Dexamethasone disodium phosphate 5mg/mL

DEKXISONE Inj.

■ **COMPOSITION**

Each ampoule (1mL) contains 5 mg of Dexamethasone disodium phosphate as active ingredient.

■ **INDICATIONS**

Usually, it is indicated in the management of various rheumatic, allergic, dermatologic, ocular and other conditions known to responsive to corticosteroid therapy.

A. By intravenous or intramuscular injection when oral therapy is not feasible.

1. Endocrine disorders
   Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice : synthetic analogs may be used in conjunction with mineralocorticoids where applicable ; in infancy, mineralocorticoid supplementation is of particular importance). Acute adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice : 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.
2. 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.
3. Collagen diseases
   During an exacerbation or as maintenance therapy in selected cases of : systemic lupus erythematosus, acute rheumatic carditis.
4. Dermatologic diseases
   Pemphigus, severe erythema multiforme (Stevens-Johnson's syndrome), exfoliative dermatitis, bullous dermatitis herpetiformis, severe seborrheic dermatitis, severe psoriasis, mycosis fungoides.
5. Allergic states
   Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in : bronchial asthma, contract dermatitis, atopic dermatitis, serum sickness, seasonal or perennial allergic rhinitis, drug hypersensitivity reactions, urticarial transfusion reactions, acute noninfectious laryngeal edema (epinephrine is the drug of first choice).
6. Ophthalmic diseases
   Severe acute and chronic allergic and inflammatory processes involving the eye, such as : herpes zoster opthalmicus, iritis, iridocyclitis, chorioretinitis, diffuse posterior uveitis and choroiditis, optic neuritis,sympathetic ophthalmia, anterior segment inflammation, allergic conjunctivitis, keratitis, allergic corneal marginal ulcers.
7. Gastrointestinal diseases
   To tide the patient over a critical period of the disease in :ulcerative colitis (systemic therapy), regional enteritis (systemic therapy)
8. Hematologic disorders
   Acquired(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.
9. Neoplastic diseases
   For palliative management of : leukemias and lymphomas in adults, acute leukemia of childhood.
10. Miscellaneous
    Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy, trichinosis with neurologic or myocardial involvement.
11. Cerebral edema associated with primary or metastatic brain tumor, 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.

B. By intra-articular or soft tissue injection
   As 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, acute gouty arthritis, epicondylitis, acute nonspecific tenosynovitis, post-traumatic osteoarthritis.

C. By intralesional injection
   Keloids, localized hypertrophic, infiltrated, inflammatory lesions of : lichen planus, psoriatic plaques, granuloma annulare, and lichen simplex chronicus (neurodermatitis), discoid lupus erythematosus, necrobiosis lipoidica diabeticorum, alopecia areata, may also be useful in cystic tumors of an aponeurosis or tendon (ganglia)

■ **DOSAGE & ADMINISTRATION**

For intravenous, intramuscular, intra-articular, intralesional and soft tissue injection. The dose of this drug varies depending on the nature and severity of the disease being treated.

1) Intravenous and Intramuscular injection : 2-8mg every 3 to 6hours
2) Instillation : 2-10mg every once or twice a day
3) Intraarticular injection, Intrabursal injection : 0.8-5mg, Dose interval is more than 2week
4) Intrasoft tissue injection : 2-6mg, Dose interval is more than 2week
5) Intratenosynovium injection : 0.8-2.5mg, Dose interval is more than 2weeks
6) Intradermal injection : 0.05-0.1mg every one week.
7) Subconjunctival injection : 0.4-2.4mg
8) Retrobulbar injection : 1-5mg

Dosage requirement are variable and must be individualized on the basis of the disease and the response of patient.

■ **PRECAUTIONS**

1. Contraindications
   1) Patients with a history of hypersensitivity to any component of this product, including sulfites.
   2) Joints, synovial capsules, tendons which the inflammatory process remains active.
   3) Corticosteroids should not be injected into unstable joints
   4) Neonate, premature (Because this drug contains benzyl alcohol.)
   5) Systemic fungal infections.
2. Precautions
   Following prolonged therapy, withdrawal of corticosteroids may result in symptoms of the corticosteroid withdrawal syndrome including fever, myalgia, arthralgia, and malaise. This may

