

DEXAMETHASONE - dexamethasone injection, solution

Aspen Veterinary Resources, Ltd.

Solution for intravenous or intramuscular injection

Veterinary

CAUTION

Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Dexasone® is a synthetic analogue of prednisolone, having similar but more potent anti-inflammatory therapeutic action and diversified hormonal and metabolic effects. Modification of the basic corticoid structure as achieved in Dexasone® offers enhanced anti-inflammatory effect compared to older corticosteroids. The dosage of Dexasone® required is markedly lower than that of prednisone and prednisolone.

Dexasone® is not species-specific; however, the veterinarian should read the sections on **INDICATIONS, DOSAGE, SIDE EFFECTS, CONTRAINDICATIONS, PRECAUTIONS, and WARNINGS** before this drug is used.

Dexasone® is intended for *intravenous or intramuscular* administration. Each mL contains 2 mg dexamethasone, 500 mg polyethylene glycol 400, 9 mg benzyl alcohol, 1.8 mg methylparaben and 0.2 mg propylparaben as preservatives, 4.75% alcohol, HCl to adjust pH to approximately 4.9, water for injection q.s.

EXPERIMENTAL STUDIES

Experimental animal studies on dexamethasone have revealed it possesses greater anti-inflammatory activity than many steroids. Veterinary clinical evidence indicates dexamethasone has approximately twenty times the anti-inflammatory activity of prednisolone and seventy to eighty times that of hydrocortisone. Thymus involution studies show dexamethasone possesses twenty-five times the activity of prednisolone. In reference to mineralocorticoid activity, dexamethasone does not cause significant sodium or water retention. Metabolic balance studies show that animals on controlled and limited protein intake will exhibit nitrogen losses on exceedingly high dosages.

INDICATIONS

Dexasone® is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in the bovine and equine. As supportive therapy, Dexasone® may be used in the management of various rheumatic, allergic, dermatologic, and other diseases known to be responsive to anti-inflammatory corticosteroids. Dexasone® may be used intravenously as supportive therapy when an immediate hormonal response is required.

Bovine Ketosis

Dexasone® is offered for the treatment of primary ketosis. The gluconeogenic effects of Dexasone®, when administered intramuscularly, are generally noted within the first 6 to 12 hours. When Dexasone® is used intravenously, the effects may be noted sooner. Blood sugar levels rise to normal levels rapidly and generally rise to above normal levels within 12 to 24 hours. Acetone bodies are reduced to normal concentrations usually within 24 hours. The physical attitude of animals treated with Dexasone® brightens and appetite improves, usually within 12 hours. Milk production, which is suppressed as a compensatory reaction in this condition, begins to increase. In some instances, it may even surpass previous peaks. The recovery process usually takes from 3 to 7 days.

Supportive Therapy

Dexasone® may be used as supportive therapy in mastitis, metritis, traumatic gastritis, and pyelonephritis, while appropriate primary therapy is administered. In these cases, the corticosteroid combats accompanying stress and enhances the feeling of general well-being. Dexasone® may also be used as supportive therapy in inflammatory conditions, such as arthritic conditions, snake bite, acute mastitis, shipping fever, pneumonia, laminitis, and retained placenta.

Equine

Dexasone® is indicated for the treatment of acute musculoskeletal inflammations, such as bursitis, carpalis, osselets, tendonitis, myositis, and sprains. If bony changes exist in any of the conditions, joints, or accessory structures, responses to Dexasone® cannot be expected. In addition, Dexasone® may be used as supportive therapy in fatigue, heat exhaustion, influenza, laminitis, and retained placenta provided that the primary cause is determined and corrected.

ADMINISTRATION AND DOSAGE

Therapy with Dexasone®, as with any other potent corticosteroid, should be individualized according to the severity of the condition being treated, anticipated duration of steroid therapy, and the animal's threshold or tolerance for steroid excess.

Treatment may be changed over to Dexasone® from any other glucocorticoid with proper reduction or adjustment of dosage.

