DEXAMETHASONE SODIUM PHOSPHATE- dexamethasone sodium phosphate injection, solution
Fresenius Kabi USA, LLC

Dexamethasone Sodium Phosphate Injection, USP

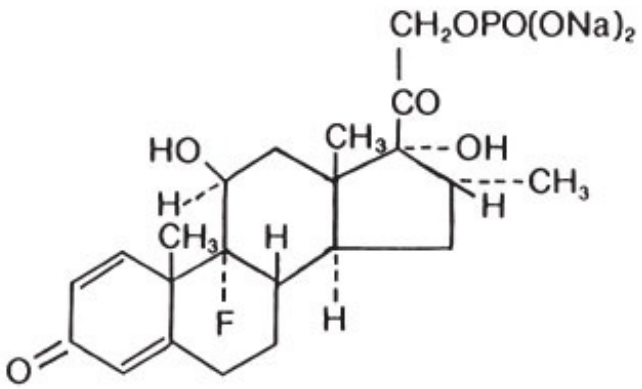
Rx only

DESCRIPTION:

Dexamethasone sodium phosphate is a water-soluble inorganic ester of dexamethasone. It occurs as a white or slightly yellow crystalline powder, is odorless or has a slight odor of alcohol, is exceedingly hygroscopic and is freely soluble in water.

Dexamethasone sodium phosphate is an adrenocortical steroid anti-inflammatory drug.

Chemically, dexamethasone sodium phosphate is 9-Fluoro-11ß,17,21-trihydroxy-16α-methylpregna-1, 4-diene-3,20-dione 21-(dihydrogen phosphate) disodium salt and has the following structural formula:



$C_{22}H_{28}FNa_2O_8P$ M.W. 516.41

Dexamethasone Sodium Phosphate Injection, USP is a sterile solution of dexamethasone sodium phosphate in water for injection for intravenous (IV), intramuscular (IM), intra-articular, soft-tissue or intralesional use.

Each mL contains dexamethasone sodium phosphate equivalent to dexamethasone phosphate 4 mg or dexamethasone 3.33 mg; benzyl alcohol 10 mg added as preservative; sodium citrate dihydrate 11 mg; sodium sulfite 1 mg as an antioxidant; Water for Injection q.s. Citric acid and/or sodium hydroxide may have been added for pH adjustment (7.0 to 8.5). Air in the container is displaced by nitrogen.

CLINICAL PHARMACOLOGY:

Dexamethasone sodium phosphate has a rapid onset but short duration of action when compared with less soluble preparations. Because of this, it is suitable for the treatment

of acute disorders responsive to adrenocortical steroid therapy.

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs, including dexamethasone, 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.

At equipotent anti-inflammatory doses, dexamethasone almost completely lacks the sodium-retaining property of hydrocortisone and closely related derivatives of hydrocortisone.

INDICATIONS AND USAGE:

Intravenous or Intramuscular Injection

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:

• 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

• 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

Acute rheumatic carditis

- Dermatologic Diseases

Pemphigus

Severe erythema multiforme (Stevens-Johnson syndrome)

Exfoliative dermatitis

Bullous dermatitis herpetiformis

Severe seborrheic dermatitis

Severe psoriasis

Mycosis fungoides

- 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

Urticarial transfusion reactions

Acute noninfectious laryngeal edema (epinephrine is the drug of first choice)

- 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

Keratitis

Allergic corneal marginal ulcers

- Gastrointestinal Diseases

To tide the patient over a critical period of the disease in:

Ulcerative colitis (Systemic therapy)

Regional enteritis (Systemic therapy)

- Respiratory Diseases

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

- Hematologic Disorders

Acquired (autoimmune) hemolytic anemia
Idiopathic thrombocytopenic purpura in adults (IV only; IM administration is contraindicated)

Secondary thrombocytopenia in adults

Erythroblastopenia (RBC anemia)

Congenital (erythroid) hypoplastic anemia

- Neoplastic Diseases

For palliative management of:

Leukemias and lymphomas in adults

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 neurologic or myocardial involvement

• Diagnostic testing of adrenocortical hyperfunction

• 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.

