DECORT

Tablets

Composition

Decort 0.5 mg Tablets
Each tablet contains Dexamethasone 0.5 mg.

Decort 0.75 mg Tablets
Each tablet contains Dexamethasone 0.75 mg.

Decort 2 mg Tablets
Each tablet contains Dexamethasone 2 mg.

Action

Dexamethasone is a synthetic corticosteroid (glucocorticoid). As such, its main actions may be grouped as follows:

Anti-inflammatory and Immunological Actions: Glucocorticoids prevent the development of the inflammatory response, i.e. Redness, swelling, tenderness. They also inhibit capillary dilation and phagocytosis and appear to prevent the hypersensitivity responses that occur after antigen-antibody reactions.

Pharmacological Actions: The principal action of dexamethasone is on gluconeogenesis, glycogen deposition, and protein and calcium metabolism, together with inhibition of corticotrophin secretion. Glucocorticoids also influence the mobilization, oxidation, synthesis, and storage of fats. Except for its use in the treatment of adrenal insufficiency it does not cure disease but it is used rather to treat disease symptoms because of its pharmacological properties, i.e. Anti-inflammatory and anti-allergic actions.

Pharmacokinetics
Intramuscular injections of dexamethasone phosphate give maximum plasma concentrations of dexamethasone at 1 hour. The biological half-life of dexamethasone is about 190 minutes.
In circulation, small amounts of dexamethasone are bound to plasma proteins. Dexamethasone penetrates into tissue fluids and cerebrospinal fluids. Metabolism of the drug takes place in the kidney and liver and excretion is via the urine.

Indications

Endocrine
Congenital adrenal hyperplasia, non-suppurative thyroiditis, hypercalcemia associated with cancer.

Rheumatic Disorders
As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in psoriatic arthritis, rheumatoid arthritis including juvenile rheumatoid arthritis (selected cases may require low dose maintenance therapy), ankylosing spondylitis, acute and subacute bursitis, acute non-specific tenosynovitis, acute gouty arthritis, post-traumatic osteoarthritis, synovitis of osteoarthritis, epicondylitis.

Collagen Diseases
In exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus, acute rheumatic carditis.

Dermatological
Pemphigus, bullous dermatitis herpetiformis, severe erythema multiforme, exfoliative dermatitis, mycosis fungoides, severe psoriasis, severe seborrheic dermatitis.

Allergic States

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

Ophthalmological
Severe, acute and chronic allergic and inflammatory processes of the eye and its adnexa, such as allergic conjunctivitis, keratitis, allergic corneal marginal ulcers, herpes zoster ophthalmicus, iritis and iridocyclitis, chorioretinitis, anterior segment inflammation, diffused posterior uveitis and choroiditis, optic neuritis, sympathetic ophthalmia.

Respiratory
Symptomatic sarcoidosis, Loeffler's syndrome not manageable by other means, berylliosis, fulminating or disseminated pulmonary tuberculosis (concurrently with appropriate antituberculous chemotherapy), aspiration pneumonitis, seasonal or perennial allergic rhinitis.

Hematological
Idiopathic thrombocytopenic purpura in adults, secondary thrombocytopenia in adults, acquired (autoimmune) hemolytic anemia, erythroblastopenia, congenital (erythroid) hypoplastic anemia.

Neoplastic Diseases
Palliative management of leukemias and lymphomas in adults, acute leukemia of childhood.

Edematous States
Induction of diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

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

Neurological
Acute exacerbations of multiple sclerosis.

Miscellaneous
Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy, trichinosis with neurologic or myocardial involvement, diagnostic testing of adrenocortical hyperfunction.

Contraindications

- Known hypersensitivity to the drug.
- Systemic fungal infections.
- Administration of vaccines, including smallpox, especially in patients receiving high corticosteroid dosages, are contraindicated because of possible neurological complications and a lack of antibody response.

Warnings

The lowest possible dose of corticosteroid should be used to control the condition being treated.

When reduction in dosage is possible, it should be gradual. In patients receiving corticosteroid therapy and subjected to unusual stress, such as trauma or surgery, increased dosage of corticosteroids before, during, and after the stressful situation is indicated. Dietary salt restriction and potassium supplementation may be necessary, especially if this drug is administered in high doses. Calcium levels should be monitored, since corticosteroids increase calcium excretion. Prolonged use may produce posterior subcapsular cataracts and glaucoma with possible damage to the optic nerves. It may also enhance the establishment of secondary ocular infections due to fungi or viruses.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. If an infection occurs during therapy, a suitable antimicrobial agent should promptly control it. The use of systemic corticosteroids in active tuberculosis should be restricted to cases of fulminating or disseminated disease, where the corticosteroid is used for management of the disease in conjunction with an appropriate antituberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Amebiasis, whether latent or active, should be ruled out before therapy with a corticosteroid is instituted in patients prone to the disease, e.g. patients with unexplained diarrhea or patients who have spent time in endemic areas.

Pregnancy
Category C
Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Nursing Mothers
Corticosteroids appear in breast milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. Mothers taking pharmacological doses of corticosteroids should be advised not to breastfeed.

Adverse Reactions

Fluid and Electrolyte Disturbances
Sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, hypokalemic alkalosis, hypertension.

Musculoskeletal
Muscle weakness, steroid myopathy, loss of muscle mass, tendon rupture, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathological fractures of long bones.

Gastrointestinal
Peptic ulcer with possible subsequent perforation and hemorrhage, pancreatitis, abdominal distension, ulcerative esophagitis.

Dermatological
Impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating. Corticosteroids may suppress reactions to skin tests.