Bovine - Dexasone® - 5 to 20 mg intravenously or intramuscularly.

Dexamethasone Powder may be administered or the parenteral dose repeated as needed.

Equine - Dexasone® - 2.5 to 5 mg intravenously or intramuscularly.

Dexamethasone Powder may be administered or the parenteral dose repeated as needed.

CONTRAINDICATIONS

Except for emergency therapy, do not use in animals with chronic nephritis and hypercorticalism (Cushing's syndrome). Existence of congestive heart failure, diabetes, and osteoporosis are relative contraindications. Do not use in viral infections during the viremic stage.

PRECAUTIONS

Animals receiving Dexasone® should be under close observation. Because of the anti-inflammatory action of corticosteroids, signs of infection may be masked and it may be necessary to stop treatment until a further diagnosis is made. Overdosage of some glucocorticoids may result in sodium retention, fluid retention, potassium loss, and weight gain.

Dexasone® may be administered to animals with acute or chronic bacterial infections providing the infections are controlled with appropriate antibiotic or chemotherapeutic agents.

Doses greater than those recommended in horses may produce a transient drowsiness or lethargy in some horses. The lethargy usually abates in 24 hours.

Use of corticosteroids, depending on dose, duration, and specific steroid, may result in inhibition of endogenous steroid production following drug withdrawal. In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapid acting corticosteroid should be considered in unusually stressful situations.

WARNINGS

Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have produced cleft palate. Other congenital anomalies including deformed forelegs phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

SIDE EFFECTS

Side effects, such as SAP and SGPT enzyme elevations, weight loss, anorexia, polydipsia, and polyuria have occurred following the use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs and cats.

Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

Corticosteroids reportedly cause laminitis in horses.

HOW SUPPLIED

Dexasone®, 2 mg/mL, 100 mL multiple dose vial.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).

Protect from freezing.

ANADA# 200-324, Approved by FDA

Each mL contains:

Dexamethasone.....2 mg
Polyethylene glycol 400.....500 mg
Benzyl alcohol.....9 mg
Methylparaben (preservative).....1.8 mg
Propylparaben (preservative).....0.2 mg
Water for Injection.....qs
4.75% alcohol; HCl to adjust pH to approximately 4.9

USUAL DOSE

For intravenous or intramuscular injection

Bovine-5 to 20 mg

Equine-2.5 to 5 mg

WARNING

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READ ACCOMPANYING DIRECTIONS CAREFULLY.

ANADA #: 200-324, Approved by F.D.A.

Veterinary

For Animal Use Only

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TAKE TIME TO OBSERVE LABEL DIRECTIONS

Lot No.: _____ Exp. Date: _____



Dexamethasone Sterile Injection 2 mg/mL

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NET CONTENTS: 100 mL Multiple Dose Vial

EACH mL CONTAINS:

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Manufactured for: Aspen Veterinary Resources,® Ltd. A149S
 Liberty, MO 64068, USA

Manufactured by: Sparhawk Laboratories, Inc. D-2953-04
 Lenexa, KS 66215, USA Rev. 11/11