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

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)

CONTRAINDICATIONS:

Systemic fungal infections (see **WARNINGS** regarding amphotericin B). Hypersensitivity to any component of this product, including sulfites (see **WARNINGS**).

WARNINGS:

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. Anaphylactoid and hypersensitivity reactions have been reported for dexamethasone

sodium phosphate (see **ADVERSE REACTIONS**).

Dexamethasone sodium phosphate injection contains sodium bisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

Corticosteroids may exacerbate systemic fungal infections and therefore, should not be used in the presence of such infections unless they are needed to control drug reactions due to amphotericin B. Moreover, there have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive failure.

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

Drug-induced secondary adrenocortical insufficiency may result from too rapid withdrawal of corticosteroids and may be minimized by 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 that period, hormone therapy should be reinstituted. If the patient is receiving steroids already, dosage may have to be increased. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. Moreover, corticosteroids may affect the nitroblue-tetrazolium test for bacterial infection and produce false negative results.

In cerebral malaria, a double-blind trial has shown that the use of corticosteroids is associated with prolongation of coma and a higher incidence of pneumonia and gastrointestinal bleeding.

Corticosteroids may activate latent amebiasis. Therefore, it is recommended that latent or active amebiasis be ruled out before initiating corticosteroid therapy in any patient who has spent time in the tropics or any patient with unexplained diarrhea.

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

Average and large doses of cortisone or hydrocortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

Administration of live virus vaccines, including smallpox, is contraindicated in individuals receiving immunosuppressive doses of corticosteroids. If inactivated viral or bacterial vaccines are administered to individuals receiving immunosuppressive doses of corticosteroids, the expected serum antibody response may not be obtained. However, immunization procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, e.g., for Addison’s disease.

Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in non-immune children or adults on corticosteroids. In such children or adults who have not had these diseases, particular care should be taken to avoid exposure. How the dose, route and duration of corticosteroid administration affects the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information). If chickenpox develops, treatment with antiviral agents may be considered.

The use of dexamethasone sodium phosphate in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the 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.

Literature reports suggest an apparent association between use of corticosteroids and left ventricular free wall rupture after a recent myocardial infarction; therefore, therapy with corticosteroids should be used with great caution in these patients.

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 has not been established, and corticosteroids are not approved for this use.

Pregnancy

Teratogenic Effects: Pregnancy Category C–

Since adequate human reproduction studies have not been done with corticosteroids, use of these 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.

PRECAUTIONS:

This product, like many other steroid formulations, is sensitive to heat. Therefore, it

should not be autoclaved when it is desirable to sterilize the exterior of the vial.

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 insufficiency.

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 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. 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 that 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 a 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.

Corticosteroids should not be injected into unstable joints.

Patients should be impressed strongly with the importance of not overusing joints in which symptomatic 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

Persons 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.

ADVERSE REACTIONS:

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.

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
- Osteoporosis

Pathologic fracture of long bones

Vertebral compression fractures

Aseptic necrosis of femoral and humeral heads

Tendon rupture

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

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 IV injection)

Other cutaneous reactions, such as allergic dermatitis, urticaria, angioneurotic edema

Neurologic:

Convulsions

Increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment

Vertigo

Headache

Psychic disturbances

Endocrine:

Menstrual irregularities

Development of cushingoid state

Suppression of growth in children

Secondary adrenocortical and pituitary unresponsiveness, particularly 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

Ophthalmic:

Posterior subcapsular cataracts

Increased intraocular pressure

Glaucoma

Exophthalmos

Metabolic:

Negative nitrogen balance due to protein catabolism

Cardiovascular:

Myocardial rupture following recent myocardial infarction (see **WARNINGS**)

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)

Charcot-like arthropathy

OVERDOSAGE:

Reports of acute toxicity and/or death following overdosage of glucocorticoids are rare. In the event of overdosage, no specific antidote is available; treatment is supportive and symptomatic.

