YSP PREDNISOLONE TABLET 5mg

Presentation(s):
Each tablet contains:
Prednisolone 5mg

Pharmacodynamic:
1. Prednisolone can decrease or prevent tissue responses to inflammatory processes, thereby reducing development of symptoms of inflammation without affecting the underlying cause. Prednisolone inhibits accumulation of inflammatory cells including macrophages and leukocytes at sites of inflammation. It also inhibits phagocytosis, lysosomal enzyme release, and synthesis and/or release of several chemical mediators of inflammatory.
2. Prednisolone is readily absorbed from the gastrointestinal tract and already exists in a metabolically active form, biological half-life is about 60 minutes.

Pharmacokinetic:
Peak plasma concentration obtained 1 or 2 hours after oral administration. It has a usual plasma half-life of 2 to 3 hours and is excreted in the urine as free and conjugated metabolites. Prednisolone crosses the placenta and small amounts are excreted in breast milk.

Indication(s):
For the treatment of bronchial asthma, allergic disease, rheumatoid arthritis, rheumatosis, Still's disease, rheumatoid myocarditis, psoriasis, osteoarthritis, rheumatic myelitis, gouty arthritis, acute and chronic gout and other inflammatory skin disease.

Dosage and Administration:
Diseases of connective tissue:
Rheumatoid arthritis: Initially 5mg of Prednisolone daily, given as a single dose in the morning or on alternate days; the dosage regimen is adjusted to individual patient response. In the absence of adequate improvement, steroid dose may be raised by 1mg increments, at intervals of a few weeks, up to a maximum of 10 mg daily.
Rheumatic carditis: Corticosteroids are indicated in patients who fail to respond to salicylates or cannot tolerate them in high doses. The dose usually is 1mg/kg body weight per day given in a single or divided doses for 7 – 10 days, thereafter reduced by 2.5mg daily every 5 – 7 days.

Asthma and other respiratory diseases:
Prednisolone 5 -10mg orally as a single daily dose or in divided doses. Larger doses may be required temporarily during exacerbations.
(For other cases, the initial adult dosage of Prednisolone may range from 5 – 60 mg daily, depending on the disease being treated, and is usually administered in 2 – 4 divided doses. The dose may be decreased by a half to 1 tablet every 2 to 3 days interval for maintenance after an improvement is seen. The dosage may be adjusted according to symptoms and age. To be dispensed on physician's prescription.)

Contraindication(s):
Prednisolone is contraindicated in patient with systemic fungal infections and those who have shown hypersensitivity to any component of this product.

Precaution(s) / Warning(s):
The adverse effects of Prednisolone are nearly always due to its use in excess of normal physiological requirement. They should be treated symptomatically, where possible, the dosage being reduced or the drug slowly withdrawn.
Prednisolone may mask some signs of infections and new infections may appear during its use. There may be decreased resistance and inability to localize infection when Prednisolone is used. The use of Prednisolone in pregnancy, nursing mothers, or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards, to the mother and embryo or fetus. Because of 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 (esp. severe history of steroid psychosis), previous steroid myopathy or peptic ulceration.

Drug Interaction(s):
Potentially hazardous interactions
- *Anticonvulsant drugs*: The actions of Prednisolone are blunted in patients receiving concomitant therapy with drugs like Barbiturates or Phenytoin. The reason is the stimulation of hepatic drug-metabolizing enzymes by these drugs, resulting in enhancement of Prednisolone clearance from circulation.
- *Rifampicin*: Non-responsiveness to Prednisolone has been attributed to concurrently administered Rifampicin which is a known inducer of drug metabolism.

Other significant interactions
- *Cyclosporine*: Cyclosporine decreases the metabolism of Prednisolone in the early phase of the combination therapy. Accordingly, plasma half lives are prolonged and clearance reduced. Prednisolone dosage in such cases may, therefore, require adjustment.
- *Corticosteroids*: Previous long-term treatment with other corticosteroids may reduce plasma Prednisolone half-life.
- *Non-steroidal anti-inflammatory drugs*: Concurrent administration of corticosteroids and large doses of aspirin may cause changes in salicylate plasma protein binding and its rate of metabolism, thereby lowering plasma salicylate levels.
- *Antacids*: Prednisolone absorption may be impaired if a small amount of it is taken with large doses of antacids.
- *Insulin*: Prednisolone may also decrease the effects of insulin by raising the level of blood sugar. As a result, the requirement of insulin is generally increased.

Side Effect(s) / Adverse Reaction(s):
The prolonged therapy may result in suppression of pituitary adrenal function and the principal complications resulting from prolonged therapy with Prednisolone are fluid and electrolyte disturbances, hyperglycemia and glycosuria; increased susceptibility to infections, including tuberculosis; peptic ulcers which may bleed or perforate; osteoporosis; a characteristic myopathy; behavioral disturbances; posterior subcapsular cataracts; arrest of growth; and Cushing's habitus, consisting of "moon face", "buffalo hump", enlargement of supraclavicular fat pads, "central obesity", striae, ecchymoses, acne and hirsutism.

Symptoms and Treatment for Overdosage, and Antidote(s):
There is no specific antidote for its overdosage, therefore, management of the patients should consist of symptomatic and supportive therapy.

Shelf-Life:
5 years from the date of manufacture.

Storage Condition(s):
Keep in a tight container. Store at temperature below 30°C. Protect from light and moisture.

Packing (s):
A pink color round tablet slighty curved at both sides, one side impressed with a " Ⓨ " mark.

Plastic bottle of 200's, 500's, 1000's and 2000's
Blister packing of 10's x 10 and 10's x 100.

YSP PREDNISOLONE TABLET 5mg

Bahan Aktif:
Setiap tablet mengandungi:
Prednisolone 5mg

Indikasi:
Untuk rawatan bronkial asma, penyakit alah, reumatoid artritis, reumatosis, penyakit Still's, reumatoid miokarditis, psoriasis, osteoartritis, reumatik mielitis, gouty arthritis, gout akut, gout kronik dan lain-lain penyakit radang kulit.

Dos:
Dos permulaan Prednisolone untuk orang dewasa biasanya meliputi 5 -60mg sehari, bergantung kepada jenis penyakit yang dirawati, dan lazimnya dos harian diambil dalam 2 – 4 dos terbahagi. Didispens mengikut preskripsi pakar perubatan.

Y. S. P.®
Manufacturer and Product Registration Holder :
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