Neurological
Convulsions, increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment, vertigo, headache.

Endocrine
Menstrual irregularities, development of Cushingoid state, suppression of growth in children, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress), decreased carbohydrate tolerance, manifestations of latent diabetes mellitus, increased requirements of insulin or oral hypoglycaemic agents in diabetics.

Ophthalmological
Posterior subcapsular cataracts, increased intraocular pressure, glaucoma, exophthalmus.

Metabolic
Negative nitrogen balance due to protein catabolism.

Cardiovascular
Myocardial rupture following recent myocardial infarction.

Other
Anaphylactoid or hypersensitivity reactions, thromboembolism, weight gain, increased appetite, nausea, malaise, hiccups.

Precautions

Drug-induced secondary adrenocortical insufficiency may be minimized by the gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy. Therefore, in any situation of stress occurring during this period, hormone therapy should be reinstituted. Since mineralocorticoid, secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently. Corticosteroids have an enhanced effect on patients with hypothyroidism and hepatic cirrhosis.

Corticosteroids should be used with caution in patients with ocular herpes simplex because of possible corneal perforation. Psychic derangements may appear when corticosteroids are used. These can range from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. In addition, corticosteroids may aggravate existing emotional instability or psychotic tendencies.

Corticosteroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess, or other pyogenic infection, diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis and myasthenia gravis. Growth and development of infants and children receiving prolonged corticosteroid therapy should be carefully observed.

Drug Interactions

Corticosteroids/ Potassium-depleting Diuretics/ Amphotericin B
Concurrent use may enhance hypokalemia; serum potassium level should be determined at frequent intervals.

Corticosteroids/ Cardiac Glycosides
Concurrent use may enhance the possibility of arrhythmias of digitals toxicity associated with hypokalemia.

Corticosteroids/ Non-steroidal Anti-inflammatory Drugs
The ulcerogenic potential of non-steroidal anti-inflammatory drugs may be increased when used concurrently with corticosteroids.

*Corticosteroids/ Hypoglycaemic*s
Corticosteroids may increase blood glucose levels; dosage adjustment of the antidiabetic agent is necessary.

Corticosteroids/ Phenytoin/ Phenobarbital/ Rifampicin/ Ephedrine
Concurrent administration of corticosteroids with one of these drugs may enhance the metabolic clearance of the corticosteroid, resulting in decrease blood levels that require adjustment of dosage.

Corticosteroids/ Salicylates
Corticosteroids may reduce serum salicylate levels by increasing metabolism and/or decrease. Concurrent use requires caution especially in hypoprothrombinemia.

Corticosteroids/ Anticoagulants
Although reports are conflicting, caution is recommended when these drugs are used together, especially in patients prone to gastrointestinal ulceration and hemorrhage.

Diagnostic Interference
Urine glucose and serum cholesterol levels may be increased. Decreased serum levels of potassium, triiodothyronine (T3), and a minimal decrease of thyroxin (T4) may occur. Thyroid 131I uptake may be decreased. Corticosteroids may affect the nitroblue-tetrazolium test for bacterial infection and produce false-negative results.

Dosage and Administration

Dosage requirements are variable and must be individualized based on the disease being treated and the response of the patient. The initial dosage of Dexamethasone may vary from 0.75-9.0 mg/day. In less severe diseases, doses lower than 0.75 mg/day may suffice, while in severe diseases doses higher than 9.0 mg/day may be required. The initial dosage should be maintained or adjusted until the patient's response is satisfactory. If satisfactory clinical response does not occur after a reasonable period, discontinue Dexamethasone and transfer the patient to other therapy.

After a favourable initial response, the proper maintenance dosage should be determined by decreasing the initial dosage in small amounts to the lowest dosage that maintains an adequate clinical response. Patients should be observed closely for signs that might require dosage adjustment. During stress, it may be necessary to increase the dosage temporarily. If the drug is to be withdrawn after more than a few days of treatment, this should be carried out gradually. When transferring therapy to Dexamethasone from other glucocorticoids, the following are equivalent to 0.75 mg Dexamethasone:

- 25.0 mg Cortisone
- 20.0 mg Hydrocortisone
- 5.0 mg Prednisone
- 5.0 mg Prednisolone
- 4.0 mg Methylprednisolone
- 4.0 mg Triamcinolone

In acute, self-limited allergic disorders or acute exacerbations of chronic allergic disorders, the following schedule, combining oral and parenteral therapy with Dexamethasone sodium phosphate injection, is suggested:

- day 1 4 or 8 mg I.M. and 0.75 mg orally.
- day 2 3 mg orally in 2 divided doses.
- day 3 3 mg orally in 2 divided doses.
- day 4 1.5 mg orally in 2 divided doses.
- day 5 0.75 mg orally.
- day 6 0.75 mg orally.
- day 7 no treatment.
- day 8 follow-up visit to physician.

This schedule is designed to ensure adequate therapy during acute episodes, while minimizing the risk of over dosage in chronic cases.

Suppression Tests
To test for Cushing's syndrome, administer 1 mg at 11 p.m. Draw blood for plasma cortisol determination at 8 a.m. the following morning. For greater accuracy, administer 0.5 mg every 6 hours for 48 hours. 24-hour urine collections should be made for determination of 17-hydroxycorticosteroid excretion. In order to distinguish Cushing's syndrome due to pituitary adrenocorticotropic hormone (ACTH) excess from Cushing's syndrome due to other causes, administer 2 mg every 6 hours for 48 hours. 24-hour urine collections should be made for determination of 17-hydroxycorticosteroid excretion.

Presentation

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