occur in patients even without evidence of adrenal insufficiecy. There is an enhanced effect of corticosteroids in patients with hypothyroidism and in those with cirrhosis. Corticosteroids should be used cautiously in patients with ocular herpes simplex for fear of corneal perforation. The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction must be gradual. 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. Aspirin should be used conutiously in conjunction with conticosteroids in hypoprothrombinemia. Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess, or other pyogenic infection, also in diverticulitis, fresh intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis, and myasthenia gravis. Signs of peritoneal irritation following gastrointestinal perforation in patients receiving large doses of corticosteroids may be minimal or absent. Fat embolism has been reported as a possible complication of hypercortisonism. When large doses are given, some authorities advise that antacids be administered between meals to help to prevent peptic ulcer. Growth and development of infants and children on prolonged corticosteroid therapy should be carefully followed. Steroids may increase or decrease motility and number of spermatozoa in some patients. Phenytoin, phenobarbital, ephedrine, and rifampin may enhance the metabolic clearance of corticosteroids resulting in decreased blood levels and lessened physiologic activity, thus requiring adjustment in corticosteroid dosage. These interactions may interfere with dexamethasone suppression tests which should be interpreted with caution during administration of these drugs.

False negative results in the dexamethasone suppression test(DST) in patients being treated with indomethacin have been reported. Thus, results of the DST should be interpreted with caution in these patients.

The prothrombin time should be checked frequently in patients who are receiving corticosteroids and coumarin anticoagulants at the same time because of reports that corticosteroids have altered the response to these anticoagulants. Studies have shown the usual effect produced by adding corticosteroids is inhibition of response to coumarins, although there have been some conflicting reports of potentiation not substantiated by studies.

When corticosteroids are administered concomitantly with potassium-depleting diuretics, patients should be observed closely for development of hypokalemia. Intra-articular injection of corticosteroid may produce systemic as well as local effects. Appropriate examination of any joint fluid present is necessary to exclude a septic process. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise is suggestive of septic arthritis. If this complication occurs and the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted.

Injection of a steroid into an infected site is to be avoided. Corticosteroid should not be injected into unstable joints. Patients should be impressed strongly with the importance of not overusing joints in which sympromatic benefit has been obtained as long as the inflammatory process remains active. Frequent intra-articular injection may result in damage to joint tissues. The slower rate of absorption by intramuscular administration should be recognized.

Information for patients : Susceptible patients who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

3. Adverse reactions
   1) Fluid and electrolyte disturbances : sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, hypokalemic alkalosis, hypertension
   2) Musculoskeletal : muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathologic fracture of long bones, tendon rupture.
   3) Gastrointestinal : peptic ulcer with possible subsequent perforation and hemorrhage, perforation of the small and large bowel, particularly in patients with inflammatory bowel disease, pancreatitis, abdominal distention, ulcerative esophagitis
   4) Dermatologic : impaired wound healing, thin fragile skin, petechiae and ecchymoses, erythema, increased sweating, may suppress reactions to skin tests, burning or tingling, especially in the perineal area(after I.V. injection), other cutaneous reactions, such as allergic dermatitis, urticaria, angioneurotic edema.
   5) Neurologic : Convulsions, increased intracranial pressure with papilledema(pseudotumor cerebri) usually after treatment, vertigo, headache, psychic disturbances.
   6) Endocrine : menstrual irregularities, development of cushingoid state, suppression of growth in children, secondary adrenocortical and pituitary unresponsiveness, particulary in times of stress, as in trauma, surgery, or illness, decreased carbohydrate tolerance, manifestations of latent diabetes mellitus, increased requirements for insulin or oral hypoglycemic agents in diabetics, hirsutism.
   7) Ophthalmic : posterior subcapsular cataracts, increased intraocular pressure, glaucoma, exophthalmos
   8) Methabolic : negative nitrogen balance de to protein catabolism
   9) Cardiovascular : myocardial rupture following recent myocardial infarction
   10) Others ; anaphylactoid or hypersensitivity reactions, thromboembolism, weight gain, increased appetite, nausea, malaise, hiccups, rare instances of blindness associated with intralesional therapy around the face and head, hyperpigmentation or hypopigmentation, subcutaneous and cutaneous atrophy, sterile abscess, postinjection flare(following intra - articular use), charcot-like arthropathy.
4. Use in pregnancy

   Since adequate human reproduction studies have not been done with corticosteroids, use of theses drugs in pregnancy or in women of childbearing potential requires that the anticipated benefits be weighed against the possible hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism. Corticosteroids appear in breast milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. Mothers taking pharmacologic doses of corticosteroids should be advised not to nurse.
5. Pediatric use

   Growth and development of pediatric patients on prolonged corticosteroid therapy should be carefully followed.

- **STORAGE** : Store protected from light at 1-30℃
- **USE TERM** : 3 years
- **PACKS** : Boxes of 50 ampoules

This drug is manufactured in accordance with Korea Good Manufacturing Practice (KGMP) as recommended by WHO.