The common daily dosage for adults varies between 20-40 mg depending on the severity of the condition. This dosage can be repeated 2-3 times daily according to the response obtained. For children, the common daily dosage is 1-3 mg/kg; for those below the age of 5 years it is approximately 10 mg; for children between 5-10 years, dosage is 20-40 mg and for those above 10 years, adult dosage is recommended.

Overdosage: In chronic overdosage, the probability of adrenal suppression should be considered. Symptomatic and supportive therapy should be administered. Methylprednisolone can be dialyzed.

STORAGE CONDITIONS: Should be kept out of reach of children, at room temperature (< 25°C) and in its package.

AVAILABLE FORMS:

PREDNOL-L freeze-dried ampoule 20 mg, 1 freeze-dried ampoule+1 diluent ampoule (2 mL)

PREDNOL-L freeze-dried ampoule 40 mg, 1 freeze-dried ampoule+1 diluent ampoule (2 mL)

PREDNOL-L freeze-dried ampoule 250 mg, 1 freeze-dried ampoule+1 diluent ampoule (4 mL)

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