

W=100 mm

Steron[®]

Tablet/ Injection

Dexamethasone

DESCRIPTION

Dexamethasone is one of the potent synthetic analogues of cortisol. Though commonly identified with the standard suppression test of hypothalamic pituitary-adrenal function, its main clinical applications are as a steroidal anti-inflammatory agent, for the prevention and treatment of cerebral oedema, in shock and as an antiemetic agent in cancer chemotherapy. Like other glucocorticoids, it is anti-allergic, anti-oxidative and anti-proliferative. It is along acting glucocorticoid with negligible sodium retaining properties and 25 times more effective than Hydrocortisone.

COMPOSITION

Tablet : Each tablet contains Dexamethasone (Micronized) BP 0.5 mg.

Injection : Each 1 ml ampoule contains Dexamethasone Sodium Phosphate BP 5 mg.

INDICATIONS

Steron is indicated in shock, bronchial asthma, rheumatoid arthritis, gout, severe allergies, skin diseases, hay fever, bacteremia, toxemia and other indications where glucocorticoid therapy is required.

DOSAGE AND ADMINISTRATION

Tablet :

Acute conditions : First 2 days 2 tablets 3 times daily. Next 2 days 1 tablet 3 times daily and last 2 days ½ tablet 3 times daily.

Chronic conditions : 1 tablet 3 times daily for 2-3 weeks, thereafter ½ tablet to be tapered off during each next 2 weekly period, finally a daily dose of ½ tablet will be the maintenance dose.

Injection :

Dexamethasone Sodium Phosphate can be given parenterally at doses of 0.5-20 mg daily either as a single (slow) intravenous or intramuscular injection or by intravenous infusion.

Large intravenous doses should be administered slowly to reduce the risk of Cardiovascular collapse. The total daily intake of Dexamethasone, even in acute conditions should not exceed 80 mg except in certain very special circumstances.

Cerebral oedema : 10 mg initially by intravenous injection, then 4 mg by intramuscular injection every 6 hours is required for 2-10 days.

Shock : By intravenous or intramuscular injection or infusion 2-6 mg/kg, repeated in necessary after 2-6 hours.

OR AS DIRECTED BY THE PHYSICIAN.

SIDE EFFECTS

Patients on prolonged Dexamethasone therapy are risk of collapse and possibly death if their daily dose is not increased at times of severe physical stress e.g. injury, surgery or infections. The somatic manifestations include growth retardation in children, osteoporosis and aseptic bone necrosis, peptic ulceration, ocular hypertension, pancreatic disturbances and myopathy, characteristic of excess glucocorticoid includes, moon-face, oedema, delayed wound healing. Dexamethasone is generally well tolerated in standard low doses. Nausea, vomiting, appetite, obesity may occur. Higher dose may result behavioral & personality changes.

Systemic reactions may also occur after long-term topical application of corticosteroids.

CONTRAINDICATIONS

Ocular herpes simplex is an example of absolute contraindication to corticosteroid therapy. Relative contraindications are gastrointestinal ulcer, acute or chronic infections, osteoporosis, pregnancy, diabetes mellitus, renal insufficiency, history of psychotic illness hypertension, and finally hypersensitivity to Dexamethasone. Systemic glucocorticoid is generally contraindicated in patients with cushing syndrome, systemic fungal infection & acute oral infection.

PRECAUTIONS

The drug should be used with caution in the presence of congestive heart failure or hypertension, in patients with diabetes, epilepsy, glaucoma, infectious diseases, chronic renal failure and in elderly persons.

USE IN PREGNANCY & LACTATION

It should only be administrated during pregnancy if the potential benefit exceeds the foreseeable risk to the fetus (Pregnancy Category C). It should be given in lactating mother if clearly indicated by the physician.

USE IN CHILDREN

Safety and effectiveness in pediatric patients below 2 years have not been established.

DRUG INTERACTIONS

Specific drug interaction studies have not been conducted with Dexamethasone.

SUPPLY

Tablet : Each box contains 10 x 10 tablets in blister strips.

Injection : Each box contains 2x5 ampoules in blister strips.

Keep all medicines out of reach of children,

Store in a cool and dry place protected from light

* Further information is available on request.



Manufactured by:

The ACME Laboratories Ltd.

Dhanrai, Dhaka, Bangladesh

For Health, Vigour and Happiness

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