



Metadaxan[®]

Dexamethasone

Presentation

Metadaxan[®] 0.5 mg Tablet: Each tablet contains Dexamethasone BP 0.5 mg.

Metadaxan[®] 5 mg Injection: Each 1 ml ampoule contains Dexamethasone Sodium Phosphate BP 5 mg.

Description

Dexamethasone, a synthetic glucocorticoid, is primarily used for its anti-inflammatory effects in disorders of many organ systems. Dexamethasone decreases inflammation by acting within cells to prevent the release of certain chemicals in the immune system. These chemicals are normally involved in producing immune and allergic responses. Thus, it has anti-allergic, antitoxic, antishock, antipyretic and immunosuppressive properties.

Indication

Severe allergies, respiratory distress syndrome, shock, asthma, rheumatoid arthritis, gout, skin diseases, atopic dermatitis, hyperpyrexia, nonsuppurative thyroiditis, renal diseases, diseases of liver & gastrointestinal tract, acquired hemolytic anemia, hypoplastic anemia, idiopathic thrombocytopenic purpura in adult and other indications where glucocorticoid therapy is required. In addition, Dexamethasone may be used as dose adjustment for high potency in most situations indicated for Prednisolone.

Dosage and administration

Normally, a glucocorticoid dosage depends on the severity of the condition and response of the patients. In chronic conditions requiring long term therapy, the lowest dosage should be used.

Tablet: Usual oral dosage range is 0.5-10 mg/day for adults & 0.02-0.30 mg/kg/day for children in three to four divided dosages. After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial dose. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

In the treatment of acute exacerbation of multiple sclerosis, daily doses of Dexamethasone is 30 mg for a week followed by 4 to 12 mg every other day for one month.

Dexamethasone suppression test: 1 mg Dexamethasone is given at 11 p.m. and plasma cortisol is measured at 8 a.m. next morning. Patients who do not show a decrease in cortisol can be exposed to a longer test: 0.5 mg Dexamethasone is given at 6 hours intervals for 48 hours followed by 2 mg every 6 hours for a further 48 hours. 24 hours urine collections are made before, during and at the end of the test for the determination of hydroxycorticosteroid excretion.

Injection: Dexamethasone injection can be given either as a single IV/IM injection or by IV infusion. Large IV doses should be given slowly to reduce the possibility of cardiovascular collapse. IM administration should be given by deep intramuscular injection to prevent atrophy of the subcutaneous adipose tissue. Intra-articular injections should be given under strict aseptic conditions as glucocorticoids decrease the resistance to infection. When diluted with the infusion fluid, Dexamethasone will keep its potency for at least 24 hours at room temperature. As infusion fluid, Sodium chloride 0.9%, anhydrous glucose 5% etc. can be used. For systemic therapy in adults, daily doses of 0.05-0.20 mg/kg body weight are usually sufficient.

Children: 200-500 mcg/kg daily. For emergencies (e.g. anaphylaxis, acute severe asthma and cerebral edema) an initial dose of 10-20 mg IV is followed by 6 mg IV or IM every 6 hours, until a satisfactory result has been obtained. Thereafter the dose has to be tapered off gradually. For local therapy, the following doses are recommended: Intra-articular therapy is given by 2-4 mg in large joint and 0.8-1 mg in small joints. Intrabursally: 2-4 mg; and in tendon sheaths: 0.4-1 mg. The frequency of these injections may vary from every 3-5 days to every 2-3 weeks.

Contraindication

In case of adrenal insufficiency, no absolute contraindications are applicable. In the treatment of non endocrine diseases where pharmacological doses are more likely to be used, the contraindications have to be considered carefully. Relative contraindications include following: Cushing's syndrome, osteoporosis, diabetes mellitus, renal insufficiency, gastrointestinal ulcers, systemic fungal infection & acute infection.

Drug Interaction

Interactions can be occurred with following drugs: diuretics, cardiac glycosides, antidiabetics, NSAIDs, anticoagulants, antacids etc. Besides, if patients undergo long term therapy of glucocorticoids with concomitant salicylates, any reduction in glucocorticoid dosage should be made with caution, since salicylate intoxication has been reported in such cases.

Side effects

Dexamethasone is generally well tolerated in standard low doses. However nausea, vomiting, increased appetite and obesity may occur. Higher doses may result in behavioral personality changes. Following adverse reactions have been associated with prolonged systemic glucocorticoid therapy: Endocrine and metabolic disturbances, fluid and electrolyte disturbances, musculo-skeletal effects like osteoporosis etc; GI effects like ulcer, bleeding, perforation; ophthalmic effects like glaucoma, increased intraocular pressure etc; immunosuppressive effects like increased susceptibility to infections etc.

Precaution

The lowest possible dose of corticosteroids should be used to control the conditions under treatment. Dexamethasone should be used with caution in patient with cardiomyopathy, heart failure, hypertension or renal insufficiency, drug induced secondary adrenocortical insufficiency, peptic ulcer, diverticulitis, intestinal anastomosis, ulcerative colitis, osteoporosis and latent tuberculosis etc.

Pregnancy and Lactation

Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies.

Lactation: Glucocorticoids appear in breast milk. Mothers taking high dosages of corticosteroids should be advised not to breast-feed.

Overdose

Overdose is unlikely; however, treatment of overdose is by supportive and symptomatic therapy.

Storage

Store in a cool & dry place, protected from light.

Commercial Pack

Metadaxan[®] 0.5 mg Tablet: Each box contains 10 blister strips of 10 tablets.

Metadaxan[®] 5 mg Injection: Each box contains 2 blister strips of 5 ampoules.

Manufactured by
 **Incepta Pharmaceuticals Ltd**
Dhaka, Bangladesh
® Registered Trademark

V.N. 01

MDI