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VEDCO, INC.

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DEXAMETHASONE SOLUTION 2 MG/ML

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Vedco

2 mg/mL

for Intravenous or Intramuscular Injection

Veterinary

ANADA 200-108, Approved by FDA

CAUTION:

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

DESCRIPTION

Dexamethasone 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 **WARNING** before this drug is used.

Dexamethasone Solution 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

Dexamethasone Solution 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 Solution may be used intravenously as supportive therapy when an immediate hormonal response is required.

Bovine Ketosis

Dexamethasone Solution 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 Solution 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 dexamethasone 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 three to seven 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, carpitis, osselets, tendonitis, myositis, and sprains. If boney changes exist in any of these conditions, joints, or accessory structures, responses 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 the 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 Solution - 5 to 20 mg intravenously or intramuscularly.

Equine - Dexamethasone Solution - 2.5 to 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 the viremic stage.

PRECAUTIONS

Animals receiving Dexamethasone 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 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 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 rapidly acting corticosteroid should be considered in unusually stressful situations.

WARNING

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.

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

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.

SIDE EFFECTS

Corticosteroids reportedly cause laminitis in horses.

HOW SUPPLIED

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

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

Distributed By **VEDCO, INC.,** St. Joseph, MO 64507

NET CONTENTS:	NDC	
100 mL Multiple Dose Vial Sterile	50989-159-12	600029 Rev0607

NAC No.: 10940432