The oral LD_{50} of dexamethasone in female mice was 6.5 g/kg. The intravenous LD_{50} of dexamethasone sodium phosphate in female mice was 794 mg/kg.

DOSAGE AND ADMINISTRATION:

Dexamethasone sodium phosphate injection, 4 mg per mL– *For intravenous, intramuscular, intra-articular, intralesional, and soft tissue injection.*

Dexamethasone sodium phosphate injection can be given directly from the vial, or it can be added to Sodium Chloride Injection or Dextrose Injection and administered by intravenous drip.

Solutions used for intravenous administration or further dilution of this product should be preservative free when used in the neonate, especially the premature infant.

When it is mixed with an infusion solution, sterile precautions should be observed. Since infusion solutions generally do not contain preservatives, mixtures should be used within 24 hours.

DOSAGE REQUIREMENTS ARE VARIABLE AND MUST BE INDIVIDUALIZED ON THE BASIS OF THE DISEASE AND THE RESPONSE OF THE PATIENT.

Intravenous and Intramuscular Injection:

The initial dosage of dexamethasone sodium phosphate injection varies from 0.5 to 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 of time, discontinue dexamethasone sodium phosphate injection and transfer the patient to other therapy.

After a favorable 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 require dosage adjustment, including changes in clinical status resulting from remissions or exacerbations of the disease, individual drug responsiveness, and the effect of stress (e.g., surgery, infection, trauma). During stress it may be necessary to increase dosage temporarily.

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

When the intravenous route of administration is used, dosage usually should be the same as the oral dosage. In certain overwhelming, acute, life-threatening situations, however, administration in dosages exceeding the usual dosages may be justified and may be in multiples of the oral dosages. The slower rate of absorption by intramuscular administration should be recognized.

Shock

There is a tendency in current medical practice to use high (pharmacologic) doses of corticosteroids for the treatment of unresponsive shock. The following dosages of

dexamethasone sodium phosphate injection have been suggested by various authors:

Author	***Dosage***
Cavanagh[1]	3 mg/kg of body weight per 24 hours by constant intravenous infusion after an initial intravenous injection of 20 mg
Dietzman[2]	2 to 6 mg/kg of body weight as a single intravenous injection
Frank[3]	40 mg initially followed by repeat intravenous injection every 4 to 6 hours while shock persists
Oaks[4]	40 mg initially followed by repeat intravenous injection every 2 to 6 hours while shock persists
Schumer[5]	1 mg/kg of body weight as a single intravenous injection

Administration of high dose corticosteroid therapy should be continued only until the patient's condition has stabilized and usually not longer than 48 to 72 hours.

Although adverse reactions associated with high dose, short term corticosteroid therapy are uncommon, peptic ulceration may occur.

Cerebral Edema

Dexamethasone sodium phosphate injection is generally administered initially in a dosage of 10 mg intravenously followed by four mg every six hours intramuscularly until the symptoms of cerebral edema subside. Response is usually noted within 12 to 24 hours and dosage may be reduced after two to four days and gradually discontinued over a period of five to seven days. For palliative management of patients with recurrent or inoperable brain tumors, maintenance therapy with two mg two or three times a day may be effective.

Acute Allergic Disorders

In acute, self-limited allergic disorders or acute exacerbations of chronic allergic disorders, the following dosage schedule combining parenteral and oral therapy is suggested:

Dexamethasone sodium phosphate injection, 4 mg per mL: *first day*, 1 or 2 mL (4 or 8 mg), intramuscularly.

Dexamethasone tablets, 0.75 mg: second and third days, 4 tablets in two divided doses each day; fourth day, 2 tablets in two divided doses; fifth and sixth days, 1 tablet each day; seventh day, no treatment; eighth day, follow-up visit.

