

hovid-Prednisolone Tablet 5 mg

Description

Round, white uncoated tablet, shallow convex faces; "HD" embossed and scored on the same face.

Composition

Each tablet contains Prednisolone 5 mg.

Pharmacodynamics

Prednisolone, a synthetic glucocorticoid, has both anti-inflammatory and immunosuppressant actions. It acts by inhibition of phagocytosis, leukocyte migration and capillary dilatation, and prevention or suppression of cell - mediated (delayed hypersensitivity) immune reactions respectively.

Pharmacokinetics

It is readily absorbed orally, metabolised in the liver and excreted via the kidneys.

Indication

Prednisolone is used in the treatment of conditions where a routine systemic corticosteroid therapy is indicated. Its weaker sodium-retaining action usually makes it more suitable than cortisone in such conditions as rheumatoid arthritis, rheumatic fever, status asthmaticus and ulcerative colitis.

Contraindications

Use is not recommended in nursing mothers, wherever possible.

Warnings and Precautions

- Caution in patients with osteoporosis, peptic ulcer, psychoses, systemic fungal infections, diabetes mellitus, hypertension, myasthenia gravis, ocular herpes simplex, glaucoma, hypothyroidism, history of tuberculosis, renal and hepatic function impairment.
- When medication is to be discontinued, dosage should be reduced gradually. Abrupt cessation of prolonged therapy may produce acute adrenal insufficiency.
- Frequent monitoring of drug effect is required.
- Caution in receiving vaccinations, other immunizations and skin test.
- Children on prolonged therapy should be closely observed.
- 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

- Safety for use in pregnancy has not been established.
- Use is not recommended in nursing mothers, wherever possible.

Side Effects

Dyspepsia, peptic ulceration; long-term use include Cushings syndrome, acne, osteoporosis, mental changes and endocrine imbalance.

Drug Interactions

- Response to prednisolone may be reduced by co-administration of barbiturates, phenytoin or rifampicin.
- Effects of oral anticoagulants or salicylates may be decreased when used concurrently with prednisolone.
- Caution in patients receiving the following drug therapy:
- Alcohol, anti-inflammatory medications, cardiac glycosides, ephedrine, heparin, hypoglycaemics.
- 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.

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Overdose

Clinical features: Nausea and vomiting, hyperglycaemia, occasional gastrointestinal bleeding.
Treat overdose by symptomatic measures.

Dosage and Administration

Adults : Oral, 5 to 60 mg a day as a single dose or in divided doses, not exceeding 250mg daily.

Children : As directed by physician.

Note: The paediatric dosage is determined more by the severity of the condition and response of the patient than by age or body weight.

Storage

: Store below 30°C

Presentation / Packing

: Blister of 10 x 10's

Product Registration Holder / Manufactured by : Hovid Berhad

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: Aug 2023