

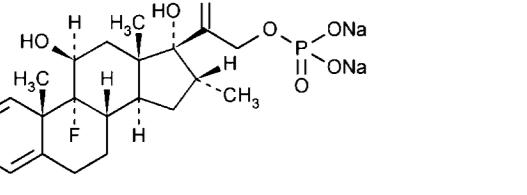
DESCRIPTION

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, $C_{21}H_{28}Na_4O_4P$, has a molecular weight of 516.41 and chemically is Pregn-4-ene-3, 20-dione, 9-fluoro-11, 17-dihydroxy-16-methyl-21 (phosphonoxy)-, disodium salt, (11 β , 16 α).

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:



Dexamethasone Sodium Phosphate Injection, USP is available in 4 mg/mL.

Each mL of Dexamethasone Sodium Phosphate injection contains Dexamethasone Sodium Phosphate, USP equivalent to 4 mg of Dexamethasone Phosphate. Made isotonic with sodium citrate. pH adjusted with citric acid or sodium hydroxide.

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 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.

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.

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.

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.

B. Intra-articular, soft tissue or intralesional administration.

The dose for intraarticular administration is usually 2 to 4 mg for large joints and 0.8 to 1 mg for small joints. For soft tissue and bursal injections a dose of 2 to 4 mg is recommended. Ganglia require a dose of 1 to 2 mg. A dose of 0.4 to 1 mg is used for injection into tendon sheaths. Injection into intervertebral joints should not be attempted at any time and hip joint injection cannot be recommended as an office procedure.

Intravascular and soft tissue injections should be employed only when affected areas are limited to 1 or 2 sites. It should be remembered that corticoids provide palliation only and that other conventional or curative methods of therapy should be employed when indicated.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Frequency of injection usually ranges from once every 3 to 5 days to once every 2 to 3 weeks. Frequent intra-articular injection may cause damage to joint tissue.

HOW SUPPLIED/STORAGE AND HANDLING

Dexamethasone Sodium Phosphate Injection, USP 4 mg/mL is available as:

4 mg/mL in a 1 mL pre-filled disposable single-use syringe (NDC 76045-210-00).

Available in a carton of twenty-four (24) syringes. NDC 76045-210-10. This product contains an RFID.

4 mg/mL in a 1 mL pre-filled disposable single-use syringe, NDC 76045-106-10

Available in a carton of twenty-four (24) syringes.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature.]

Protect from light. Sensitive to heat—Do not autoclave.

Do not place syringe on a sterile field.

INSTRUCTIONS FOR USE:

Figure 1: Outer Packaging and Prefilled Syringe

For more information concerning this drug, please call Fresenius Kabi USA, LLC at 1-800-551-7176.
To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

The brand names mentioned in this document are the trademarks of their respective owners.

U.S. Patent 9,731,082

**FRESENIUS
KABI**

Lake Zurich, IL 60047

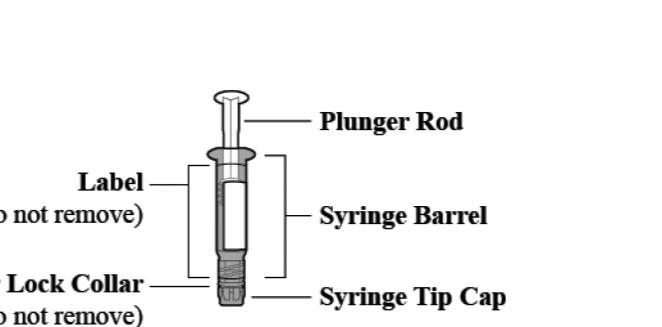
www.fresenius-kabi.com/us

451612

Revised: 10/2020

Rx Only
Injection, USP
Dexamethasone Sodium Phosphate
Injection, USP

Rx Only
451612 1020



NOTES:

- Do not introduce any other fluid into the syringe at any time.
- Do not dilute for IV push.
- Do not re-sterilize the syringe.
- Do not use this product on a sterile field.
- This product is for single dose only.

1. Inspect the outer packaging (blister pack) to confirm the integrity of the packaging. Do not use if the blister pack or the prefilled syringe has been damaged.
2. Remove the syringe from the outer packaging. (See Figure 2)

Figure 2



3. Visually inspect the syringe. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

4. Twist off the syringe tip cap. Do not remove the label around the luer lock collar. (See Figure 3)

Figure 3



5.

Expel air bubble(s). Adjust the dose (if applicable).

6. Administer the dose ensuring that pressure is maintained on the plunger rod during the entire administration.

7. Discard the used syringe into an appropriate receptacle.

6.

7.