This schedule is designed to ensure adequate therapy during acute episodes, while minimizing the risk of overdosage in chronic cases.

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 from 0.2 to 6 mg. The frequency usually ranges from once every three to five days to once every two to three weeks. Frequent intra-articular injection may result in damage to joint tissues.

Some of the usual single doses are:

Site of Injection	Amount of Dexamethasone Phosphate (mg)
Large Joints (e.g., Knee)	2 to 4
Small Joints (e.g., Interphalangeal, Temporomandibular)	0.8 to 1
Bursae	2 to 3
Tendon Sheaths	0.4 to 1
Soft Tissue Infiltration	2 to 6
Ganglia	1 to 2

Dexamethasone sodium phosphate injection is particularly recommended for use in conjunction with one of the less soluble, longer-acting steroids for intra-articular and soft tissue injection.

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

HOW SUPPLIED

Dexamethasone Sodium Phosphate Injection, USP phosphate, is supplied as follows:

Product Code	Unit of Sale	Strength	Each
RF16501	NDC 63323-165-51 Unit of 25	4 mg per mL	NDC 63323-165-11 1 mL fill, in a 2 mL Flip-Top Single Dose Vial This product contains an RFID.
16501	NDC 63323-165-01 Unit of 25	4 mg per mL	NDC 63323-165-02 1 mL fill, in a 2 mL Flip-Top Single Dose Vial

RF16505	NDC. 63323-165-53 Unit of 25	20 mg per 5 mL (4 mg per mL)	NDC 63323-165-13 5 mL fill, in a 5 mL Flip-Top Multiple Dose Vial This product contains an RFID.
16505	NDC 63323-165-05 Unit of 25	20 mg per 5 mL (4 mg per mL)	NDC 63323-165-03 5 mL fill, in a 5 mL Flip-Top Multiple Dose Vial
16530	NDC 63323-165-30 Packaged Individually	120 mg per 30 mL (4 mg per mL)	NDC 63323-165-30 30 mL fill, in a 30 mL Flip-Top Multiple Dose Vial

STORE AT: 20° to **25**°C (**68**° to **77**°F) [see USP Controlled Room Temperature].
Protect from freezing. Sensitive to heat. Do not autoclave.
Protect from light. Store container in carton until contents have been used.
Do not use if precipitate is present.

REFERENCES:

1. Cavanagh, D.; Singh, K.B.: Endotoxin shock in pregnancy and abortion, in: "Corticosteroids in the Treatment of Shock", Schumer, W.; Nyhus, L.M., Editors, Urbana, University of Illinois Press, 1970, pp. 86-96.
2. Dietzman, R.H.; Ersek, R.A.; Bloch, J.M.; Lillehei, R.C.: High-output, low-resistance gram-negative septic shock in man, Angiology *20*: 691-700, Dec. 1969.
3. Frank, E.: Clinical observations in shock and management (In: Shields, T.F., ed.: Symposium on current concepts and management of shock), J. Maine Med. Ass. *59*: 195-200, Oct. 1968.
4. Oaks, W. W.; Cohen, H.E.: Endotoxin shock in the geriatric patient, Geriat. *22*: 120-130, Mar. 1967.
5. Schumer, W.; Nyhus, L.M.: Corticosteroid effect on biochemical parameters of human oligemic shock, Arch. Surg. *100*: 405-408, Apr. 1970.

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Revised: May 2024

PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 1 mL Vial Label

NDC 63323-165-11 RF16501

Dexamethasone

Sodium Phosphate

Injection, USP

4 mg per mL

For IM or IV use. See insert

for other routes. Sterile.

1 mL

Single Dose Vial Rx only

PACKAGE LABEL - PRINCIPAL DISPLAY - Dexamethasone Sodium Phosphate 1 mL Tray Label

NDC 63323-165-51 RF16501

Dexamethasone

Sodium Phosphate

Injection, USP

4 mg per mL*

For intramuscular or intravenous use.

