DEXAMETHASONE - dexamethasone injection, solution
Agri Laboratories, Ltd.

DEXAMETHASONE INJECTION 2 mg/mL

Solution for intravenous or intramuscular injection

Veterinary

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

DESCRIPTION
DEXAMETHASONE INJECTION 2 mg/mL 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 INJECTION 2 mg/mL offers enhanced anti-inflammatory effect compared to older corticosteroids. The dosage of DEXAMETHASONE INJECTION 2 mg/mL required is markedly lower than that of prednisone and prednisolone.

DEXAMETHASONE INJECTION 2 mg/mL 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 INJECTION 2 mg/mL 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 INJECTION 2 mg/mL is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in the bovine and equine.

As supportive therapy, DEXAMETHASONE INJECTION 2 mg/mL may be used in the management of various rheumatic, allergic, dermatologic, and other diseases known to be responsive to anti-inflammatory corticosteroids. DEXAMETHASONE INJECTION 2 mg/mL may be used intravenously as supportive therapy when an immediate hormonal response is required.

Bovine Ketosis
DEXAMETHASONE INJECTION 2 mg/mL is offered for the treatment of primary ketosis. The gluconeogenic effects of DEXAMETHASONE INJECTION 2 mg/mL, when administered intramuscularly, are generally noted within the first 6 to 12 hours. When DEXAMETHASONE

INJECTION 2 mg/mL 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 INJECTION 2 mg/mL 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

DEXAMETHASONE INJECTION 2 mg/mL may be used as supportive therapy in mastits, 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 INJECTION 2 mg/mL 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 INJECTION 2 mg/mL 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 the conditions, joints, or accessory structures, responses to DEXAMETHASONE INJECTION 2 mg/mL cannot be expected. In addition, DEXAMETHASONE INJECTION 2 mg/mL 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 INJECTION 2 mg/mL, as with any other potent corticosteroid, should be individualized according to the severity of the condition being treated, anticipated duration of steroid therapy, and teh animal's threshold or tolerance for steroid excess.

Treatment may be changed over to DEXAMETHASONE INJECTION2 mg/mL from any other glucocorticoid with proper reduction or adjustment of dosage.

Bovine - DEXAMETHASONE INJECTION 2 mg/mL - 5 to 20 mg intravenously or intramuscularly.

Dexamethasone Powder may be administered or the parenteral dose repeated as needed.

Equine - DEXAMETHASONE INJECTION 2 mg/mL - 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 DEXAMETHASONE INJECTION 2 mg/mL 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.

DEXAMETHASONE INJECTION 2 mg/mL 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.

HOW SUPPLIED

DEXAMETHASONE INJECTION 2 mg/mL, 100 mL multiple dose vial.

Store at 20ºC to 25ºC (68ºF to 77ºF), excursions permitted between 15ºC and 30ºC (between 59ºF and 86ºF).

Protect from freezing.

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
1.75% alcohol; HCl to adjust pH to
approximately 4.9

TAKE TIME OBSERVE LABEL DIRECTIONS

For Intravenous or Intra-muscular Injection Usual Dose

Bovine-5 to 20 mg
Equine-2.5 to 5 mg

NDC 57561-953-04

Dexamethasone Injection 2 mg/mL

Dexamethasone Sterile Injection

Veterinary

FOR ANIMAL USE ONLY

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ANADA200-324, Approved by FDA

MULTIPLE DOSE VIAL

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D-2953-04
Rev. 10-12

Manufactured by Sparhawk Laboratories, Inc.
Lenexa, KS 66215, USA

ANADA# 200-324, Approved by FDA

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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

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Sparhawk Laboratories, Inc.
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Rev. 10-12 D-2953-04

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WARNINGS
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DEXAMETHASONE

dexamethasone injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG LABEL	**Item Code (Source)**	NDC:57561-953
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXAMETHASONE (DEXAMETHASONE)	DEXAMETHASONE	2 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57561-953-04	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200324	07/21/2006	

Labeler - Agri Laboratories, Ltd. (155594450)

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