

Cortisol[®]

Prednisolone

Composition:

Cortisol[®] - 5 Tablet : Each tablet contains Prednisolone USP 5 mg.

Cortisol[®] - 10 Tablet : Each tablet contains Prednisolone USP 10 mg.

Cortisol[®] - 20 Tablet : Each tablet contains Prednisolone USP 20 mg.

Cortisol[®] Oral Solution: Each 5 ml oral solution contains Prednisolone Sodium Phosphate USP equivalent to Prednisolone 5 mg.

Pharmacology:

Prednisolone is a synthetic corticosteroid used as anti-inflammatory or immunosuppressive agent. Prednisolone can inhibit leukocyte infiltration at the site of inflammation, interfere with mediators of inflammatory responses and suppresses humoral immune response.

Indications:

- **Allergy and anaphylaxis:** bronchial asthma, drug hypersensitivity reactions, serum sickness, angioneurotic oedema, anaphylaxis.
- **Respiratory disease:** allergic pneumonitis, asthma, occupational asthma, pulmonary aspergillosis, pulmonary fibrosis, pulmonary alveolitis, aspiration of foreign body, aspiration of stomach contents, pulmonary sarcoid, drug induced lung disease, adult respiratory distress syndrome, spasmodic croup.
- **Rheumatic disorders:** rheumatoid arthritis, polymyalgia rheumatica, juvenile chronic arthritis, systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease.
- **Arteritis/collagenosis:** giant cell arteritis/polymyalgia rheumatica, mixed connective tissue disease, polyarteritis nodosa, polymyositis.
- **Blood disorders:** haemolytic anaemia (auto-immune), leukaemia (acute and chronic lymphocytic), lymphoma, multiple myeloma, idiopathic thrombocytopenic purpura.
- **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 coeliac syndrome (coeliac disease unresponsive to gluten withdrawal), auto-immune chronic active hepatitis, multisystem disease affecting liver, biliary peritonitis.
- **Infections (with appropriate chemotherapy):** helminthic infestations, Herxheimer reaction, infectious mononucleosis, miliary tuberculosis, mumps orchitis (adult), tuberculous meningitis, rickettsial disease.
- **Muscular disorders:** polymyositis, dermatomyositis.
- **Neurological disorders:** infantile spasms, Shy-Drager syndrome, sub-acute demyelinating polyneuropathy.
- **Ocular disease:** scleritis, posterior uveitis, retinal vasculitis, pseudo-tumours of the orbit, giant cell arteritis, malignant ophthalmic Graves disease.
- **Renal disorders:** lupus nephritis, acute interstitial nephritis, minimal change glomerulonephritis.
- **Skin disorders:** pemphigus vulgaris, bullous pemphigoid, systemic lupus erythematosus, pyoderma gangrenosum.
- **Miscellaneous:** sarcoidosis, hyperpyrexia, Behçets disease, immunosuppression in organ transplantation.

Dosage & administrations:

General dosage guidelines : The initial dosage of **Cortisol[®]** may vary from 5 mg to 60 mg daily depending on the disorder being treated. Divided daily dosage is usually used. The appropriate individual dose must be determined by trial and error and must be re-evaluated regularly according to activity of the disease. In general, initial dosage shall be maintained or adjusted until the anticipated response is observed. The dose should be gradually reduced until the lowest dose, which will maintain an adequate clinical response is reached. During prolonged therapy, dosage may need to be temporarily increased during periods of stress or during exacerbations of the disease.

Intermittent dosage regimen: A single dose of **Cortisol[®]** in the morning on alternate days or at longer intervals is acceptable therapy for some patients. When this regimen is practical, the degree of pituitary-adrenal suppression can be minimised. **Specific dosage guidelines:** *Allergic and skin disorders:* Initial doses of 5-15 mg daily are commonly adequate. *Collagenosis:* Initial doses of 20-30 mg daily are frequently effective. Those with more severe symptoms may require higher doses. *Rheumatoid arthritis:* The usual initial dose is 10-15 mg daily. The lowest daily maintenance dose compatible with tolerable symptomatic relief is recommended. *Blood disorders and lymphoma:* An initial daily dose of 15-60 mg is often necessary with reduction after an adequate clinical or haematological response. Higher doses may be necessary to induce remission in acute leukaemia.

Dosage for Children:

General dosage	0.14-2 mg/kg/day in three to four divided doses for 3-10 days
Asthma	1-2 mg/kg/day in single or divided doses
Nephritic syndrome	2 mg/kg/day in three to four divided doses for 4 weeks followed by 4 weeks of single dose alternate day therapy at 1 mg/kg/day
Treatment of rheumatoid arthritis	7.5 mg daily in moderate to severe rheumatoid arthritis

Contraindications:

Systemic infections unless specific anti-infective therapy is employed. Hypersensitivity to any ingredient. Ocular herpes simplex because of possible perforation.

Side effects:

General side-effects include leucocytosis, hypersensitivity including anaphylaxis, thromboembolism and nausea.

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.

Drug interactions:

Prednisolone may interact with phenobarbital, phenytoin, rifampicin, rifabutin, carbamazepine, primidone and aminoglutethimide, ketoconazole, toleandomycin, indomethacin, erythromycin, anticoagulants, amphotericin, ritonavir, methotrexate etc.

Use in special group:

Use in pregnancy:

Corticosteroids should only be prescribed when the benefits to the mother and child outweigh the risks. Patients with pre-eclampsia or fluid retention require close monitoring.

Use in lactation:

Corticosteroids should be administered to nursing mothers only if the benefits of therapy are judged to outweigh the potential risks to the infant.

Use in the elderly:

Treatment of elderly patients, particularly if long term, should be planned bearing in mind the more serious consequences of the common side-effects of corticosteroids in old age, especially osteoporosis, diabetes, hypertension, hypokalaemia, susceptibility to infection and thinning of the skin. Close clinical supervision is required to avoid life-threatening reactions.

Overdose:

Report of acute toxicity and/or death following overdose of glucocorticosteroids are rare. No specific antidote is available; treatment is supportive and symptomatic, serum electrolytes should be monitored.

Storage:

- Store below 30° C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:

Cortisol[®] - 5 Tablets : Each box contains 100/200 tablets in blister pack.

Cortisol[®] - 10 Tablets : Each box contains 100/200 tablets in blister pack.

Cortisol[®] - 20 Tablets : Each box contains 50/100 tablets in blister pack.

Cortisol[®] Oral Solution: Each bottle contains 50 ml/100 ml oral solution.

Manufactured by:



ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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