See insert for other routes.

25 x 1 mL

Single Dose Vials Rx only

PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 1 mL Vial Label

NDC 63323-165-02 16501

Dexamethasone

Sodium Phosphate

Injection, USP

4 mg per mL

For IM or IV use.

See insert for other routes. Sterile.

1 mL

Single Dose Vial Rx only

PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 1 mL Tray Label

NDC 63323-165-01 16501

Dexamethasone

Sodium Phosphate

Injection, USP

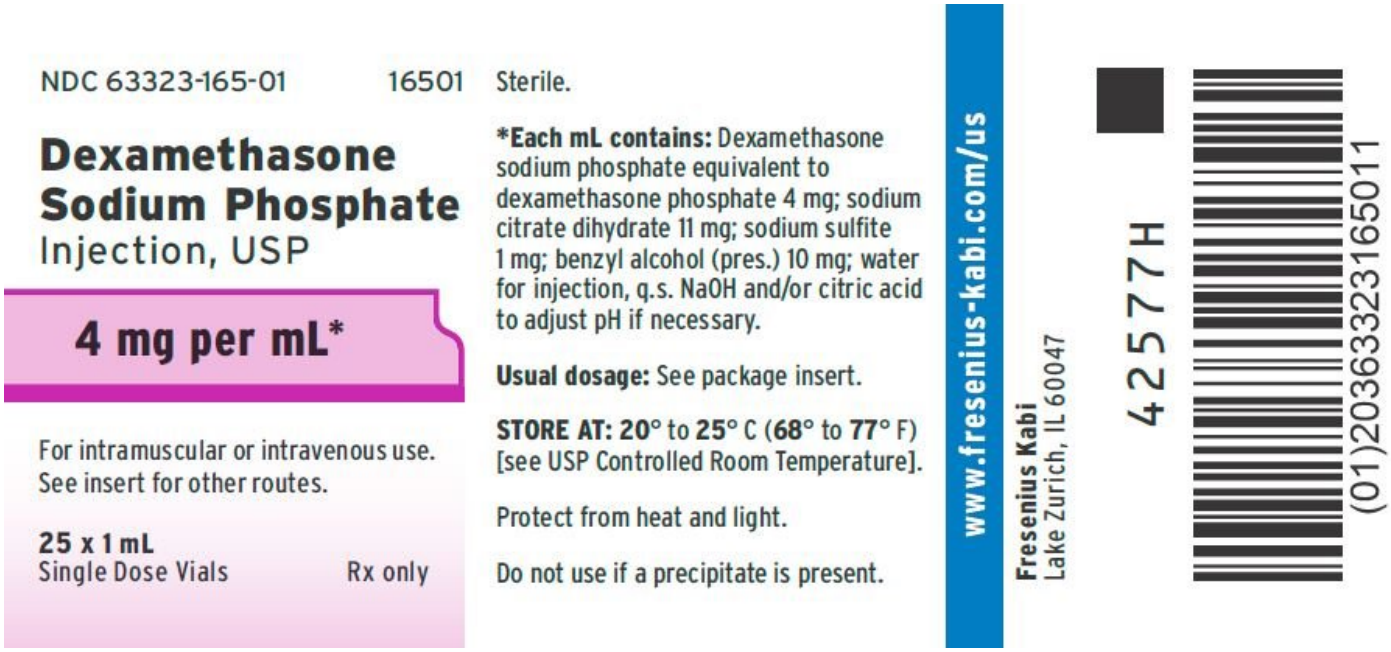
4 mg per mL*

For intramuscular or intravenous use.

See insert for other routes.

25 x 1 mL

Single Dose Vial Rx only



PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 5 mL Vial Label

NDC 63323-165-13 RF16505

Dexamethasone

Sodium Phosphate

Injection, USP

20 mg per 5 mL

(4 mg per mL)

For IM or IV use.

See insert for other routes.

