



Prednol

Prednol tablet 4-16 mg, 20 tablets

COMPOSITION: Each tablet contains 4-16 mg methylprednisolone.

PHARMACOLOGICAL PROPERTIES: A non-fluorinated synthetic corticosteroid.

More potent antiinflammatory effect compared to hydrocortisone and prednisolone.

Minimum mineralocorticoid activity. A corticosteroid with intermediate duration of action ideal for alternate-day therapy.

INDICATIONS:

- Endocrine disorders
- Rheumatic and collagen tissue disorders
- Respiratory tract disorders
- Severe infections
- Neoplastic disorders
- Nephrotic syndrome
- Allergic disorders
- Dermatologic disorders
- Ophthalmic disorders

CONTRAINDICATIONS: It is contraindicated in prolonged treatments; herpes simplex, keratitis, acute psychosis, in patients with latent or active tuberculosis (however, in some lung and meningitis tuberculosis cases, it can be life-saving when used concomitantly with anti-tuberculosis agents), peptic ulcers, Cushing syndrome, diverticulitis, newly formed anastomosis in the colon, osteoporosis, renal failure, thrombo-embolytic tendencies, chronic psychosis reactions, varicella, fungal diseases and other eczematous diseases.

WARNINGS AND PRECAUTIONS: In patients on corticosteroid therapy subjected to any unusual stress, increased dosage of rapidly acting corticosteroids before, during and after the stressful situation is indicated. 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 may also 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. Safety of administration during pregnancy has not been established. Infants born to mothers who had to receive substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism. During prolonged therapies, growth and development of infants and children should be closely observed.

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SIDE EFFECTS / ADVERSE EFFECTS: Although the side effects observed during methylprednisolone therapy are milder than those seen with other corticosteroids, they follow the same pattern. Side effects such as peptic ulcer, decreases in resistance to infections, development of osteoporosis, psychic disturbances, hirsutism, amenorrhea and acne purpura that are observed with glucocorticoid treatment can also be seen after methylprednisolone therapy but they are milder.

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. Salicylate metabolism is accelerated, especially in males.

DOSAGE AND ADMINISTRATION: Unless recommended by the physician otherwise: The starting dosage of Prednol tablet is 4-48 mg dependint on the severity of the disease and the condition of the patient. The starting dose should be continued until a favorable response is obtained. If the desired response is not obtained after a reasonable period, drug should be discontinued. After obtaining the desired response, dosage should be decreased gradually and the treatment should be continued with the minimum dosae required to maintain the desired response. In less severe cases, the daily dosage or the total of 2 doses for 2 alternate days should be given in the morning between 6-8 as one dose. In very severe cases, the daily starting dosage should be given divided to 4 equal doses and after adequate control is obtained, treatment should be continued as a single dose in the mornings or preferably, as alternate day therapy.

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 tablet 4 - 16 mg, 20-tablet blister packs

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