

# Prednisolone (Tablets)

Prednisolone  
Glucocorticoid



7100

Ref No.:B2127100/23.05

PREDNISOLONE TABLETS 5MG  
PREDNISOLONE TABLETS 20MG

## PRESENTATION:

**Prednisolone Tablets 5mg:** Blue, circular, flat bevelled-edge tablet plain on both sides. Each tablet contains: Prednisolone 5mg, Lactose and other excipients.

**Prednisolone Tablets 20mg:** Blue, circular, standard biconvex tablets embossed 'COSMOS' on one side and 'BREAKLINE' on other side. Each tablet contains: Prednisolone 20mg, Lactose and other excipients.

## CLINICAL PHARMACOLOGY:

Prednisolone is a corticosteroid with mainly glucocorticoid activity with potent anti-inflammatory and immunosuppressive effects. They also have profound metabolic effects: blood glucose concentrations are maintained or increased by a decrease in peripheral glucose utilization and an increase in gluconeogenesis; glycogen deposition, protein breakdown, and lipolysis are increased, and effects on calcium uptake and excretion lead to a decrease in body calcium stores. Glucocorticoid play a facilitative or permissive role in the function of many other active endogenous substances, and have effects on the function of cardiovascular system, kidneys, skeletal muscle and CNS.

## Pharmacokinetics:

Prednisolone is readily absorbed from the gastro-intestinal tract. Peak plasma concentrations of Prednisolone are obtained 1 or 2 hours after administration by mouth and it has a plasma half-life of 2 to 4 hours. Prednisolone is extensively bound to plasma proteins. It is excreted in the urine as free and conjugated metabolites. Prednisolone crosses the placenta and small amounts are excreted in breast milk. It has a biological half-life lasting several hours, intermediate between those of hydrocortisone (cortisol) and the longer-acting glucocorticoids, such as dexamethasone. It is this intermediate duration of action which makes it suitable for the alternate-day administration regimens which have been found to reduce the risk of adrenocortical insufficiency, yet provide adequate corticosteroid coverage in some disorders.

## USES:

Prednisolone is a glucocorticoid used for all conditions in which routine systemic corticosteroid therapy is indicated i.e. for anti-inflammatory or immunosuppressant effects.

## DOSAGE AND ADMINISTRATION:

Dosage of Prednisolone depends on the condition being treated and the response of the patient. The initial adult dose may range from 2.5-60mg daily in divided doses, as a single daily dose after breakfast, or as a double dose on alternate days.

**Elderly:** Doses may be adjusted by the doctor depending of the severity of the side effects.

**Use in children and adolescents:** Children do not take as many tablets as adults. Your doctor will tell you what the right number of tablets is for your child. Your doctor may change your dose in order to use the lowest effective dose, depending on your response to the medicine.

## CONTRA-INDICATIONS AND WARNINGS:

Corticosteroids should only be used systematically with great caution in the presence of congestive heart failure, recent myocardial infarctions, or hypertension, in patients with diabetes mellitus, epilepsy, glaucoma, hypothyroidism, liver failure, osteoporosis, peptic ulceration, psychoses or severe affective disorders, and renal impairment. Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if corticosteroid therapy is prolonged. During prolonged courses of corticosteroid therapy, patients should be examined regularly.

## Adverse Effects:

**Mineralocorticoid:** Adverse effects result from unwanted mineralocorticoid or glucocorticoid actions or from the inhibitions of the hypothalamic-pituitary-adrenal axis. Retention of sodium and water, with oedema and hypertension, and in the increased excretion of potassium with the possibility of hypokalaemic alkalosis.

# Prednisolone (Tablets)

**Glucocorticoid:** Prednisolone leads to mobilisation of calcium and phosphorus, with osteoporosis and spontaneous fractures; muscle wasting and nitrogen depletion; and hyperglycaemia with accentuation or precipitation of the diabetic state. The insulin requirement of diabetic patients are increased. Increased appetite is often reported. Impaired tissue repair and immune function can lead to delayed wound healing, and increased susceptibility to infection.

Others include amenorrhoea, hyperhidrosis, skin thinning, mental and neurological disturbances, benign intracranial hypertension, acute pancreatitis and avascular necrosis of bone.

**Infections and infestations:** Increases susceptibility to and severity of infections with suppression of clinical symptoms and signs, opportunistic infections, recurrence of dormant tuberculosis.

**Psychiatric disorders:** Euphoria, psychological dependence, depression, insomnia, dizziness, headache, vertigo, aggravation of schizophrenia, aggravation of epilepsy

**Eye disorders:** Increased intra-ocular pressure, glaucoma, papilloedema, posterior subcapsular cataracts, exophthalmos, corneal or scleral thinning, exacerbation of ophthalmic viral or fungal disease and vision, blurred.

**Vascular disorders:** Thromboembolism

## OVERDOSAGE:

Reports of acute toxicity and/or death following overdosage of glucocorticoids are rare. No specific antidote is available; treatment is supportive and symptomatic. Serum electrolytes should be monitored.

## PREGNANCY AND BREAST-FEEDING:

There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate/lip in man. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation. Therefore consult a physician before taking the medicine.

## Breast-feeding:

Corticosteroids are excreted in small amounts in breast milk. However, doses of up to 40mg daily of prednisolone are unlikely to cause systemic effects in the infant. Infants of mothers receiving 40mg or more daily should be monitored for signs of adrenal suppression but the benefits of breast-feeding are likely to outweigh any theoretical risk.

## Interactions:

Concurrent administration of barbiturates, carbamazepine, phenytoin, primidone, or rifampicin may enhance the metabolism and reduce the effects of corticosteroids. Concurrent administration of corticosteroids with potassium-depleting diuretics, such as thiazides or frusemide, may cause excessive potassium loss. There may be an increased incidence of gastro-intestinal bleeding and ulcerations when corticosteroids are given with NSAIDs. Response to anti-coagulants may be altered by corticosteroids and requirements of antidiabetic agents and antihypertensives may be increased. Corticosteroids may decrease serum concentrations of salicylates and may decrease the effect of antimuscarinics in myasthenia gravis.

## PHARMACEUTICAL PRECAUTIONS:

Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

## LEGAL CATEGORY:

Prescription Only Medicine (POM)



Cosmos Limited,  
Rangwe Rd; Off Lunga Lunga Rd,  
Nairobi, Kenya