5 mL

Multiple Dose Vial Rx only

PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 5 mL Tray Label

NDC 63323-165-53 RF16505

Dexamethasone

Sodium Phosphate

Injection, USP.

20 mg per 5 mL

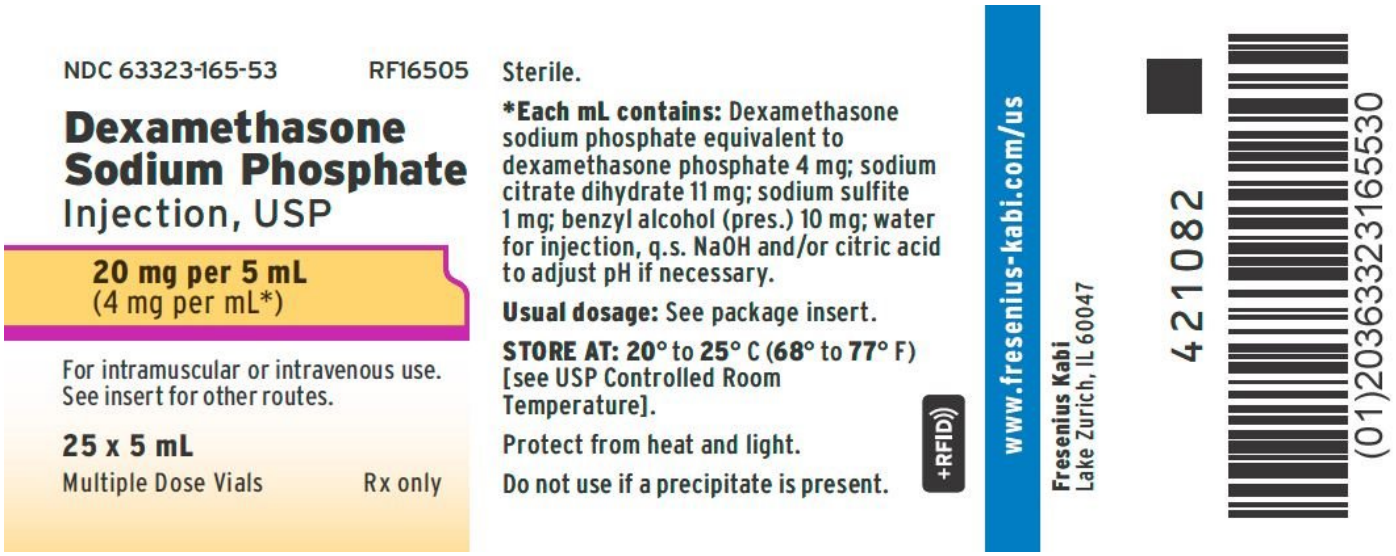
(4 mg per mL*)

For intramuscular or intravenous use.

See insert for other routes.

25 x 5 mL

Multiple Dose Vial Rx only



PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 5 mL Vial Label

NDC 63323-165-03 16505

Dexamethasone

Sodium Phosphate

Injection, USP

20 mg per 5 mL

(4 mg per mL)

For IM or IV use.

See insert for other routes.