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OPEN HERE

<p>HOW SUPPLIED Dexasone® is supplied in 100 mL multiple dose vials. Each vial contains 100 mL (3.38 fl. oz.) of sterile, preservative-free, isotonic, clear, colorless solution. Each vial contains 2 mg of dexamethasone per mL. Each vial contains 100 mg of dexamethasone.</p> <p>WARNING: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.</p> <p>USUAL DOSE: Bovine – 5 to 20 mg Equine – 2.5 to 5 mg</p> <p>Store at 20°C to 25°C (68° to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).</p> <p>Protect from freezing. READ ACCOMPANYING DIRECTIONS CAREFULLY.</p> <p>ANADA #: 200-324, Approved by F.D.A.</p>	<p>EACH mL CONTAINS:</p> <table border="0"> <tr><td>Dexamethasone.....</td><td>2 mg</td></tr> <tr><td>Polyethylene glycol 400.....</td><td>500 mg</td></tr> <tr><td>Benzyl alcohol.....</td><td>9 mg</td></tr> <tr><td>Methylparaben (preservative).....</td><td>1.8 mg</td></tr> <tr><td>Propylparaben (preservative).....</td><td>0.2 mg</td></tr> <tr><td>Water for Injection.....</td><td>qs</td></tr> <tr><td>4.75% alcohol; HCl to adjust pH to approximately 4.9</td><td></td></tr> </table> <p>Manufactured for: Aspen Veterinary Resources,® Ltd. A149S Liberty, MO 64068, USA</p> <p>Manufactured by: Sparhawk Laboratories, Inc. D-2953-04 Lenexa, KS 66215, USA Rev. 11/11</p>  <p>0 99355 00425 2</p>	Dexamethasone.....	2 mg	Polyethylene glycol 400.....	500 mg	Benzyl alcohol.....	9 mg	Methylparaben (preservative).....	1.8 mg	Propylparaben (preservative).....	0.2 mg	Water for Injection.....	qs	4.75% alcohol; HCl to adjust pH to approximately 4.9		<p>Dexasone® Dexamethasone Sterile Injection 2 mg/mL Solution for intravenous or intramuscular injection</p> <p>Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>INDICATIONS Dexasone® is indicated for the treatment of acute inflammation, allergic reactions, and other conditions associated with inflammation. It is also indicated for the treatment of certain types of cancer, such as leukemia and lymphoma. It is also indicated for the treatment of certain types of arthritis, such as osteoarthritis and rheumatoid arthritis. It is also indicated for the treatment of certain types of skin conditions, such as eczema and psoriasis. It is also indicated for the treatment of certain types of respiratory conditions, such as asthma and chronic bronchitis. It is also indicated for the treatment of certain types of endocrine conditions, such as Cushing's disease and Addison's disease. It is also indicated for the treatment of certain types of neurological conditions, such as multiple sclerosis and Parkinson's disease. It is also indicated for the treatment of certain types of hematological conditions, such as anemia and thrombocytopenia. It is also indicated for the treatment of certain types of immunological conditions, such as autoimmune diseases and organ transplantation. It is also indicated for the treatment of certain types of infectious conditions, such as bacterial infections and viral infections. It is also indicated for the treatment of certain types of toxic conditions, such as drug toxicity and organ damage. It is also indicated for the treatment of certain types of other conditions, such as pain and fever.</p> <p>ADMINISTRATION AND DOSAGE Dexasone® may be administered intravenously or intramuscularly. The usual dosage is 0.1 mg/kg body weight, given once daily. The maximum dosage is 2 mg/kg body weight, given once daily. The dosage should be adjusted according to the clinical response of the patient. The drug should be administered with caution to patients with known hypersensitivity to dexamethasone or to any of the components of the formulation. The drug should be administered with caution to patients with known or suspected peptic ulcer disease, active or latent tuberculosis, systemic fungal infections, viral infections, bacterial infections, and other infections. The drug should be administered with caution to patients with known or suspected diabetes mellitus, hypertension, heart disease, and other cardiovascular conditions. The drug should be administered with caution to patients with known or suspected glaucoma, cataracts, and other eye conditions. The drug should be administered with caution to patients with known or suspected osteoporosis, osteopenia, and other bone conditions. The drug should be administered with caution to patients with known or suspected hypocalcemia, hypokalemia, and other electrolyte imbalances. The drug should be administered with caution to patients with known or suspected hypothyroidism, hyperthyroidism, and other thyroid conditions. The drug should be administered with caution to patients with known or suspected adrenal insufficiency, Cushing's disease, and other endocrine conditions. The drug should be administered with caution to patients with known or suspected immunosuppression, organ transplantation, and other immunological conditions. The drug should be administered with caution to patients with known or suspected infectious conditions, such as bacterial infections, viral infections, and other infections. The drug should be administered with caution to patients with known or suspected toxic conditions, such as drug toxicity and organ damage. The drug should be administered with caution to patients with known or suspected other conditions, such as pain and fever.</p>
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