

DEXASONE- dexamethasone injection, solution
Aspen Veterinary Resources, Ltd.

Dexasone® Dexamethasone Sterile Injection 2 mg/mL

Dexasone®

Dexamethasone Sterile Injection 2 mg/mL

Veterinary

NOT FOR USE IN HUMANS

KEEP OUT OF REACH OF CHILDREN

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, carpalitis, 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.

CONTACT INFORMATION

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Sparhawk Laboratories Inc. at

1-800-255-6388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

HOW SUPPLIED

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

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

Protect from freezing.

Manufactured for:

Aspen Veterinary Resources[®], Ltd.
Liberty, MO 64068
www.aspenveterinaryresources.com

Approved by FDA under ANADA # 200-324

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

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

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).

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READ ACCOMPANYING DIRECTIONS CAREFULLY.

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Approved by FDA under ANADA # 200-324



Lot No.: _____ Exp. Date: _____

NDC # 46066-223-04



DEXASONE®

Dexamethasone Sterile Injection 2 mg/mL



**Veterinary
NOT FOR USE IN HUMANS
KEEP OUT OF REACH OF CHILDREN**

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

NET CONTENTS:
3.38 fl oz (100 mL)
Multiple Dose Vial

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 q.s.
4.75% alcohol; HCl to adjust pH to approximately 4.9

Manufactured for:

Aspen Veterinary Resources®, Ltd.
Liberty, MO 64068
www.aspenveterinaryresources.com



A149S
D-2953-04
Rev. 02/24



<p>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.</p> <p>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>SIDE EFFECTS Side effects such as SAP and SGPT enzyme elevations, weight loss, anorexia, polyuria, and polyata have occurred following the use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs and cats.</p> <p>Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy. Corticosteroids reportedly cause laminitis in horses.</p> <p style="text-align: right;">8</p>	<p>CONTACT INFORMATION: To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Spawhawk Laboratories Inc. at 1-800-255-6388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/tepatoinfo.</p> <p>HOW SUPPLIED Dexasone®, 2 mg/mL, 100 mL, multiple dose vial.</p> <p>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).</p> <p>Protect from freezing.</p> <p>Manufactured for: Aspen Veterinary Resources®, Ltd. D-2953-04 Liberty, MO 64068 Rev. 02/24 www.aspenveterinaryresources.com</p> <p>Approved by FDA under ANADA # 200-324</p> <p style="text-align: right;">9</p>	<p>EACH mL CONTAINS:</p> <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 q.s. 4.75% alcohol; HCl to adjust pH to approximately 4.9</p> <p>Manufactured for: Aspen Veterinary Resources®, Ltd. D-2953-04 Liberty, MO 64068 Rev. 02/24 www.aspenveterinaryresources.com</p> <p style="text-align: right;">A149S D-2953-04 Rev. 02/24</p> <p style="text-align: right;">1</p>	<p>Dexasone® Dexamethasone Sterile Injection 2 mg/mL Solution for Intravenous or Intramuscular Injection</p> <p>Veterinary NOT FOR USE IN HUMANS KEEP OUT OF REACH OF CHILDREN</p> <p>CAUTION Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>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.</p> <p style="text-align: right;">1</p>	<p>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.</p> <p>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.</p> <p>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. Thymsus involution studies show dexamethasone possesses twenty-five times the activity of prednisolone. In reference to mineralocorticoid activity, dexamethasone does not</p> <p style="text-align: right;">2</p>
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<p>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.</p> <p>INDICATIONS Dexasone® is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in the bovine and equine.</p> <p>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.</p> <p>Bovine Ketosis Dexasone® is offered for the treatment of primary ketosis. The glucocorticoid 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</p> <p style="text-align: right;">3</p>	<p>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 attack 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.</p> <p>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.</p> <p>Dexasone® may also be used as supportive therapy in inflammatory conditions, such as arthritic conditions, stake bite, acute mastitis, shipping fever, pneumonia, laminitis, and retained placenta.</p> <p style="text-align: right;">4</p>	<p>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.</p> <p>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.</p> <p>Treatment may be changed over to Dexasone® from any other glucocorticoid with proper reduction or adjustment of dosage.</p> <p style="text-align: right;">5</p>	<p>Bovine – Dexasone® – 5 to 20 mg intravenously or intramuscularly. Dexamethasone Powder may be administered or the parental dose repeated as needed.</p> <p>Equine – Dexasone® – 2.5 to 5 mg intravenously or intramuscularly. Dexamethasone Powder may be administered or the parental dose repeated as needed.</p> <p>CONTRAINDICATIONS Except for emergency therapy, do not use in animals with chronic nephritis and hyperosteoarthritis (Cushing's syndrome). Existence of congestive heart failure, diabetes, and osteoporosis are relative contraindications. Do not use in viral infections during the virulent stage.</p> <p>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</p> <p style="text-align: right;">6</p>	<p>glucocorticoids may result in sodium retention, fluid retention, potassium loss, and weight gain.</p> <p>Dexasone® may be administered to animals with acute or chronic bacterial infections providing the infections are controlled with appropriate antibiotic or chemotherapeutic agents.</p> <p>Doses greater than those recommended in horses may produce a transient drowsiness or lethargy in some horses. The lethargy usually abates in 24 hours.</p> <p>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.</p> <p>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</p> <p style="text-align: right;">7</p>
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DEXASONE

dexamethasone injection, solution

Product Information

Product Type	PREScription ANIMAL DRUG	Item Code (Source)	NDC:46066-223
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXAMETHASONE (UNII: 7S517G3JQL) (DEXAMETHASONE - UNII: 7S517G3JQL)	DEXAMETHASONE	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	

POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46066-223-04	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200324	02/21/2006	

Labeler - Aspen Veterinary Resources, Ltd. (627265361)

Registrant - Sparhawk Laboratories, Inc. (147979082)

Establishment

Name	Address	ID/FEI	Business Operations
Sparhawk Laboratories, Inc.		147979082	analysis, manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Pharmacia & Upjohn Company LLC		618054084	api manufacture

Revised: 5/2024

Aspen Veterinary Resources, Ltd.