5 mL

Multiple Dose Vial Rx only

PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 5 mL Tray Label

NDC 63323-165-05 16505

Dexamethasone

Sodium Phosphate

Injection, USP

20 mg per 5 mL

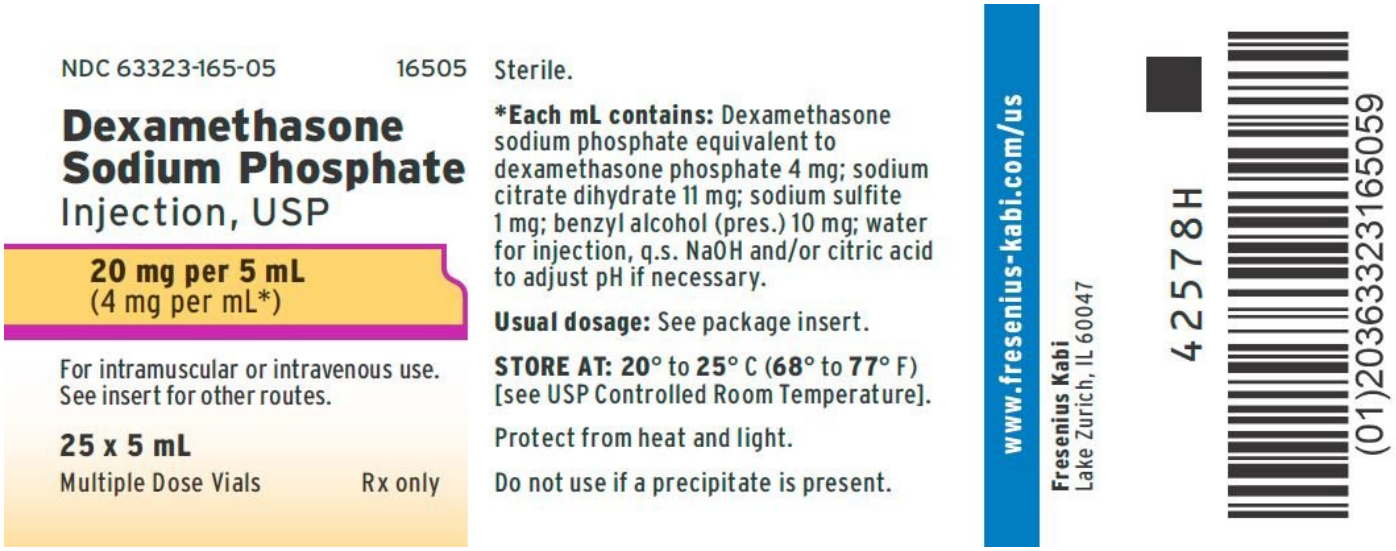
(4 mg per mL*)

For intramuscular or intravenous use.

See insert for other routes.

25 x 5 mL

Multiple Dose Vial Rx only



PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 30 mL Vial Label

NDC 63323-165-30 16530

Dexamethasone

Sodium Phosphate

Injection, USP

120 mg per 30 mL

(4 mg per mL*)

For intramuscular or

intravenous use.

See insert for other routes.

30 mL

Multiple Dose Vial Rx only

PACKAGE LABEL - PRINCIPAL DISPLAY – Dexamethasone Sodium Phosphate 30 mL Individual Carton Label

NDC 63323-165-30 16530

Dexamethasone

Sodium Phosphate

Injection, USP

120 mg per 30 mL

(4 mg per mL*)

