MED-PHARMEX, INC.
2727 THOMPSON CREEK ROAD, POMONA, CA, 91767-1861
Telephone: 909-593-7875
Fax: 909-593-7862
Website: www.med-pharmex.com
Email: egbert@medpharmex.com

DEXAMETHASONE SOLUTION

Med-Pharmex

NDC 54925-067-10
2 mg/mL
For intravenous or intramuscular injection.
Veterinary
For Animal Use Only
Keep Out Of Reach Of Children

CAUTION:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.
ANADA 200-456, Approved By FDA

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

Dexamethasone Solution 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 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 and/or sodium hydroxide to adjust pH to approximately 4.9, Water for Injection q.s.

EXPERIMENTAL STUDIES:

Experimental animal studies on dexamethasone have revealed that 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 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 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 Solution 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 six to twelve 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 Solution 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 Solution 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 Solution 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 Solution cannot be expected. In addition, Dexamethasone Solution 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 Solution, 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 Solution from any other glucocorticoid with proper reduction or adjustment of dosage.

Bovine-Dexamethasone Solution-5 to 20 mg intravenously or intramuscularly. The parenteral dose may be repeated as needed.

Equine-Dexamethasone Solution-2.5 to 5 mg intravenously or intramuscularly. The parenteral dose may be 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 Dexamethasone Solution 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 Solution 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.

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.

RESIDUE 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.

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:

Dexamethasone Solution 2 mg/mL, 100-mL multiple dose vial. **Store between 20° - 25°C (68° - 77°F).**

Med-Pharmex, Inc., Pomona, CA 91767-1861

rev 2/12

CPN: 1027033.1