PREDSOLONE SYRUP

MAL19910171AZ

DESCRIPTION:
SYRUP
Colour : Red
Flavour : Apricot

CONTENT:
Each 5 ml contains:
Prednisolone .....2.5 mg
Preservatives: Methyl Paraben 0.1% w/v, Propyl Paraben 0.01% w/v & Sodium Benzoate 0.1% w/v

PHARMACODYNAMICS:
Prednisolone is a synthetic adrenocorticoid hormone. It has anti-inflammatory action, a weaker sodium-retaining effect than cortisone in normal dosage, anti-allergic, antishock and immunosuppressant action. At cellular level, it diffuses across cell membranes and complexes then enter the cell nucleus, bind to DNA and stimulate transcription of mRNA and subsequent protein synthesis of various enzymes thought to be responsible for the glucocorticoid effects and mineralocorticoid effects.

PHARMACOKINETICS:
Prednisolone is absorbed after oral administration. The biological half-life is about 3 hours. About 50 % is bound to plasma proteins. It is metabolised by reduction to 20-dihydroprednisolone, 20-dihydroprednisone and hydrocortisone and conjugation occur to some extent. About 10 to 30 % of a dose is excreted in the urine as unchanged prednisolone and the remainder as metabolites, 60 to 80 % of which is conjugated; a dose is completely excreted in 3 days. Prednisolone is excreted in milk in insignificant amounts.

INDICATION:
Corticosteroid indicated conditions include allergic disorders such as bronchial asthma & allergic skin reactions; blood disorders; selected collagen & rheumatic disorders; connective tissue disorders; gastrointestinal disorders such as inflammatory bowel disease, and also disorders responsive to adrenocortical hormone therapy.

RECOMMENDED DOSE:
Adults : 5 - 60 mg daily in 2 - 4 divided doses depending on the disease being treated.
Children : 0.14 - 2 mg/kg body weight in 4 divided doses or 4 - 6 mg/meter square daily in 4 divided doses.

ROUTE OF ADMINISTRATION:
FOR ORAL USE ONLY

CONTRAINDICATIONS:
Osteoporosis; active ulcer, psychoses or severe psychoneuroses. Systematic fungal infections. Acute infections unless effective, specific concurrent chemotherapy can be administered. Patients should not undergo immunisations. Tuberculosis, except as adjunctive treatment with tuberculostatic drugs.

WARNINGS AND PRECAUTIONS:
It may cause growth retardation in children. Care should be taken when there is an infection. It should be carefully considered when use in patients with diabetes mellitus, peptic ulcer, tuberculosis, cardiac disease, hypertension, hyperlipidemia, hypothyroidism, myasthenia gravis, osteoporosis, renal function impairment or stones.
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.
Pheochromocytoma crisis, which may be fatal, has been reported after administration of systemic corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.

DRUG INTERACTIONS:
Rifampicin, rifabutin, carbamazepine, phenobarbitone and other barbiturates, phenytoin, phenylbutazone, primidone and aminoglutethimide enhance the metabolism of corticosteroids and its therapeutic effects may be reduced.
The desired effects of hypoglycaemic agents (including insulin), anti-hypertensives and diuretics are antagonised by the corticosteroids and the hypokalaemic effects of acetazolamide, loop diuretics, thiazide diuretics and carbenoxolone are enhanced.
The efficacy of coumarin anticoagulants may be enhanced by concurrent corticosteroid therapy and close monitoring of the INR or prothrombin time is required to avoid spontaneous bleeding.
The renal clearance of salicylates increased by corticosteroids and steroid withdrawal may result in salicylate intoxication.
In patients treated with systemic corticosteroids, use of non-depolarizing muscle relaxants can result in prolonged relaxation and acute myopathy. Risk factors for this include prolonged and high dose corticosteroids treatment and prolonged duration of muscle paralysis. This interaction is more likely to occur following prolonged ventililation (such as in an ITU setting).
Corticosteroid requirements may be reduced in patients taking estrogens (e.g. contraceptive products)
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.

PREGNANCY AND LACTATION:
Risk-benefit must be considered when used during pregnancy and breast-feeding.

SIDE EFFECTS:
Cushing's syndrome, dyspepsia and peptic ulceration may occur. More serious effects are crush fractures of vertebrae, mental changes, hypertension, and possibly thrombo-embolic episodes. Fluid and salt retention, oedema, amenorrhoea, hyperhydrosis, acute pancreatitis, muscle weakness, growth retardation, delayed wound healing & increased risk of infection.

SYMPTOMS AND TREATMENT OF OVERDOSE:
Large doses may produce symptoms typical of hyperactivity of the adrenal cortex, with moon-face, sometimes with hirsutism, buffalo hump, flushing, increased bruising, striae, and acne, sometimes leading to a fully developed Cushing's syndrome. If administration is discontinued, these symptoms are usually reversed. Withdrawal should always be gradual, the rate depending on the individual patient's response, the dose, and the duration of therapy.

PACKAGING/PACK SIZE(S):
Plastic bottles of 60 ml and 100 ml.

JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN
SHAKE WELL BEFORE USE

MANUFACTURER/PRODUCT REGISTRATION HOLDER:
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PI1PL P001-07
Latest Revision: May 2023