

DEXAMETHASONE SOLUTION- dexamethasone solution MWI/VetOne

MWI/VetOne Dexamethasone 2mg Injection (dexamethasone solution) ANADA 200-312

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

Dexamethasone Solution 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 Dexamethasone offers enhanced anti-inflammatory effect compared to older corticosteroids. The dosage of Dexamethasone required is markedly lower than that of prednisone and prednisolone.

Dexamethasone 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. Dexamethasone is intended for intravenous or intramuscular administration.

Each mL contains 2 mg dexamethasone, 500 mg propylene 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 animal studies on dexamethasone have revealed it possesses greater anti-inflammatory activity than many steroids. Veterinary clinical evidence indicates dexamethasone has approximately 20 times the anti-inflammatory activity as prednisolone and 70 to 80 times that of hydrocortisone. Thymus involution studies show dexamethasone possesses 25 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.

Dexamethasone is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in the bovine and equine.

As supportive therapy, Dexamethasone may be used in the management of various rheumatic, allergic, dermatologic, and other diseases known to be responsive to anti-inflammatory corticosteroids. Dexamethasone may be used intravenously as supportive therapy when an immediate hormonal response is required.

Bovine Ketosis

Dexamethasone is offered for the treatment of primary ketosis. The gluconeogenic effects of Dexamethasone, when administered intramuscularly, are generally noted within the first 6 to 12 hours. When Dexamethasone is used intravenously, the effects may be noted sooner. Blood sugar levels rise to normal levels within 12 to 24 hours. Acetone bodies are reduced to normal concentrations usually within 24 hours. The physical attitude of animals 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

Dexamethasone 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.

Dexamethasone 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

Dexamethasone 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 these conditions, joints, or accessory structures, a response to Dexamethasone cannot be expected. In addition, Dexamethasone may be used as supportive therapy in fatigue, heat exhaustion, influenza, laminitis, and retained placenta provided that the primary cause is determined and corrected.

Therapy with Dexamethasone, as with any other potent corticosteroid, should be individualized accordingly to the severity of the condition being treated, anticipated duration of steroid therapy, and animal's threshold or tolerance for steroid excess. Treatment may be changed over to Dexamethasone from any other glucocorticoid with proper reduction or adjustment of dosage.

Bovine: Dexamethasone 5-20mg intravenously or intramuscularly. Equine: Dexamethasone 2.5-5mg intravenously or intramuscularly.

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

Animals receiving Dexamethasone should be under close observation. Because of the anti-inflammatory action of corticosteroids, sign 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.

Dexamethasone 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 transient drowsiness or lethargy in some horses. The lethargy usually abates in 24 hours.

use of corticosteroids, depending on the dose, duration, and specified 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 rapidly acting corticosteroid should be considered in unusually stressful situations.

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 premature 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, 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 cats and dogs. Cushing's Syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

Corticosteroids reportedly cause laminitis in horses.

Dexamethasone, 2mg per mL, 100mL multiple dose vial.

Store between 2degree C and 30degree C (36degree F and 86degree F).

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.

NDC 13985-037-02

100 mL

VETone
Dexamethasone

Solution

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Pull

USUAL DOSE:
Bovine - 5 to 20 mg
Equine - 2.5 to 5 mg

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Sterile Vial (2 mg/mL)

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FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

ANADA# 200-312, Approved by FDA

V1 501012

Net Contents: 100 mL

For intravenous or intramuscular injection. Read accompanying directions carefully.

8DEX028D
Rev 07 11



Distributed by:
MWI
Boise, ID 83705
Manufactured by:
Bimeda-MTC Animal Health Inc.
Cambridge, Ontario, Canada N3C 2W4
Bimeda-MTC Animal Health Inc. is a
Division of Cross Vetpharm Group Ltd.

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DESCRIPTION: Dexamethasone Solution 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 Dexamethasone offers enhanced anti-inflammatory effect compared to older corticosteroids. The dosage of Dexamethasone required is markedly lower than that of prednisone and prednisolone.

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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 20 times the anti-inflammatory activity of prednisolone and 70 to 80 times that of hydrocortisone. Thymus involution studies show dexamethasone possesses 25 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: Dexamethasone is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in the bovine and equine.

As supportive therapy, Dexamethasone may be used in the management of various rheumatic, allergic, dermatologic, and other diseases known to be responsive to anti-inflammatory corticosteroids. Dexamethasone may be used intravenously as supportive therapy when an immediate hormonal response is required.

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even surpass previous peaks. The recovery process usually takes from 3 to 7 days.

Supportive Therapy

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as bursitis, carpalis, osselets, tendonitis, myositis, and sprains. If bony changes exist in any of these conditions, joints, or accessory structures, a response to Dexamethasone cannot be expected. In addition, Dexamethasone 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 Dexamethasone, as with any other potent corticosteroid, should be individualized according to the severity of the condition being treated, anticipated duration of steroid therapy, and animal's threshold or tolerance for steroid excess.

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following drug withdrawal. In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in unusually stressful situations.

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

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HOW SUPPLIED: Dexamethasone, 2 mg per mL, 100 mL multiple dose vial.

STORAGE: Store between 2°C and 30°C (36°F and 86°F).

DEXAMETHASONE SOLUTION

dexamethasone solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG LABEL	Item Code (Source)	NDC:13985-037
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dexamethasone (Dexamethasone)	Dexamethasone	2 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-037-02	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200312	10/20/2003	

Labeler - MWI/VetOne (019926120)

Registrant - Bimeda, Inc., Division of Cross Vetpharm Group (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda-MTC Animal Health, Division of Cross Vetpharm Group		256232216	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Tianjin Tianyao Pharmaceutical Co		654534197	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Sanofi Chimie		291538267	api manufacture

Revised: 11/2013

MWI/VetOne