REGAL PHARMACEUTICALS LIMITED
NAIROBI, KENYA

1.5.3 PATIENT INFORMATION LEAFLET (PIL)

APPLICATION FOR REGISTRATION–PREDILONE TABLETS
MINISTRY OF HEALTH, REPUBLIC OF RWANDA

PRODUCT NAME-PREDILONE TABLETS 5GM PATIENT INFORMATION LEAFLET

PREDILONE TABLETS

PREDNISOLONE TABLETS

Presentation
Predilone tablets are available as white, round, flat-faced tablets, scored on one side each containing 5mg Prednisolone BP.

Pharmacological Actions
Prednisolone is a glucocorticoid, which acts by controlling the rate of synthesis of proteins. It reacts with receptor proteins in the cytoplasm of sensitive cells in many tissues to form a steroid receptor complex. The complex undergoes a modification, as noted by an increase in the sedimentation constant, and then moves into the nucleus, where it binds to chromatin and regulates transcription of specific genes. Binding of it, by their receptor results in dissociation of a phosphorylated protein of approximately 90000 dalton size from the receptor complex in the cytosol. The release of this intriguing protein plays a major part in the transformation of the receptor, enabling the hormone-receptor complex to proceed to its nuclear destination or to interact fruitfully with DNA

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 usual plasma half-life of 2 to 4 hours. Its initial absorption, but not its overall bioavailability, is affected by food.
Prednisolone is extensively bound to plasma proteins. The volume of distribution, and also the clearance are reported to increase with an increase from low to moderate doses; at very high doses, clearance appears to become saturated.
Prednisolone is excreted in the urine as free and conjugated metabolites, together with an appreciable proportion of unchanged prednisolone. Prednisolone crosses the placenta and small amounts are excreted in breast milk.

Indication
Prednisolone is a glucocorticoid given in the treatment of various disorders in which corticosteroids are indicated, except adrenal deficiency. It is indicated for states like bronchial asthma, severe hyper-sensitivity reactions, anaphylaxis, rheumatoid arthritis, systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease, polyarteritis nodosa, inflammatory skin disorders, nephrotic syndrome, acute interstitial nephritis, ulcerative colitis, Crohn's disease, pulmonary sarcoid, rheumatic carditis, haemolytic anaemia, acute and lymphatic leukaemia, malignant lymphoma, multiple myeloma, idiopathic thrombocytopenic purpura, immuno-suppression in transplantation.

Dosage and Administration
Predilone tablets can be swallowed whole without difficulty or can be taken by dissolving in water. Dose: 5 to 60 mg i.e. 1 tablet to 12 tablets daily in divided doses, as a single daily dose after breakfast, or as a double dose on alternate days.

Contra-indications
Patients with a history of hypersensitivity to prednisolone should not take predilone tablets.
Prednisolone is contra-indicated in the presence of acute infections uncontrolled by appropriate antimicrobial chemotherapy.

Precautions
Prednisolone should be used with caution in the presence of congestive heart failure, recent myocardial infarction, or hypertension, in patients with diabetes mellitus, epilepsy, glaucoma, hypothyroidism, liver failure, osteoporosis, peptic ulceration, psychoses or severe affective disorders, and renal impairment. Children may be at increased risk of some adverse effects: in addition, corticosteroids may cause growth retardation, and prolonged administration is rarely justified. The elderly too may be at greater risk from adverse effects. Patients with active or doubtfully quiescent tuberculosis should not be given prednisolone except, very rarely, as adjuncts to treatment with antitubercular drugs. Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if prednisolone therapy is prolonged. The risks of chickenpox and probably of severe herpes zoster are increased in non-immune patients receiving therapeutic doses of systemic corticosteroids, and patients should avoid close personal contact with either infection. Passive immunisation is recommended for non-immune patients who do come into contact with chickenpox. Similar precautions apply to measles. Live vaccines should not be given to patients receiving high-dose systemic corticosteroid therapy nor for at least 3 months afterwards: killed vaccines or toxoids may be given although the response may be attenuated. During prolonged courses of prednisolone therapy, patients should be examined regularly. Sodium intake may need to be reduced and calcium and potassium supplements may be necessary. Monitoring of the fluid intake and output, and daily weight records may give early warning of fluid retention. Back pain may signify osteoporosis. Children are at special risk from raised intracranial pressure.
When the treatment is to be discountinued, the dose should be reduced gradually over a period of several weeks or months depending on the dosage and duration of the therapy.

Side-Effects
Adverse effects lead 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 requirements of diabetic patients are increased. Increased appetite is often reported. Increased susceptibility to all kinds of infection, including septicaemia, tuberculosis, fungal infections, and viral infections, has been reported. Infections may also be masked by the anti-inflammatory, analgesic, and antipyretic effects of glucocorticoids.
Other adverse effects include amenorrhoea, hyperhidrosis, skin thinning, ocular changes including development of glaucoma and cataract, mental a neurological disturbances, benign intracranial hypertension, acute pancreatitis, and avascular necrosis of bone. An increase in the coagulability of the blood may lead to thrombo-embolic complications

Storage
Store below 25°C, in a dry place. Protect from light. Keep out of reach of children.

Legal Category
Prescription Only Medicine (POM)

Package Quantities
1000 Tablets.
100 x 10 Tablets blister pack
10 x 10 Tablets blister pack

Ref: P07P01/3

REGAL PHARMACEUTICALS LTD.
Plot No. 7879/18, Off Baba Dogo Road, Ruaraka
P.O. Box 44421 - 00100, Nairobi

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When the treatment is to be discontinued, the dose should be reduced gradually over a period of several weeks or months depending on the dosage and duration of the therapy.

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