

Dexamethasone Sodium Phosphate Injection, USP

For Intravenous or Intramuscular use only.

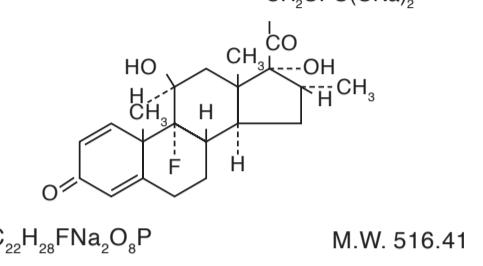
Rx only

DESCRIPTION

Dexamethasone Sodium Phosphate Injection, USP, is a water-soluble inorganic ester of dexamethasone which produces a rapid response even when injected intramuscularly.

Dexamethasone Sodium Phosphate, USP has a molecular weight of 516.41 and chemically is *Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17-dihydroxy-16-methyl-21-(phosphonoxy), disodium salt, (11_B, 16_A).*

It occurs as a white to creamy white powder, is exceedingly hygroscopic, is soluble in water and its solutions have a pH between 7.0 and 8.5. It has the following structural formula:



C₂₂H₂₈FN₄O₄P M.W. 516.41

Each mL of Dexamethasone Sodium Phosphate Injection, USP (Preservative Free) contains Dexamethasone Sodium Phosphate, USP equivalent to 10 mg dexamethasone phosphate; 25.80 mg sodium citrate dihydrate; and water for injection, q.s. pH adjusted with citric acid or sodium hydroxide, if necessary. pH: 7.0 to 8.5.

ACTIONS
Naturally occurring glucocorticoids (hydrocortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs are primarily used for their potent anti-inflammatory effects in disorders of many organ systems.

Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

INDICATIONS

A. Intravenous or intramuscular administration. When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, those products labeled for intravenous or intramuscular use are indicated as follows:

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 Syndrome)

Exfoliative dermatitis

Bullous dermatitis herpetiformis

Severe seborheic 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

Contact dermatitis

Atopic dermatitis

Serum sickness

Seasonal or perennial allergic rhinitis

Drug hypersensitivity reactions

Urticular 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 ophthalmicus

Iritis, iridocyclitis

Chorioretinitis

Diffuse posterior uveitis and choroiditis

Optic neuritis

Sympathetic ophthalmia

Anterior segment inflammation

Allergic conjunctivitis

Allergic corneal marginal ulcers

Keratitis

7. Gastrointestinal diseases.

To tide the patient over a critical period of the disease in: Ulcerative colitis (systemic therapy)

Regional enteritis (systemic therapy)

8. Respiratory diseases:

Symptomatic sarcoidosis

Berylliosis

Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate anti-tuberculosis chemotherapy.

Loeffler's syndrome not manageable by other means.

Aspiration pneumonitis

9. 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

10. Neoplastic diseases:

For palliative management of:

Leukemias and lymphomas in adults

Acute leukemia of childhood

11. 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.

12. Nervous system.

Acute exacerbations of multiple sclerosis

13. Miscellaneous.

Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculosis chemotherapy.

Trichinosis with neurologic or myocardial involvement.

Diagnostic testing of adrenocortical hyperfunction.

Cerebral edema of diverse etiologies in conjunction with adequate neurological evaluation and management.

A. Intravenous or soft tissue administration.

When the strength and dosage form of the drug lend the preparation to the treatment of the condition, those products labeled for intra-articular or soft tissue administration are indicated 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.

B. Intra-articular or soft tissue administration.

When the strength and

dosage form of the drug lend the preparation to the treatment of the condition, those products labeled for intra-articular or soft tissue administration are indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

Synovitis of osteoarthritis.

Acute and subacute bursitis.

Acute gouty arthritis.

Epicondylitis.

Acute nonspecific tenosynovitis.

Post-traumatic osteoarthritis.

C. Intralesional administration.

When the strength and dosage form of the drug lend the preparation to the treatment of the condition, those products labeled for intralesional administration are indicated for:

Keloids.

Localized hypertrophic, infiltrated, inflammatory lesions of: lichen planus, psoriatic plaques, granuloma annulare, and lichen simplex chronicus (neurodermatitis).

Discoid lupus erythematosus.

Necrobiosis lipoidica diabetorum.

Alopecia areata.

They also may be useful in cystic tumors of an aponeurosis tendon (ganglia).

CONTRAINDICATIONS

Systemic fungal infection.

WARNINGS

Serious Neurologic Adverse Reactions with Epidural Administration

Serious neurologic events, some resulting in death, have been reported with epidural injection of corticosteroids. Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. The safety and effectiveness of epidural administration of corticosteroids have not been established, and corticosteroids are not approved for this use.

In patients on corticosteroid therapy subject to any unusual stress, increased dosage of rapidly acting corticosteroids before, during and after the stressful situation is indicated.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerve, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Immunosuppression and Increased Risk of Infection

Corticosteroids, including dexamethasone sodium phosphate injection, suppress the immune system and increase the risk of infection with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic pathogens. Corticosteroids can:

- Reduce resistance to new infections

- Exacerbate existing infections

- Increase the risk of disseminated infections

- Increase the risk of reactivation or exacerbation of latent infections

- Mask some signs of infection

Corticosteroid-associated infections can be mild but can be severe and at times fatal. The rate of infectious complications increases with increasing corticosteroid dosages.

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 cautiously in conjunction with corticosteroids 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.

Growth and development of infants and children on prolonged corticosteroid therapy should be monitored.

For the treatment of unresponsive shock high pharmacologic doses of this product are currently recommended. Regimens range from 1 to 6 mg/kg of body weight as a single intravenous injection to 40 mg initially followed by repeat intravenous injection every 2 to 6 hours while shock persists.

For the treatment of cerebral edema in adults an initial intravenous dose of 10 mg is recommended followed by 4 mg intramuscularly every 6 hours until maximum response has been noted. This regimen may be continued for several days postoperatively in patients requiring brain surgery. Oral dexamethasone, 1 to 3 mg t.i.d., should be given as soon as possible and dosage tapered off over a period of five to seven days. Nonoperative cases may require continuous therapy to remain free of symptoms of increased intracranial pressure. The smallest effective dose should be used in children, preferably orally. This may approximate 0.2 mg/kg/24 hours in divided doses.

Appropriate examination of any joint fluid present is necessary to exclude aseptic arthritis.

A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of septic arthritis. If this complication occurs and the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted.

Local injection of a steroid into a previously infected joint is to be avoided. Corticosteroids should not be injected into unstable joints.

Screen patients for hepatitis B infection before initiating immunosuppressive (e.g., prolonged) treatment with dexamethasone sodium phosphate injection. For patients who show evidence of hepatitis B infection, recommend consultation with physicians in expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.

Fungal Infections

Corticosteroids, including dexamethasone sodium phosphate injection, may exacerbate systemic fungal infections; therefore, avoid dexamethasone sodium phosphate injection use in the presence of such infections unless dexamethasone sodium phosphate injection is needed to control drug reactions. For patients on chronic dexamethasone sodium phosphate injection therapy who develop systemic fungal infections, dexamethasone sodium phosphate injection withdrawal or dosage reduction is recommended.

Amebiasis

Corticosteroids, including dexamethasone sodium phosphate injection, may activate latent amebiasis. Therefore, it is recommended that latent amebiasis or active amebiasis be ruled out before initiating dexamethasone sodium phosphate injection in patients who have spent time in the tropics or patients with unexplained diarrhea.

Strongyloidiasis

Corticosteroids, including dexamethasone sodium phosphate injection, should be used with great care in patients with known or suspected *Strongyloides*