DEXIUM - dexamethasone injection, solution
Bimeda, Inc.

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: 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 Dexium® offers enhanced anti-inflammatory effect compared to older corticosteroids. The dosage of Dexium® required is markedly lower than that of prednisone and prednisolone. Dexium® 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. Dexium® 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 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 prenisolone. In reference to mineralcorticoid activity, dexamethasone does not caused 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: Dexium® is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in the bovine and equine. As supportive therapy, Dexium® may be used in the management of various rheumatic, allergic, dermatologic, and other diseases known to be responsive to anti-inflammatory corticosteroids. Dexium® *may be used intravenously as supportive therapy when an immediate hormonal response is required.*

Bovine Ketosis

Dexium® is offered for the treatment of primary ketosis. The gluconeogenic effects of Dexium®, when administered intramuscularly, are generally noted within the first 6 to 12 hours. When Dexium® 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 Dexium® 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

Dexium® 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.

Dexium® 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

Dexium® is indicated for the treatment of acute musculoskeletal inflammations, such as bursitis, carpitis, osselets, tendonitis, myositis, and sprains. If boney changes exist in any of these conditions,

joints or accessory structures, a response to Dexium® cannot be expected. In addition, Dexium® 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 Dexium®, 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. Treatment may be changed over to Dexium® from any other glucocorticoid with proper reduction or adjustment of doage.

Bovine:Dexium®: 5 - 20 mg intravenously or intramuscularly.

Equine:Dexium®: 2.5 - 5 mg intravenously or intramuscularly.

CONTRAINDICATIONS: 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 with viremic stage.

PRECAUTIONS: Animals receiving Dexium® 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.

Dexium® 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.

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 premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

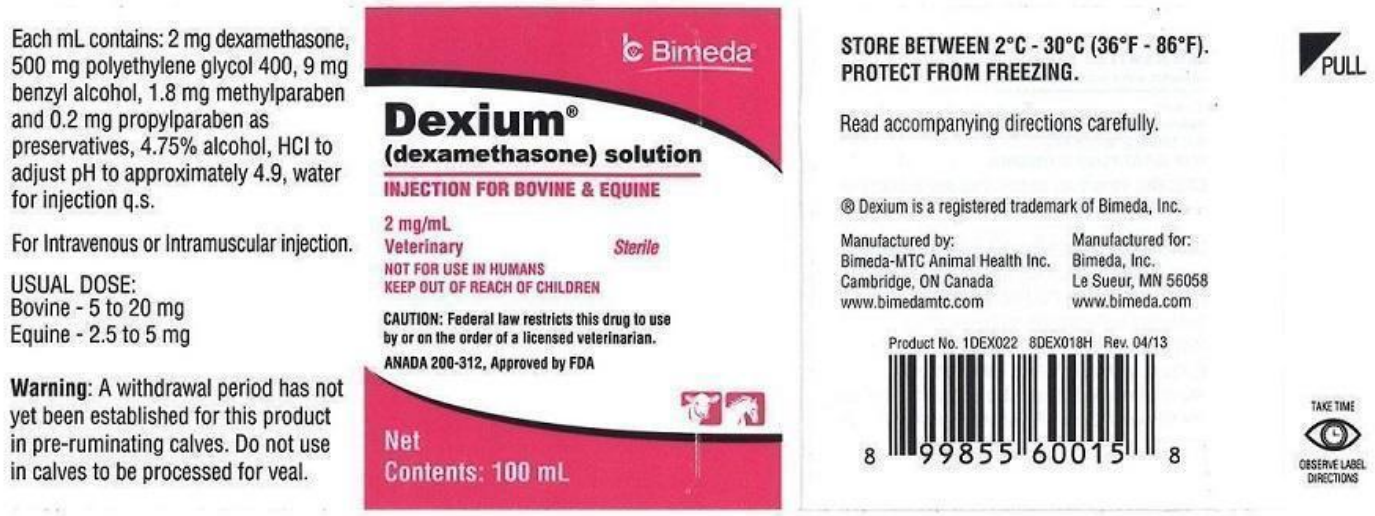
Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have produced cleft palate. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy.

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: Side effects, such as SAP and SGPT enzyme elevations, weight loss, anorexia, polydipsia, and polyuria, have occurred following yhe use of corticosteroids in dogs. Vomiting and diarrhea (occassionally 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.

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

STORE BETWEEN 2°C-30°C (36°F-86°F). PROTECT FROM FREEZING.



DEXIUM

dexamethasone injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:61133-0899
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dexamethasone (UNII: 7S5I7G3JQL) (Dexamethasone - UNII:7S5I7G3JQL)	Dexamethasone	2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Propylparaben (UNII: Z8IX2SC1OH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61133-0899-9	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 - Bimeda, Inc. (060492923)

Registrant - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda-MTC Animal Health		256232216	manufacture

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Bimeda, Inc.