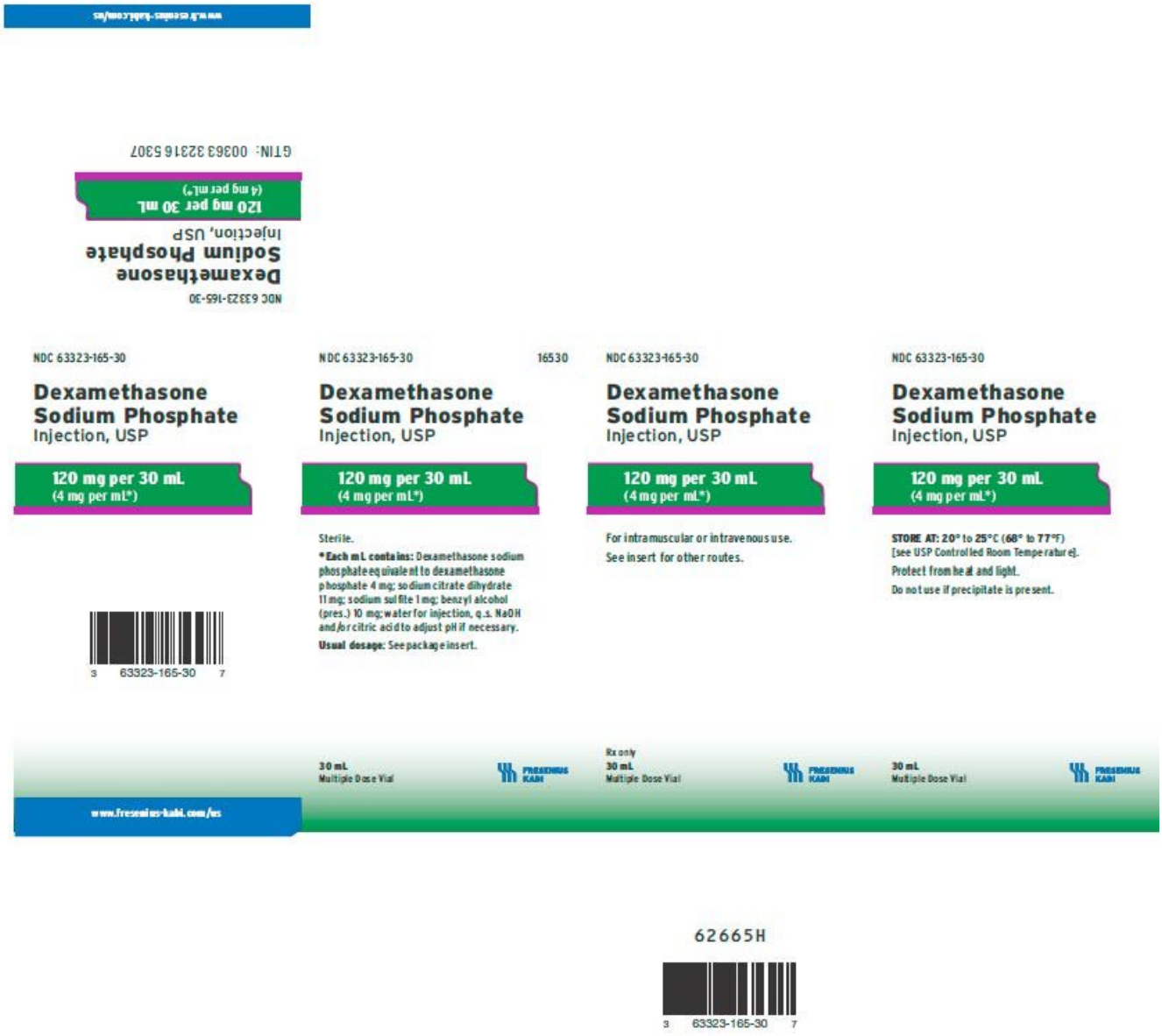
For intramuscular or intravenous use.

See insert for other routes.

Rx only

30 mL

Multiple Dose Vial



DEXAMETHASONE SODIUM PHOSPHATE

dexamethasone sodium phosphate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-165
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXAMETHASONE SODIUM PHOSPHATE (UNII: AI9376Y64P) (DEXAMETHASONE - UNII:7S5I7G3JQL)	DEXAMETHASONE PHOSPHATE	4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	11 mg in 1 mL
SODIUM SULFITE (UNII: VTK01UQK3G)	1 mg in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	10 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63323-165-51	25 in 1 TRAY	02/17/2025	
1	NDC:63323-165-11	1 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:63323-165-53	25 in 1 TRAY	02/17/2025	
2	NDC:63323-165-13	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
3	NDC:63323-165-01	25 in 1 TRAY	09/07/2000	
3	NDC:63323-165-02	1 mL in 1 VIAL; Type 0: Not a Combination Product		
4	NDC:63323-165-05	25 in 1 TRAY	09/07/2000	
4	NDC:63323-165-03	5 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		
5	NDC:63323-165-30	1 in 1 BOX	09/07/2000	
5		30 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA084916	09/07/2000	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		023648251	MANUFACTURE(63323-165) , ANALYSIS(63323-165)