Inflagic®

Prednisolone BP

COMPOSITION :
Inflagic® 5 Tablet: Each tablet contains Prednisolone BP 5 mg. **Inflagic®** 20 Tablet: Each tablet contains Prednisolone BP 20 mg.

Indication and usage:
1. Endocrine Disorders: Primary or secondary adrenocortical insufficiency, Congenital adrenal hyperplasia, Hypercalcemia associated with cancer, Nonsuppurative thyroiditis. **2. Rheumatic Disorders :** As adjunctive therapy for short-term administration in Psoriatic arthritis, Rheumatoid arthritis, Including juvenile rheumatoid arthritis, Ankylosing spondylitis, Acute and subacute bursitis, Acute nonspecific tenosynovitis, Acute gouty arthritis, Post-traumatic osteoarthritis, Synovitis of osteoarthritis, Epicondylitis. **3. Collagen Diseases :** During an exacerbation or as maintenance therapy in selected cases of Systemic lupus erythematosus, Systemic-dermatomyositis (polymyositis), Acute rheumatic carditis. **4. Dermatologic Diseases :** Pemphigus, Bullous dermatitis herpetiformis, Severe erythema multiforme (Stevens-Johnson syndrome), Exfoliative dermatitis, Mycosis fungoides, Severe psoriasis, Severe seborrheic dermatitis **5. 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. **6. Ophthalmic Diseases :** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as : Allergic cornea marginal ulcers, Herpes zoster ophthalmicus, Anterior segment inflammation, Diffuse posterior uveitis and choroiditis,Sympathetic ophthalmia, Allergic conjunctivitis, Keratitis, Chorioretinitis, Optic neuritis, Iritis and iridocyclitis. **7. 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. **8. Hematologic Disorders:** Idiopathic thrombocytopenic purpura in adults, Secondary thrombocytopenia in adults, Acquired (autoimmune) hemolytic anemia, Erythroblastopenia (RBC anemia), Congenital (erythroid) hypoplastic anemia. **9. Neoplastic Diseases:** For palliative management of Leukemias and lymphomas in adults acute leukemia of childhood **10. 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. **11.Gastrointestinal Diseases:** To tide the patient over a critical period of the disease in: Ulcerative colitis, Regional enteritis. **12. Nervous System:** Acute exacerbations of multiple sclerosis. **13. Miscellaneous:** Tuberculous meningitis with subarachnoid block or impending block when used concurrently with, appropriate antituberculous chemotherapy trichinosis with neurologic or myocardial involvement.

DOSAGE AND ADMINISTRATION :
The initial dose may vary from 5 mg to 60 mg per day depending on the specific disease. 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. Constant monitoring is needed in regard to drug dosage. If after long-term therapy the drug is to be stopped, it is recommended that it should be withdrawn gradually rather than abruptly. ***Multiple Sclerosis*:** In the treatment of acute exacerbations of multiple sclerosis daily doses of 200 mg of prednisolone for a week followed by 80 mg every other day for 1 month have been shown to be effective.

CONTRAINDICATION:
Systemic fungal infections and known hypersensitivity to components.

PRECAUTION:
Drug-induced secondary adrenocortical insufficiency, hypothyroidism, cirrhosis, herpeas simplex, ulcerative colitis may be minimized by gradual reduction of dosage. The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.

PREGNANCY AND LACTATION:
Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, 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 hypoadrenalism. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

DRUG INTERACTION:
Drugs that induce hepatic enzymes such as phenobarbital, phenytoin and rifampicin may increase the clearance of corticosteroids and may require increases in corticosteroid dose to achieve the desired response. Drugs such as troleandomycin and ketoconazole may inhibit the metabolism of corticosteroids and thus decrease their clearance. Therefore, the dose of corticosteroid should be titrated to avoid steroid toxicity. Corticosteroids may increase the clearance of chronic high dose aspirin. This could lead to decreased salicylate serum levels or increase the risk of salicylate toxicity when corticosteroid is withdrawn. Aspirin should be used cautiously in conjunction with corticosteroids in patients suffering from hypoprothrombinemia. There are reports of enhanced as well as diminished effects of anticoagulants when given concurrently with corticosteroids. Therefore, coagulation indices should be monitored to maintain the desired anticoagulant effect.

SIDE EFFECT :
Fluid and Electrolyte Disturbance: 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, Tendon rupture, particularly of the Achilles tendon, 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, Increases in alanine transaminase (ALT, SGPT), aspartate transaminase (AST, SGOT) and alkaline phosphatase have been observed following corticosteroid treatment. These changes are usually small, not associated with any clinical syndrome and are reversible upon discontinuation. **Dermatologic:** Impaired wound healing, Thin fragile skin, Petechiae and ecchymoses, Facial erythema, Increased sweating, May suppress reactions to skin tests. **Metabolic:** Negative nitrogen balance due to protein catabolism. **Neurological:** Increased intracranial pressure with papilledema ,(pseudo-tumor cerebri) usually after treatment, Convulsions Vertigo, Headache. **Endocrine:** Menstrual irregularities, Development of Cushingoid state, Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness, Suppression of growth in children, Decreased carbohydrate tolerance, Manifestations of latent diabetes mellitus, Increased requirements for insulin or oral hypoglycemic agentsin diabetics. **Ophthalmic:** Posterior subcapsular cataracts, Increased intraocular pressure, Glaucoma, Exophthalmos. **Additional Reactions:** Urticaria and other allergic, anaphylactic or hypersensitivity reactions.

STORAGE CONDITION:
Store in a cool and dry place, protect from light and moisture.

OVERDOSE:
Symptoms of a prednisolone overdose may include weight gain (especially around the stomach), a round face, excessive appetite, hair loss or increased hair growth, acne, bruising, swelling in your hands or feet, fast heart rate, worsened menopause symptoms, numbness or tingling, feeling light-headed or fainting.

HOW SUPPLIED:
Inflagic® 5 Tablet : Each box contains 10 x 10 tablets in blister packs.
Inflagic® 20 Tablet : Each box contains 5 x 10 tablets in blister packs.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH