# DHASOLONE TABLET

PRODUCT DESCRIPTION :
White, round and flat tablets with 6 mm diameter, score-line on one side and "DHA" logo on the other side.

COMPOSITION :
Each tablet contains : Prednisolone BP (micronised) 5 mg

PHARMACOLOGY:
Prednisolone is a glucocorticoid with anti-inflammatory and immune suppressant effects.

PHARMACOKINETIC :
Prednisolone is readily absorbed from the gastro-intestinal tract. Peak plasma concentrations of prednisolone are obtained 1 or 2 hours after oral administration. It has a usual plasma half-life of 2 or 4 hours, but its biological half-life lasts several hours. It is extensively bound to plasma proteins and is excreted in urine as free and conjugated metabolites, with an appreciable proportion of unchanged prednisolone.

INDICATIONS:
For the suppression of inflammatory and allergic disorders and for the treatment of conditions for which corticosteroid therapy is indicated except in adrenal-deficiency states.

RECOMMENDED DOSES:
Orally administered:
Dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.
Adults : 5-60 mg daily in divided doses or as a single daily or double dose on alternate days.
In long term therapy, dosage should be maintained at not more than 7 mg daily whenever possible.
Children: As directed by physician.
For short term treatment of not more than 2 weeks, as it may lead to growth retardation in children.

PHARMACODE AREA

SIDE EFFECTS :
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%).
Metabolic effects leading to mobilisation of calcium and phosporous, with osteoporosis and spontaneous fractures, nitrogen depletion and hyperglycaemia with accentuation or precipitation of the diabetic state. Possible peptic ulceration which may result in haemorrhage or perforation. Delayed wound healing and increased liability to all kinds of infection, possible growth retardation in children. High doses of prednisolone may cause Cushing's syndrome, with symptoms like moon face, striae, acne and muscle weakness. Mental disturbance or euphoria may occur.
Vision, blurred.

WARNINGS AND PRECAUTIONS :
In the presence of congestive heart failure, in patient with diabetes mellitus disease, chronic renal failure, and uraemia and in elderly persons. Acute adrenal insufficiency may occur during prolonged treatment or on cessation treatment.
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 15 mg 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:
It should be avoided in pregnancy and lactation.

CONTRA-INDICATION:
Patients with active or doubtfully quiescent tuberculosis. In the presence of acute infections, including herpes zoster and herpes simplex, ulceration of the eye. Patients with peptic ulcer, osteoporosis, pyschoses or severe psychoneuroses.

DRUG INTERACTION:
Barbiturates, or rifampicin may reduce the effect of concomitantly administered prednisolone. Concurrent administration of aspirin or sodium salicylate with prednisolone may lower the plasma concentration of salicylate.

INCOMPATIBILITY:
Not reported.

OVERDOSAGE & TREATMENT:
Gastric lavage and emesis if indicated. Treatment is symptomatic and supportive.

AVAILABILITY:
10x10x10's

STORAGE:
Keep below 30$^{0}$C. Protect from light.

EXPIRY PERIOD:
Do not use after the expiry date stated on the label.

DATE OF REVISION: October 2020

For further information, please consult your physician or pharmacist.

Manufactured by:
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