

PRED[®]

Prednisolone Film Coated Tablet & Oral Solution

DESCRIPTION

Pred[®] film-coated tablet & oral solution contains Prednisolone. It has anti-inflammatory, immunosuppressive and glucocorticoid properties.

INDICATIONS

Pred[®] is indicated in the following conditions:

Endocrine disorders:

Primary or secondary adrenocortical insufficiency, congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis.

Rheumatic disorders:

As adjunctive therapy for short-term administration in psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis, acute and subacute bursitis, acute nonspecific tenosynovitis, acute gouty arthritis, post-traumatic osteoarthritis, synovitis of osteoarthritis, epicondylitis.

Collagen diseases:

During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, acute rheumatic carditis.

Dermatologic diseases:

Pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme (Stevens-Johnson syndrome), exfoliative dermatitis, mycosis fungoides, severe psoriasis, severe seborrheic dermatitis.

Allergic states:

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: seasonal or perennial allergic rhinitis, bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness, drug hypersensitivity reactions.

Ophthalmic diseases:

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic corneal marginal ulcers, herpes zoster ophthalmicus, anterior segment inflammation, diffuse posterior uveitis and choroiditis, sympathetic ophthalmia, allergic conjunctivitis, keratitis, chorioretinitis, optic neuritis, iritis and iridocyclitis.

Respiratory diseases:

Symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means, berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, aspiration pneumonitis.

Haematologic disorders:

Idiopathic thrombocytopenic purpura in adults, secondary thrombocytopenia in adults, acquired (autoimmune) hemolytic anemia, erythroblastopenia (RBC anemia), congenital (erythroid) hypoplastic anemia.

Neoplastic diseases:

For palliative management of acute leukemia of childhood, leukemias and lymphomas in adults.

Edematous states:

To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

Gastrointestinal diseases:

To aid the patient over a critical period of the disease in: ulcerative colitis, regional enteritis.

Miscellaneous:

Tuberculous meningitis with subarachnoid block or impending block used concurrently with appropriate antituberculous chemotherapy. Trichinosis with neurologic or myocardial involvement. In addition to the above indications Pred[®] is indicated for systemic dermatomyositis (polymyositis).

DOSAGE

Dosage of Pred[®] should be individualized according to the severity of the disease and the response of the patient. Dosage should be decreased or discontinued gradually when the drug has been administered for more than a few days.

The initial dosage of Pred[®] may vary from 5 mg to 60 mg per day depending on the specific disease being treated. In situations of less severity lower doses will generally suffice while in selected patients higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, prednisolone should be discontinued and the patient transferred to other appropriate therapy.

It should be emphasized that dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.

After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached.

For Adult:

Allergic and skin disorders: Initial doses of 5-15 mg daily are commonly adequate.

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 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 leukemia.

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

For 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. It should be taken in the morning after food. No gradual decrease of the food is required. Children aged 12-18 years: 40-50 mg once daily for at least 5 days.

Other indications: 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 is 0.125-0.25 mg/kg/day.

CONTRAINdications

Systemic fungal infections, systemic infections process of any etiology and known hypersensitivity to prednisolone and prednisone.

WARNINGS & PRECAUTIONS

Patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay. In patients on corticosteroid therapy subjected to unusual stress, increased dosage of rapidly acting corticosteroids before, during and after the stressful situation is indicated.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Average and large doses of hydrocortisone or cortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium.

While on corticosteroid therapy, patient should not be vaccinated against smallpox. Other immunization procedures should not be undertaken in patients who are on corticosteroids, specially on high dose, because of possible hazards of neurological complications and a lack antibody response.

Children who are on drugs, which suppress the immune system, are more susceptible to infections than healthy children.

Chickenpox and measles, for example, can have more serious or even fatal course in non-immune children or adults on corticosteroids.

PREGNANCY AND LACTATION

Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancies, nursing mothers or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalinism.

PEDIATRIC USE

In the treatment of endocrine disorders such as primary and secondary adrenocortical insufficiency in infancy, mineralocorticoid supplementation is of particular importance. Infants born to mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalinism. Immunization procedures should not be undertaken in patients who are on corticosteroids. Pediatric patients who are on drugs which suppress the immune system are more susceptible to infections than healthy pediatric patients. Chickenpox and measles, for example, can have more serious or even fatal course in non-immune patients on corticosteroids. Growth and development in pediatric population on prolonged corticosteroid therapy should be carefully observed. See contraindications and warnings for complete information.

SIDE EFFECTS

Fluid and Electrolyte Disturbances:

Sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, hypokalemic alkalosis, hypertension.

Musculoskeletal:

Muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathologic fracture of long bones.

Gastrointestinal:

Peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, ulcerative esophagitis.

Dermatologic:

Impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, may suppress reactions to skin tests.

Neurological:

Convulsions, increased intracranial pressure with papilledema (cerebral pseudo-tumor) usually after treatment, vertigo, headache.

Endocrine:

Menstrual irregularities, development of Cushingoid state, suppression of growth in children, secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress as in trauma surgery or illness, decreased carbohydrate tolerance, manifestations of latent diabetes mellitus, increased requirements for insulin or oral hypoglycemic agents in diabetics.

Ophthalmic:

Posterior subcapsular cataracts, increased intraocular pressure, glaucoma, exophthalmos.

Metabolic:

Negative nitrogen balance due to protein catabolism.

PHARMACEUTICAL PRECAUTIONS

Keep away from light & wet place. Keep out of reach of children.

PACKAGING

Pred® 5 FC tablet : Box containing 20 strips of 10 tablets each. Each tablet contains Prednisolone BP 5 mg.

Pred® 10 FC tablet : Box containing 10 strips of 10 tablets each. Each tablet contains Prednisolone BP 10 mg.

Pred® 20 FC tablet : Box containing 5 strips of 10 tablets each. Each tablet contains Prednisolone BP 20 mg.

Pred® Oral Solution: Each bottle contains 50 ml (5 mg/5 mL) Prednisolone Oral Solution.



Manufactured by:

ESKAYEF BANGLADESH LIMITED

DHAKA, BANGLADESH

® REGD.TRADEMARK

M/PM00714 V03