PACKAGE INSERT

SP-CORTIL 10 SYRUP

Each 5ml contains:
Prednisolone 10mg

Pharmacodynamics:
Prednisolone has the capacity to prevent or suppress the development of local heat redness, swelling and tenderness by which inflammation is recognised at the gross level of observation. At the microscopic level, it inhibits not only the early phenomenon of the inflammatory process (edema, fibrin deposition, capillary dilatation, migration of phagocytes into the inflamed area, and phagocytes activity) but also the later manifestations (capillary proliferation, fibroblast proliferation, deposition of collagen, and still later cicatrization). Its mechanism of action is the stabilization of the membranes of lysosomes promoting the containment of cathespins and other enzymes within the lysosomal sac against disrupting influences of hypoxia, bacterial and chemical toxins. Other actions include influence on the carbohydrate, protein, fat and purine metabolism, electrolyte and water balance and the functional capacities of the cardiovascular system, the kidney, skeletal muscle, the nervous system and other organs and tissues.

Pharmacokinetics:
Prednisolone has potent anti-inflammatory and anti-allergic effects. In addition, glucocorticoids such as prednisolone cause profound and varied metabolic effects. The metabolic effects include action on the electrolyte balance, gluconeogenesis, the action on tissue repair and healing, and an inhibitory effect on the secretion of corticotrophin by the anterior lobe of the pituitary gland.
Prednisolone is effective when given by mouth and is absorbed from the gastro-intestinal tract. The steroid exists in the plasma in two forms: a protein bound form and a free form. The biological half life of prednisolone is about 200 minutes.

Indications:
It is indicated for bronchial asthma, allergic dermatoses, rheumatic disorders, lupus erythematosus and other collagen diseases, inflammatory eye diseases, nephrosis and certain blood disorders.

Side Effects / Adverse Reactions:
Side effects include fluid and electrolyte disturbance, muscle weakness, oedema, hypertension, osteoporosis, acute pancreatitis, amenorrhea, cushingoid state, growth retardation, mental disturbances, increased intraocular pressure, visual disturbances, local atrophy and increased appetite.
Two categories of toxic effects are observed in the therapeutic use of adrenocorticosteroids: those resulting from continued use of large doses and those resulting from withdrawal. Acute adrenal insufficiency results from too rapid withdrawal of corticosteroid therapy. Corticosteroids withdrawal syndrome consists of fever, myalgia, arthralgia and malaise.
The principal complications resulting from prolonged therapy with corticosteroids are fluid and electrolyte disturbances, hyperglycemia and glycosuria, susceptibility to infections, including tuberculosis; peptic ulcers, which may bleed or perforate; osteoporosis; a characteristic myopathy, psychosis and Cushing's habitus, consisting of 'moon face', buffalo hump, superclavicular fat pads, central obesity, striae, ecchymoses, acne and hirsutism.

Precautions / Warnings:
Warning : Unsuitable for phenylketonurics.
It should be used with caution in congestive heart failure, diabetes mellitus, chronic renal failure, hypertension, recent intestinal anastomoses, infectious diseases, uraemia, elderly persons, pregnancy, diverticulitis, myasthenia gravis and ocular herpes simplex.
Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if corticosteroid therapy is prolonged.
Growth and development of infants and children on prolonged corticosteroids therapy should be carefully observed.
Following prolonged therapy, withdrawal of corticosteroids may result in symptoms of fever, myalgia, arthralgia and malaise.
Concurrent administration of barbiturates, phenytoin or rifampicin may enhance the metabolism and reduce the effects of corticosteroids.
Response to anticoagulants may be reduced and, on some occasions, enhanced by corticosteroids.
Adrenocortical insufficiency may persist for months after stopping the corticosteroid; therefore, replacement therapy may be needed during period of stress.
Corticosteroid may mask the signs of infection and decrease resistance to infection. If new infection arises during treatment, there may be an ability to localize the infection.
Systemic therapy with corticosteroid may increase the risk of serious or fatal infection in individuals exposed to viral illnesses such as chicken pox or measles.
After prolonged use, corticosteroid therapy should be tapered slowly to prevent the corticosteroid withdrawal syndrome.
Corticosteroid may cause psychic derangements including euphoria, insomnia, mood swings, personality changes, severe depression or frank psychosis. Pre-existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

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.

Contraindications:
It is contraindicated in peptic ulcer, osteoporosis, psychoses, or psychoneuroses, live vaccines and systemic fungal infections.

Drug Interactions:
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. These interactions may interfere with dexamethasone suppression tests which should be interpreted with caution during administration of these drugs.

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 outweights the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Dosage:
Oral administration.
Dosage of SP-Cortil 10 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 SP-Cortil 10 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 it be withdrawn gradually better than abruptly. Constant monitoring is required in regard to drug dosage.

Symptoms and Treatment for Overdosage and Antidote:
Symptoms are as mentioned in 'Side Effects/ Adverse Reactions'. The toxic effects of overdosage should be treated symptomatically and dosages reduced or the drug slowly withdrawn. Sodium intake may need to be reduced to less than 1g daily and potassium supplements may be necessary.

Pack Sizes: A bottle of 60ml, 100ml and 120ml.
Pack Sizes (export only): A bottle of 3.6 litres and 3.8 litres.

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

Shelf-life: 1.5 years.

Description: A clear, colourless syrup without flavour.

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

Manufacturer & Product Registration Holder:
SUNWARD PHARMACEUTICAL SDN. BHD.
No. 9, 11 & 17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.

SL330A-R7
Revision Date : 25/07/2023