

Dextor[®]

Dexamethasone BP Tablet

DESCRIPTION

Dexamethasone is a synthetic adrenocortical steroid, with high anti-inflammatory potency. It also has anti-allergic, antipyretic and immunosuppressive properties. Dexamethasone has practically no water and salt-retaining properties and is therefore, particularly suitable for the use in patients with cardiac failure or hypertension.

INDICATIONS AND USAGE

Allergic States

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis and serum sickness.

Rheumatic Disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute rheumatic carditis, ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, polymyositis and systemic lupus erythematosus.

Dermatologic Diseases

Bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, and severe erythema multiforme (Stevens-Johnson syndrome).

Endocrine Disorders

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; may be used in conjunction with synthetic mineralocorticoid analogs where applicable; in infancy mineralocorticoid supplementation is of particular importance), congenital adrenal hyperplasia, hypercalcemia associated with cancer, and nonsuppurative thyroiditis.

Gastrointestinal Diseases

To tide the patient over a critical period of the disease in regional enteritis and ulcerative colitis.

Hematologic Disorders

Acquired (autoimmune) hemolytic anemia, congenital (erythroid) hypoplastic anemia (Diamond-Blackfan anemia), idiopathic thrombocytopenic purpura in adults, pure red cell aplasia and selected cases of secondary thrombocytopenia.

Miscellaneous

Diagnostic testing of adrenocortical hyperfunction, trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used with appropriate antituberculous chemotherapy.

Neoplastic Diseases

For the palliative management of leukemias and lymphomas.

Nervous System

Acute exacerbations of multiple sclerosis, cerebral edema associated with primary or metastatic brain tumor, craniotomy or head injury.

Ophthalmic Diseases

Sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids.

Renal Diseases

To induce a diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus.

Respiratory Diseases

Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis.

DOSAGE AND ADMINISTRATION

The initial dosage varies from 0.75 to 9 mg a day depending on the disease being treated.

It should be emphasized that dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.

In pediatric patients, the initial dose of dexamethasone may vary depending on the specific disease entity being treated. The range of initial doses is 0.02 to 0.3 mg/kg/day in three or four divided doses (0.6 to 9 mg/m²/day).

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 that maintains an adequate clinical response is reached. Withdrawal of dexamethasone at completion of treatment should be gradual, rather than abrupt.

CONTRAINDICATIONS

- ☐ Hypersensitivity to corticosteroids.
- ☐ Gastric and duodenal ulcers.
- ☐ Severe systemic viral, bacterial and fungal infections.
- ☐ Pre-existing wide angle glaucoma.

PRECAUTIONS

General

The lowest possible dose of corticosteroids should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual.

Cardio-Renal

As sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension or renal insufficiency.

Endocrine

Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage.

Gastrointestinal

Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses and nonspecific ulcerative colitis, since they may increase the risk of a perforation.

Musculoskeletal

Corticosteroids decrease bone formation and increase bone resorption both through their effect on calcium regulation (i.e., decreasing absorption and increasing excretion) and inhibition of osteoblast function. Special consideration should be given to patients at increased risk of osteoporosis (e.g., postmenopausal women) before initiating corticosteroid therapy.

Neuro-Psychiatric

An acute myopathy has been observed with the use of high doses of corticosteroids, most often occurring in patients with disorders of neuromuscular transmission (e.g., myasthenia gravis), or in patients receiving concomitant therapy with neuromuscular blocking drugs (e.g., pancuronium). Elevation of creatinine kinase may occur.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be

aggravated by corticosteroids.

Ophthalmic

Intraocular pressure may become elevated in some individuals. If steroid therapy is continued for more than 6 weeks, intraocular pressure should be monitored.

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 the potential risk to the fetus.

Nursing Mothers

Glucocorticoids appear in breast milk. Decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

In order to minimize the potential growth effects of corticosteroids, pediatric patients should be titrated to the lowest effective dose.

Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or other drug therapy.

Drug Interactions

Digitalis Glycosides: Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia.

Antidiabetics: Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.

Nonsteroidal Anti-Inflammatory Agents (NSAIDs): Concomitant use of aspirin (or other nonsteroidal antiinflammatory agents) and corticosteroids increases the risk of gastrointestinal side effects. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. The clearance of salicylates may be increased with concurrent use of corticosteroids.

Anticoagulants, Oral: Co-administration of corticosteroids and warfarin usually results in inhibition of response to warfarin, although there have been some conflicting reports. Therefore, coagulation indices should be monitored frequently to maintain the desired anticoagulant effect.

Antibiotics: Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance.

Vaccines: Patients on corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response.

ADVERSE REACTIONS

The following adverse reactions have been reported with dexamethasone:

Allergic Reactions

Anaphylactoid reaction, anaphylaxis, angioedema.

Cardiovascular

Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction, edema, pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis.

Dermatologic

Acne, allergic dermatitis, dry scaly skin, ecchymoses and petechiae, erythema, impaired wound healing, increased sweating, rash, striae, suppression of reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria.

Endocrine

Development of cushingoid state, hyperglycemia, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness, suppression of growth in pediatric patients.

Fluid and Electrolyte Disturbances

Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention.

Gastrointestinal

Abdominal distention, elevation in serum liver enzyme levels, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, ulcerative esophagitis.

Musculoskeletal

Aseptic necrosis of femoral and humeral heads, loss of muscle mass, muscle weakness, osteoporosis, steroid myopathy, tendon rupture, vertebral compression fractures.

Neurological/Psychiatric

Convulsions, depression, emotional instability, euphoria, headache, vertigo, increased intracranial pressure with papilledema (pseudotumor cerebri), neuropathy, paresthesia, psychic disorders.

Ophthalmic

Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts.

Metabolic

Negative nitrogen balance due to protein catabolism.

OVERDOSAGE

Treatment of overdosage is by supportive and symptomatic therapy. In the case of acute overdosage, according to the patient's condition, supportive therapy may include gastric lavage or emesis.

PHARMACEUTICAL PRECAUTION

Store not above 25°C, keep away from light and moisture. Keep out of reach of children.

PACKAGING

Dextor[®] 0.5 Tablet:

Box containing 20 strips of 10 tablets each. Each tablet contains Dexamethasone BP 0.5 mg.

Dextor[®] 6 Tablet:

Box containing 20 strips of 10 tablets each. Each tablet contains Dexamethasone BP 6 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

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