PRELONE SYRUP 3MG/5ML

Each 5ml contains:-

Prednisolone	3mg
Sodium Benzoate	4.7mg
Alcohol	1.71% v/v

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.
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, although less so than hydrcortisone (cortisol).
Prednisolone is excreted in the urine as free and conjugated metabolites, together with an appreciable proportion of unchanged prednisolone.
Prednisolone has a biological half-life lasting several hours, intermediate between those of hydrocortisone (cortisol) and the longer-acting glucocorticoids, such as dexamethasone.

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 (leukemias), edematous states and gastrointestinal diseases ulcerative colitis.

Dosage:
Oral administration.
Dosage of Prelone Syrup should be individualized according to the severity of the diseases and the response of the patient. For infants and children, the recommended dosage should be governed by the same consideration rather than strict adherence to the ratio indicated by age or body. The initial dosage of Prelone Syrup may vary from 5mg to 60mg daily in divided doses, as a single daily dose after breakfast or as a double dose on alternate days depending on the specific disease entity being treated. In situation of less severity lower doses will generally suffice while in selected patients higher initial doses may be required. The initial dosage should be maintained or adjusted until a satisfactory response is noted. After a favourable 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. If after long-term therapy the drug is to be stopped, it is recommended that is be withdrawn gradually better than abruptly. Constant monitoring is required in regard to drug dosage.

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 chemoprohylaxis 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.
Scleroderma renal crisis
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.

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.

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, manifestations of latent diabetes mellitus, peptic ulcer with possible perforation and hemorrhage, impaired wound healing, convulsion and increased intracranial pressure with papilledema.

Interactions with Other Medicaments:
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 Prelone 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 / Adverse reactions'. The effects of accidental ingestion of large quantities of prednisolone over a very short period of time have not been reported but prolonged use of the drug can produce symptoms as mentioned in 'Toxicology'. 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: A bottle of 60ml, 100ml and 120ml.
Pack size (export only): A bottle of 3.6 litres and 3.8 litres.

Storage conditions: Store at or below 30ºC. Protect from light.

Shelf-life: 1.5 years

Description: A clear, red syrup with raspberry flavour.

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

Manufacturer & Product Registration Holder:
Malaysia:
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