# DELTASOLONE TABLET 5MG

Each tablet contains:-
Prednisolone 5 mg
Corn Starch
Lactose
Plasdone K90
Magnesium Stearate
Isopropyl Alcohol

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**Pharmacology:**
Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs such as Prednisolone are primarily used for their potent anti-inflammatory effects in disorders of many organ systems. In addition, Prednisolone cause profound and varied metabolic effects. The pharmacologic effects include action on the electrolyte balance, gluconeogenesis, lipolysis, protein catabolism, the action on tissue repair and healing, and the secretion of corticotrophin by the anterior lobe of the pituitary gland, glucose utilization and anti-insulin activity. Prednisolone is effective when given by mouth and is absorbed from the gastrointestinal tract. Prednisolone is 70-90% protein bound in the plasma and it is eliminated from the plasma with a half-life of 2-4 hours.

**Indications:**
It is indicated for primary or secondary adrenocortical insufficiency, rheumatic disorders, collagen diseases (systemic lupus erythematosus), dermatologic diseases (pemphigus, severe psoriasis, severe seborrheic dermatitis), bronchial asthma, ophthalmic diseases (eye inflammation, herpes zoster ophthalmicus, allergic conjunctivitis), hematologic disorders, neoplastic diseases (leukemia), edematous states and gastrointestinal diseases (ulcerative colitis).

**Side Effects/Adverse Reactions:**
Adverse reactions include fluid and electrolyte disturbance, muscle weakness, osteoporosis, acute pancreatitis, cushingoid state, growth retardation, menstrual irregularities, increased intraocular pressure, visual disturbances, manifestation of latent diabetes mellitus, peptic ulcer with possible perforation and hemorrhage, impaired wound healing, convulsion and increased intracranial pressure with papilloedema.
Vision, blurred.
Scleroderma renal crisis: Amongst the different subpopulations the occurrence of scleroderma renal crisis varies. The highest risk has been reported in patients with diffuse systemic sclerosis. The lowest risk has been reported in patients with limited systemic sclerosis (2%) and juvenile onset systemic sclerosis (1%).

**Contraindications:**
It is contraindicated in systemic fungal infection and hypersensitivity to any component of the product.

**Precautions:**
It should be used with caution in congestive heart failure, diabetes mellitus, chronic renal failure, hypertension, recent intestinal anastomoses, infectious diseases, elderly persons, pregnancy, myasthenia gravis and ocular herpes simplex.
Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if corticosteroid therapy is prolonged.
Growth and development of infants and children on prolonged corticosteroids therapy should be carefully observed.
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. Caution is required in patients with systemic sclerosis because of an increased incidence of (possibly fatal) scleroderma renal crisis with hypertension and decreased urinary output observed with a daily dose of 15mg or more prednisolone. Blood pressure and renal function (s-creatinine) should therefore be routinely checked. When renal crisis is suspected, blood pressure should be carefully controlled.

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

**Use in Pregnancy and Lactation:**
Since adequate human reproduction studies have not been done with corticosteroids, use of these drugs in pregnancy or in women of childbearing potential requires that the anticipated benefits be weighed against the possible 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. Corticosteroids appear in breast milk and could suppress growth, interfere with endogenous corticosteroids production, or cause other unwanted effects. Mothers taking pharmacologic doses of corticosteroids should be advised not to nurse.

**Dosage:**
Oral administration.
It is usually given in a dose range of 5 to 60mg daily, in divided doses or as a single daily dose at 8am or as a double dose on alternate days.
In long term therapy, dosage should be maintained at not more than about 7mg daily whenever possible as side effects inevitably occur with higher dosage.

**Drug Interactions:**
Phenytoin, phenobarbital, ephedrine and rifampicin may enhance the metabolism of corticosteroids resulting in decreased blood levels and lessened physiologic activity, thus requiring adjustment in corticosteroid dosage. Drugs such as barbiturates which induce hepatic microsomal drug metabolizing enzyme activity may enhance metabolism of Prednisolone and require the dosage of Deltasolone to be adjusted.
Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

**Symptoms and Treatment for Overdosage and Antidote(s):**
Symptoms are as mentioned in 'Side Effects'. The effects of accidental ingestion of large quantities of Prednisolone over a very short period of time have not been reported. Elevation of blood pressure and increased potassium excretion may be controlled with dietary salt restriction and potassium supplementation. Treatment of acute overdosage is by immediate gastric lavage or emesis. For chronic overdosage in the face of severe disease requiring continuous steroid therapy the dosage of Prednisolone may be reduced only temporarily, or alternate day treatment may be introduced.

**Pack Size:** Bottle pack: A bottle of 1000 tablets.
Blister pack: A box of 10x10 tablets and 1000 tablets.

**Storage Conditions:** Store at or below 30ºC.

**Shelf-life:** 5 years.

**Description:** Round, white, flat, plain tablet with "S.W." debossed on one side only.

**FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.**

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