

Pednisol

Prednisolone USP 5mg, 10mg & 20mg Tablet

Composition : Pednisol 5 : Each Film Coated Tablet Contains Prednisolone USP 5mg.

Pednisol 10 : Each Film Coated Tablet Contains Prednisolone USP 10mg.

Pednisol 20 : Each Film Coated Tablet Contains Prednisolone USP 20mg.

Pharmacology : Prednisolone is a synthetic adrenocortical drug with predominantly glucocorticoid properties. Prednisolone directly inhibits the action of the Phospholipase A₂ enzyme which is responsible for the production of different inflammatory mediators like Leukotrienes, SRS-A, Prostaglandins etc. Prednisolone is rapidly and well absorbed from the GI tract following oral administration. Prednisolone is 70-90% protein-bound in the plasma and it is eliminated from the plasma with a half-life of 2 to 4 hours. It is metabolized mainly in the liver and excreted in the urine.

Indications : It is indicated in the treatment of **Allergy and anaphylaxis :** Bronchial asthma, drug hypersensitivity reactions, angioneurotic oedema, anaphylaxis. **Respiratory disease :** Allergic pneumonitis, asthma. **Rheumatic disorders :** Rheumatoid arthritis, juvenile chronic arthritis, systemic lupus erythematosus, mixed connective tissue disease. **Arteritis/collagenosis :** Giant cell arteritis/polymyalgia rheumatica, polyarteritis nodosa, polymyositis. **Blood disorders :** Haemolytic anaemia (autoimmune), leukaemia (acute and lymphocytic), multiple myeloma. **Cardiovascular disorders :** Post myocardial infarction syndrome, rheumatic fever with severe carditis. **Endocrine disorders :** Primary and secondary adrenal insufficiency, congenital adrenal hyperplasia. **Gastro-intestinal disorders :** Crohn's disease, ulcerative colitis, persistent celiac syndrome, multisystem disease affecting liver, biliary peritonitis. **Infections :** Military tuberculosis, mumps orchitis (adult), rickettsial disease. **Muscular disorders :** Polymyositis, dermatomyositis. **Neurological disorders :** Infantile spasms, sub-acute demyelinating polyneuropathy. **Ocular disease :** Scleritis, retinal vasculitis, malignant ophthalmic Graves disease. **Renal disorders :** Lupus nephritis, acute interstitial nephritis. **Skin disorders :** Pemphigus vulgaris, bullous pemphigoid. **Miscellaneous :** Sarcoidosis, hyperpyrexia, Behcet's disease.

Dosage and administration : The initial dosage may vary from 5mg to 60mg daily in divided doses, as a single daily dose after breakfast, or as a double dose on alternative days depending on the specific disease entity being treated.

The appropriate individual dose must be determined by trial and error and must be re-evaluated regularly according to activity of the disease.

During prolonged therapy, dosage may need to be temporarily increased during periods of stress or during exacerbations of the disease. When the drug is to be stopped, it must be withdrawn gradually and not abruptly. It is depending on the specific disease entity being treated in the following conditions

Diseases	Dosage Regimen
Allergic & skin disorders	An initial daily dose of 5-15mg.
Collagenosis	An Initial daily dose of 20-30mg. Those with more severe symptom require higher doses.
Rheumatoid arthritis	An initial daily dose of 10-15mg.
Blood disorders & lymphoma	An initial daily dose of 15-60mg. It is often necessary with reduction after an adequate clinical or haematological response. Higher doses may be necessary to induce remission in acute leukaemia.

Tapering : Dosage should be tapered down with 5 mg and 2 mg tablets after the treatment period.

Children : Acute asthma : Children aged 18 months to 12 years : 0.5-2 mg/kg/day (max 40 mg) once daily for up to a total of 3 days or longer if necessary. Pednisol should be taken in the morning after food. No gradual decrease of the dose is required. Children aged 12-18 years : 40-50 mg once daily for at least 5 days.

Other indications for children : Initial dosage: 0.5 mg/kg/day in three or four divided doses after food. This dosage can be doubled or tripled if necessary maintenance dosage 0.125 to 0.25 mg/kg/day. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients with a known hypersensitivity to any of the ingredients. Systemic infections unless specific anti-infective therapy is employed. Ocular herpes simplex because of possible perforation.

Precautions : Caution is necessary when oral corticosteroids, including Prednisolone, are prescribed in patients with the following conditions like-Tuberculosis, Hypertension, Congestive heart failure, Liver failure, Renal insufficiency, Diabetes mellitus or in those with a family history of diabetes, Osteoporosis, Patients with a history of severe affective disorders and particularly those with a previous history of steroid-induced psychoses. Epilepsy, Peptic ulceration, Previous Steroid Myopathy. Undesirable effects may be minimized by using the lowest effective dose for the minimum period and by administering the daily requirement as a single morning dose on alternate days. Frequent patient review is required to titrate the dose appropriately against disease activity.

Side effects : Most common side effects are leucocytosis, hypersensitivity including anaphylaxis, thromboembolism, nausea and malaise.

Use in pregnancy and lactation : There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Corticosteroids are excreted in small amounts in breast milk and infants of mothers taking pharmacological doses of steroids should be monitored carefully for signs of adrenal suppression.

Use in Child : It is not recommended for children under 12 years of age.

Drug interactions : Prednisolone should be used with caution when it is administered concomitant with hepatic microsomal enzyme inducers (eg. phenobarbitone, phenytoin, rifampicin). Non-steroidal anti-inflammatory drugs (eg. indomethacin, aspirin), anticoagulants etc.

Overdose : Report of acute toxicity or death following overdose of glucocorticoids are rare. No specific antidote is available; treatment is supportive and symptomatic. Serum electrolytes should be monitored.

Storage : Store below 30°C in a dry place.

Packing : Pednisol 5 : Each box contains 10 x 10's tablets in blister pack.

Pednisol 10 : Each box contains 10 x 10's tablets in blister pack.

Pednisol 20 : Each box contains 5 x 10's tablets in blister pack.

Manufactured by



DRUG INTERNATIONAL LTD.

Tongi, Gazipur, Bangladesh