

## DECORT

Ampoule

### Composition

#### Decort 4 mg Injection

Each ampoule of 1 ml contains Dexamethasone phosphate (as sodium) 4 mg.

#### Decort 20 mg Injection

Each ampoule of 1 ml contains Dexamethasone phosphate (as sodium) 20 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

#### Decort 4 mg ampoule (I.V. or I.M. Injection)

##### *Endocrine Disorders*

- Primary or secondary adrenocortical insufficiency (the drug of choice is hydrocortisone or cortisone - synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance).
- Acute adrenocortical insufficiency (the drug of choice is hydrocortisone or cortisone - mineralocorticoid supplementation may be necessary, particularly when synthetic analogs are used).
- Preoperatively, and in the event of serious trauma or illness in patients with known adrenal insufficiency, or when adrenocortical reserve is doubtful.
- Shock unresponsive to conventional therapy if adrenocortical insufficiency exists or is suspected.
- Congenital adrenal hyperplasia.
- Nonsuppurative 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 post-traumatic osteoarthritis, synovitis of osteoarthritis, rheumatoid arthritis including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), acute and subacute bursitis, epicondylitis, acute nonspecific tenosynovitis, acute gouty arthritis, psoriatic arthritis, ankylosing spondylitis.

##### *Collagen Diseases*

During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus and acute rheumatic carditis.

### *Dermatological*

Pemphigus, severe erythema multiforme (Stevens-Johnson syndrome), exfoliative dermatitis, bullous dermatitis herpetiformis, severe seborrheic dermatitis, severe psoriasis, mycosis fungoides.

### *Allergic States*

Severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness, seasonal or perennial allergic rhinitis, drug hypersensitivity reactions, urticarial transfusion reactions, acute non-infectious laryngeal edema (adrenaline is the drug of first choice).

### *Ophthalmological*

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

### *Gastrointestinal*

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

### *Respiratory*

Symptomatic sarcoidosis, berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, Loeffler's syndrome not manageable by other means, aspiration pneumonitis.

### *Hematological*

Autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura in adults (I.V. only; I.M. administration is contraindicated), secondary thrombocytopenia in adults, erythroblastopenia (RBC anemia), congenital (erythroid) hypoplastic anemia.

### *Neoplastic Diseases*

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

### *Edematous States*

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

### *Miscellaneous*

- Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy, trichinosis with neurological or myocardial involvement.
- Diagnostic testing of adrenocortical hyperfunction.
- Cerebral edema associated with primary or metastatic brain tumour, craniotomy or head injury. Use in cerebral edema is not a substitute for careful neurosurgical evaluation and definitive management, such as neurosurgery or other specific therapy

### *Intra-articular or Soft Tissue Injection*

Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in synovitis of osteoarthritis, rheumatoid arthritis, acute and subacute bursitis, epicondylitis, acute nonspecific tenosynovitis, acute gouty arthritis, post-traumatic osteoarthritis.

### *Intralesional Injection*

- Keloids.
- Localized hypertrophic, infiltrated, inflammatory lesions of lichen planus, psoriatic plaques, granuloma annulare, lichen simplex chronicus (neurodermatitis). Discoid lupus erythematosus.
- Necrobiosis lipoidica diabetorum.

- Alopecia areata.
- May also be useful in cystic tumors of an aponeurosis or tendon (ganglia).

### **Decort 20 mg Injection**

Intravenous use as adjunctive treatment of severe shock of hemorrhagic, traumatic. Surgical or septic origin.

### **Contraindications**

- Known hypersensitivity to Dexamethasone.
- 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.

Because rare instances of anaphylactoid reactions have occurred in patients receiving parenteral corticosteroid therapy, appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of allergy to any drug.

These preparations contain a sulphite preservative that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible individuals. The overall prevalence of sulphite sensitivity in the general population is unknown, but is probably low. Sulphite sensitivity is observed more frequently in asthmatic individuals.

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*

Since adequate human reproduction studies have not been performed with corticosteroids, the use of these drugs in pregnant women or women of childbearing potential requires that the expected benefits of the drug be weighed against the possible hazards to mother and fetus. Infants born to mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

### **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 hypoglycemic 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.

The following additional adverse reactions are related to parenteral corticosteroid therapy: rare instances of blindness associated with intralesional therapy around the face and head, hyperpigmentation or hypopigmentation, subcutaneous and cutaneous atrophy, sterile abscess, post-injection flare (following intra-articular use) and Charcot-like arthropathy.

## 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 reinstated. 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 pyrogenic 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 digitalis 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/ Hypoglycemics*

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 decreased blood levels that require adjustment of dosage.

### *Corticosteroids/ Salicylates*

Corticosteroids may reduce serum salicylate levels by increasing metabolism and/or clearance. 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. False negative results in the dexamethasone suppression test (DST) in patients being treated with indomethacin have been reported. Therefore, DST results should be interpreted with caution in these patients.

### **Dosage and Administration**

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Dosage requirements are variable, and must be individualized based on the disease and the response of the patient.

#### **Decort 4 mg I.V. and I.M. Injection**

The initial, dose of Decort injection varies from 0.5-9 mg a day, depending on the disease being treated. In less severe diseases, doses lower than 0.5 mg may suffice, while in severe diseases, doses higher than 9 mg may be required. The initial dosage should be maintained or adjusted until the patient's response is satisfactory. If a satisfactory clinical response does not occur after a reasonable period, use should be discontinued and the patient transferred 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 indicate the necessity for dosage adjustment. These include changes in clinical status resulting from remissions or exacerbations of the disease, individual drug responsiveness, and the effect of stress (e.g. surgery, infection, and trauma). During stress, it may be necessary to temporarily increase dosage.

If the drug is discontinued after more than a few days of treatment, it should usually be withdrawn gradually.

#### *Cerebral Edema*

Decort injection is generally administered initially in a dosage of 10 mg I.V., followed by 4 mg, every 6 hours, I.M., until the symptoms of cerebral edema subside. Response is usually noted within 12-24 hours, and dosage may be reduced after 2-4 days and gradually discontinued over a period of 5-7 days. For palliative treatment of patients with recurrent or inoperable brain tumours, maintenance therapy with 2 mg, 2-3 times a day, may be effective.

#### *Intra-articular, Intralesional and Soft Tissue Injection*

Intra-articular, intralesional and soft tissue injections are generally employed when the affected joints or areas are limited to one or two sites. Dosage and frequency of injection varies, depending on the condition and the site of injection. The usual dose is 0.2-6 mg. The frequency usually ranges from once every 3-5 days to once every 2-3 weeks. Frequent intra-articular injections may result in damage to joint tissues.

Some of the usual single doses are:

-large joints	2-4 mg	-small joints	0.8-1 mg
-bursae	2-3 mg	-tendon sheaths	0.4-1 mg
-soft tissue infiltration	2-6 mg	-ganglia	1-2 mg

#### **Decort 20 mg Ampoule**

Decort 20 mg injection, which is indicated for the adjunctive treatment of severe shock, must be given by I.V. administration only.

Reported regimens range from 1-6 mg/kg body weight as a single I.V. injection, to 40 mg initially followed by repeated I.V. injections every 2-6 hours, while shock persists.

Administration of high dose corticosteroid therapy should be continued only until the patient's condition has stabilized, and usually not longer than 48-72 hours. Although adverse reactions associated with high dose, short-term corticosteroid therapy are uncommon, peptic ulceration may occur.

### **Presentation**

#### **Decort 4 mg Ampoule**

Box of 5 ampoules of 1 ml.

#### **Decort 20 mg Ampoule**

Box of 100 ampoules of 1 ml.