Dexamethasone Sodium Phosphate

Introduction: Dexamethasone Injectable Suspension is a sterile aqueous suspension containing 3 mg per milliliter betamethasone, as betamethasone sodium phosphate, and 3 mg per milliliter betamethasone acetate.

Mechanism of action: Decreases inflammation by suppression of neutrophil migration, decreased production of inflammatory mediators, and reversal of increased capillary permeability; suppresses normal immune response. Dexamethasone's mechanism of antiemetic activity is unknown.

Pharmacology:
Onset of action: Acetate: Prompt
Duration of metabolic effect: 72 hours; acetate is a long-acting repository preparation
Metabolism: Hepatic
Half-life elimination: Normal renal function: 1.8-3.5 hours; Biological half-life: 36-54 hours
Time to peak, serum: Oral: 1-2 hours; I.M.: ~8 hours
Excretion: Urine and feces

Indications:

- **Allergic States**
  - Asthma,
  - Atopic dermatitis,
  - Contact dermatitis,
  - Drug hypersensitivity reactions,
  - Perennial or seasonal allergic rhinitis,
  - Serum sickness,
  - Transfusion reactions

- **Dermatologic Diseases**
  - Bullous dermatitis herpetiformis,
  - Exfoliative erythroderma,
  - Mycosis fungoides,
  - Pemphigus,
  - Stevens-Johnson syndrome

- **Endocrine Disorders**
  - Congenital adrenal hyperplasia,
  - Hypercalcemia associated with cancer,
  - Nonsuppurative thyroiditis.

- **Gastrointestinal Diseases**
    - Regional enteritis
    - Ulcerative colitis.

- **Hematologic Disorders**
    - Acquired (autoimmune) hemolytic anemia
    - Diamond-Blackfan anemia
    - Pure red cell aplasia,
    - Selected cases of secondary thrombocytopenia.

- **Neoplastic Diseases**
    - Leukemias
    - Lymphomas

- **Nervous System**
    - Multiple sclerosis
    - Cerebral edema associated with primary or metastatic brain tumor
    - Craniotomy, or head injury

- **Ophthalmic Diseases**
    - Sympathetic ophthalmia,
    - Temporal arteritis,
    - Uveitis
    - Ocular inflammatory conditions

- **Respiratory Diseases**
    - Berylliosis,
    - Fulminating or disseminated pulmonary tuberculosis
    - Idiopathic eosinophilic pneumonias,
    - Symptomatic sarcoidosis

- **Rheumatic Disorders**
    - Acute gouty arthritis;
    - Acute rheumatic carditis;
    - Ankylosing spondylitis;
    - Psoriatic arthritis;
    - Rheumatoid arthritis, including juvenile rheumatoid arthritis
    - Dermatomyositis,
    - Polymyositis,
    - Systemic lupus erythematosus.

Dosage:

Intravenous and Intramuscular Administrations: I.M. or I.V. dosage of dexamethasone phosphate is variable, depending on the condition being treated. It usually ranges from 0.5 - 24 mg daily. The duration of therapy is dependent on the clinical response of the patient and as soon as improvement is indicated, the dosage should be adjusted to the minimum required to maintain the desired clinical response. Withdrawal of the drug on completion of therapy should be gradual.

Shock: A single I.V. injection of 2 to 6 mg/kg bodyweight which may be repeated in 2-6 hours if shock persists. High-dose therapy should be continued only until the patient's condition has stabilized and usually for no longer than 48-72 hours. An alternative regime of 20 mg by I.V. injection initially followed by continuous I.V. infusion of 3 mg/kg bodyweight per 24 hours has been suggested. If required for I.V. infusion, dexamethasone phosphate 120 mg/5 mL may be diluted with glucose or sodium chloride injection.

Cerebral Oedema: An initial dose of 10 mg I.V. followed by 4 mg I.M. every 6 hours until the symptoms of oedema subside (usually after 12 to 24 hours). After 2 to 4 days the dosage should be reduced and gradually stopped over a period of 5 to 7 days. Patients with cerebral malignancy may require maintenance therapy with doses of 2 mg I.M. or I.V. 2-3 times daily.

Life-Threatening Cerebral Oedema:

High Dose Schedule:	Adults	Children > 35kg	Children < 35kg
Initial Dose	50mg IV	25mg IV	20mg IV
1st day	8mg IV every 2 hrs	4mg IV every 2 hrs	4mg IV every 3 hrs
2nd day	8mg IV every 2 hrs	4mg IV every 2 hrs	4mg IV every 3 hrs
3rd day	8mg IV every 2 hrs	4mg IV every 2 hrs	4mg IV every 3 hrs
4th day	4mg IV every 2 hrs	4mg IV every 4 hrs	4mg IV every 6 hrs
5th-8th day	4mg IV every 4 hrs	4mg IV every 6 hrs	2mg IV every 6 hrs
After 8 days	Decrease by daily reduction of 4mg	Decrease by daily reduction of 2mg	Decrease by daily reduction of 1mg

Intra-Synovial & Soft Tissue Injections:

Dosage varies with the degree of inflammation and the size and location of the affected area. Injections may be repeated from once every 3-5 days (eg. for bursae) to once every 2-3 weeks (for joints).

Site of injection	*Dosage*
Large Joints	2mg to 4mg
Small Joints	800 microgram to 1mg
Bursae	2mg to 3mg
Tendon Sheaths	400 microgram to 1mg
Soft tissue Infiltration	2mg to 6mg

Side effects: Except for allergy the adverse effects listed have been associated with prolonged therapy and/or high doses.

- Adrenal Suppression
- Allergy
- Blood/Vascular Disorders:
- Thromboembolism
- Polymorphonuclear leucocytosis
- Neuropathy
- Vasculitis
- Development of Diabetes Mellitus
- Effects on Bones and Joints:
- Osteoporosis
- Arthropathy
- Osteonecrosis of femoral and/or humeral heads (aseptic or avascular necrosis)
- Glaucoma
- Cataract
- Exophthalmos
- Stunting of growth in children
- Impaired myocardial contractility (prolonged treatment)
- Muscular atrophy
- Impaired wound healing
- Allergic dermatitis
- Urticaria
- Erythema
- Effects on Gastrointestinal System:
- Peptic ulcer
- Pancreatitis
- Euphoric side effects
- Headache
- Convulsion
- Electrolyte imbalance (retention of sodium and water with oedema and hypertension)
- Hyperglycaemia

Precautions:

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. This type of relative insufficiency may persist for months after discontinuation of therapy.

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.

Intra-Articular and Soft Tissue Administration: Intra-articular injected corticosteroids may be systematically absorbed. Injection of a steroid into an infected site is to be avoided. Local injection of a steroid into a previously injected joint is not usually

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 (ie, 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 (eg, myasthenia gravis), or in patients receiving concomitant therapy with neuromuscular blocking drugs (eg, pancuronium). This acute myopathy is generalized, may involve ocular and respiratory muscles, and may result in quadriparesis. Elevation of creatinine kinase may occur. Clinical improvement or recovery after stopping corticosteroids may require weeks to years.

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: Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Nursing mothers: Systematically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

Pediatric Use: Indications for pediatric use of corticosteroids, eg, severe asthma and wheezing, are based on adequate and well-controlled trials conducted in adults, on the premises that the course of the diseases and their pathophysiology are considered to be substantially similar in both populations.

Geriatric Use: Use with caution in elder patients.

Contraindications: Dexamethasone is contraindicated in patients who are hypersensitive to any components of this product. Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura.

How supplied: Customized as per request.