PREDSONE SYRUP 3mg/5ml

DESCRIPTION:

Colourless to pale yellow coloured clear syrup having fruity flavour

COMPOSITION:

Each 5 ml contains Prednisolone 3mg.
Sodium benzoate 5mg (as preservative)

ACTIONS & PHARMACOLOGY:

Prednisolone is an anti-inflammatory glucocorticoid. Glucocorticoids decrease or prevent tissue responses to inflammatory processes, thereby reducing development of symptoms of inflammation without affecting the underlying cause. Glucocorticoids inhibit accumulation of inflammatory cells, including macrophages and leukocytes, at sites of inflammation. They also inhibit phagocytosis, lysosomal enzyme release, and synthesis and/or release of several chemical mediators of inflammation. Prednisolone is readily absorbed from the G.I.T. Plasma concentrations of prednisolone are obtained 1 or 2 hours after oral administration. Prednisolone is extensively bound to plasma proteins. It has a biological half-life lasting several hours. 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.

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.

CONTRAINDICATIONS:

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, psychoses or severe psychoneuroses.

SIDE EFFECTS:

Prolonged treatment with corticosteroids in high dosage is occasionally associated with subcapsular cataract, skin thinning, osteoporosis and glaucoma. In addition, any of the features of hypercorticism, such as suppression of the HPA axis, may occur. Aseptic osteonecrosis, particularly of the femoral head, may occur after prolonged corticosteroid therapy, or after repeated short courses involving high dosage. Peptic ulceration may develop, or be aggravated. In children, prolonged therapy may retard growth. In patients on long-term therapy, fluid and electrolyte balance may be altered. Other rare side-effects which have been reported include benign intracranial hypertension and psychic instability.
Gastro-intestinal effects include dyspepsia, peptic ulceration (with perforation), abdominal distension, acute pancreatitis, oesophageal ulceration and candidiasis;
musculoskeletal effects include proximal myopathy, osteoporosis, vertebral and long bone fractures, avascular osteonecrosis, tendon rupture;
endocrine effects include adrenal suppression, menstrual irregularities and amenorrhoea, Cushing's syndrome (with high doses, usually reversible on withdrawal), hirsutism, weight gain, negative nitrogen and calcium balance, increased appetite; increased susceptibility to and severity of infection;

neuropsychiatric effects include euphoria, psychological dependence, depression, insomnia, increased intracranial pressure with papilloedema in children (usually after withdrawal), psychosis and aggravation of schizophrenia, aggravation of epilepsy.

WARNINGS AND PRECAUTIONS:

Administration of corticosteroids may impair the ability to resist and counteract infection e.g. where there is a previous history of tuberculosis; in addition, clinical signs and symptoms of infection are suppressed. Corticosteroid treatment is likely to reduce the response of the pituitary- adrenal axis to stress, and relative insufficiency may persist for up to a year after withdrawal of prolonged therapy. Because of the possibility of fluid retention, care must be taken when corticosteroids are administered to patients with congestive heart failure. Corticosteroids may worsen diabetes mellitus, osteoporosis, hypertension, glaucoma and epilepsy. Care should be taken when there is a history of severe affective disorders (especially a previous history of steroid psychosis), previous steroid myopathy or peptic ulceration. Since corticosteroids are secreted in breast milk, the advisability of breast feeding should be considered in women on high dosage. Steroids may reduce the effects of anticholinesterases in myasthenia gravis, cholecystographic X-ray media and salicylates. The effect of steroids may be reduced by phenytoin, phenobarbitone, ephedrine and rifampicin. The dosage of concomitantly administered anti-coagulants may have to be altered (usually decreased). In patient with liver failure, blood levels of corticosteroid may be increased, as with other drugs which are metabolised in the liver. Systemic corticosteroids may cause growth retardation in infancy, childhood and adolescence. Treatment should be limited to the minimum dosage for the shortest possible time. In order to minimize suppression of the HPA axis and growth retardation, consideration should be given to administration of a single dose on alternate days. Treatment of elderly patients, particularly if long-term, should be planned bearing in mind the more serious consequences of common side- effects of corticosteroids in old age, especially osteoporosis, diabetes, hypertension, susceptibility to infection and thinning of the skin. When 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.

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.

PREGNANCY AND LACTATION:

Corticosteroids cross the placenta. Although adequate studies have not been done in humans, there is some evidence that corticosteroids can cause abnormalities of foetal development. Breast feeding during the use of higher pharmacologic doses is not recommended because corticosteroids are excreted into breast milk and may cause unwanted effects such as growth suppression and inhibition of endogenous steroid production in the infant.

DRUG INTERACTIONS:

Amphotericin B
Concurrent use of Amphotericin B by injection with corticosteroids may result in severe hypokalemia and should be undertaken with caution; serum potassium concentrations and cardiac function should be monitored during concurrent use.

Digitalis glycosides
Concurrent use of digitalis glycosides with corticosteroids may increase the possibility of arrhythmias or digitalis associated with hypokalemia.

Alcohol/NSAIDs
Concurrent use of alcohol and NSAIDs may have the risk of gastrointestinal ulceration.

Isoniazid
Concurrent use of isoniazid may increase hepatic metabolism and / or excretion of isoniazid; isoniazid dosage adjustment may be required during and following concurrent use.

Mitotane
Concurrent use of mitotane suppresses adrenocortical; glucocorticoid supplementation is usually required during mitotane administration.

Salicylates
Although concurrent use of salicylates with glucocorticoids in the treatment of arthritis may provide additive therapeutic benefit and permit glucocorticoid dosage reduction, glucocorticoids may increase salicylate excretion and reduce salicylate plasma concentrations so that the salicylate dosage requirement may be increased.

Anticoagulants
The potential occurrence of gastrointestinal ulceration or hemorrhage during glucocorticoid therapy, and the effects of glucocorticoids on vascular integrity, may cause increased risk to patients receiving anticoagulant or thrombolytic therapy.

Antidiabetic agents
Glucocorticoids may increase blood glucose concentration; dosage adjustment of one or both agents may be necessary during concurrent use; with antidiabetic agents dosage readjustment of the hypoglycemic agent may also be required when glucocorticoid therapy is discontinued.

Estrogens
Estrogens may after the metabolism and protein binding of glucocorticoids, leading to decreased clearance, increased elimination half-life, and increased therapeutic and toxic effects of the glucocorticoid; glucocorticoid dosage adjustment may be required during and following concurrent use with oral contraceptives.

Anticholinesterases
Steroids may reduce the effects of anticholinesterases in myasthenia gravis, cholecystographic X-ray media and non-steroidal anti-inflammatory agents. It should also be remembered that the effects of steroids may be reduced by phenytoin, phenobarbitone, ephedrine and rifampicin.

DOSAGE & ADMINISTRATION:

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 dose on alternate days. In long term therapy, dosage should be maintained at not more than 7mg whenever possible.

Children: As directed by the physician. For short term treatment of not more than 2 weeks, as it may lead to growth retardation in children.

ROUTE OF ADMINISTRATION:
Oral administration.

OVERDOSAGE & TREATMENT:
Treatment is unlikely to be needed in cases of acute overdosage.
Treatment is supportive and symptomatic.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE:
Not applicable

PRESENTATION:
Bottle of 60 and 120ml

STORAGE CONDITION:
Store in a dry place below 30°C.
Keep the container tightly closed.
Protect from light.
Keep medicines out of reach of children.

MANUFACTURED BY:
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