Predimax

Tablet

Prednisolone BP

COMPOSITION

Predimax 5 tablet : Each film-coated tablet contains Prednisolone BP 5 mg.
Predimax 10 tablet : Each film-coated tablet contains Prednisolone BP 10 mg.
Predimax 20 tablet : Each film-coated tablet contains Prednisolone BP 20 mg.

PHARMACOLOGY

Prednisolone is a corticosteroid drug with predominant glucocorticoid & low mineralocorticoid activity. It is the active metabolite of prednisone. It is useful for the treatment of a wide range of inflammatory and autoimmune conditions.

INDICATIONS

Allergy and Anaphylaxis: Bronchial asthma, drug hypersensitivity reactions, serum sickness, angioneurotic oedema, anaphylaxis.
Respiratory disease: Allergic pheumonitis, 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 rheumatic, juvenile chronic arthritis, systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease.
Arteritis / collagenosis: Giant cell arteritis/polymyalgia rheumatic, mixed connective tissue disease polyarteritis nodosa polymyositis.
Blood disorders: Haemolytic anaemia (autoimmune), leukaemia (acute and 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 celiac syndrome, autoimmune chronic active hepatitis, multisystem disease affecting liver, biliary peritonitis.
Infections: 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: sclertis, posterior uveitis, retinal vasculitis, pseudo tumours of the orbit malignant ophthalmic graves disease.
Renal disorders: Lupus nephritis, acute intersititial nephritis, minimal change glomerulonephritis.
Skin disorders: Pemphigus vulgaris, bullous pemphigoid, systemic lupus erythematosus, pyoderma gangrenosum.
Miscellaneous: Sarcoidosis, hyperpyrexia, Behcets disease, immunosuppression in organ transplantation.

DOSAGE AND ADMINISTRATION

Route of administration: Orally.
The initial dosage of Prednisolone 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. When the drug is to be stopped, it must be withdrawn gradually and not abruptly.
Intermittent dosage regimen : A single dose of Prednisolone 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 minimized.
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 required higher doses.
Rheumatoid arthritis: The usual initial dose is 10-15 mg dialy. 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.
OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

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

WARNING & PRECAUTION

Caution is necessary when taken 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 kin 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

Common: General side-effects include leukocytosis, hypersensitivity including anaphylaxis, thromboembolism, nausea and malaise.
Rare: Rare side-effects include weight gain, rash, redness of skin, headache, hives etc.

USE IN PREGNANCY AND LACTATION

Use in pregnancy: There is evidence of harmful effects on pregnancy in animals.
Use in lactation: 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 CHILDREN & ADOLESCENTS

Corticosteroids cause growth retardation in infancy, childhood and adolescence, which may be irreversible. Treatment should be administered where possible as a single dose on alternate days.

DRUG INTERACTIONS

With Medicine: Hepatic microsomal enzyme inducers : Drugs which can cause liver enzyme induction such as phenobarbitone, phenytoin, rifampicin, rifabutin, carbamazepine, primidone and aminoglutethimide may reduce the therapeutic efficacy of corticosteroids by increasing the rate of metabolism.
Non-steroidal anti-inflammatory drugs: concomitant administration of ulcerogenic drugs such as indomethacin during corticosteroid therapy may increase the risk of GI ulceration.
Anticoagulants: Response to anticoagulants may be reduced or less often, enhanced by corticosteroids.
Vaccines: Live vaccines should not be given to individuals with impaired immune responsiveness. The antibody response to other vaccines may be diminished.
Oestrogens: Oestrogens may potentiate the effects of glucocorticoids and dosage adjustment may be required if oestrogens are added to or withdrawn from a stable dosage regimen.
With food & others: The desired effects of hypoglycaemic agents (including insulin), anti-hypertensives and diuretics are antagonized by corticosteroids and the hypokalaemic effect of acetazolamide, loop diuretics, thiazide diuretics and carbenoxolone are enhanced.

OVERDOSE

Report of acute toxicity and/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 30^0 C, protected from light & moisture.
Keep all medicines out of reach of children.

PACKING

Predimax 5 tablet: Each box contains 20x10 tablets in blister strilps.
Predimax 10 tablet: Each box contains 10x10 tablets in blister strilps.
Predimax 20 tablet: Each box contains 5x10 tablets in blister strilps.

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* Further information is available on request.

Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness