DEXAMETHASONE- dexamethasone injection, solution Clipper Distributing Company, LLC

DEXAMETHASONE INJECTION 2 mg/mL

Solution for intravenous or intramuscular injection

Veterinary

NOT FOR UE IN HUMANS

KEEP OUT OF REACH OF CHILDREN

Multiple Dose Vial

Approved by FDA Under ANADA # 200-324

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 of **INDICATIONS**, **DOSAGE**, **SIDE EFFECTS**, **CONTRAINDICATIONS**, **PRECAUTIONS**, and **WARNINGS** before this drug is used.

DEXAMETHASONE INJECTION 2 mg/mL is intended for *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 in adjust pH to approximately 4.9, water for injection g.s.

EXPERIMENTAL STUDIES

Experimental animal studies on dexamethasone have revealed it possesses greater antiinflammatory 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 the animal's threshold or tolerance for steroid excess.

Treatment may be changed over to DEXAMETHASONE INJECTION 2 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 preruminating 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.

CONTACT INFORMATION

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Sparhawk Laboratories Inc. at 1-800-255-6388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

HOW SUPPLIED

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

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F)

Protect from freezing.

Approved by FDA under ANADA # 200-324

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 qs.

TAKE TIME OBSERVE LABEL DIRECTIONS

Usual Dose

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

WARNING

A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C AND 30°C (between 59°F and 86°F).

Protect from freezing

READ ACCOMPANYING DIRECTIONS CAREFULLY

For Intravenous or Intramuscular Injection

Usual Dose:

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

Warning: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for yeal.



ANADA # 200-324

LOT NO .:

EXP. DATE:

NDC 57319-519-05

Dexamethasone Injection 2 mg/mL

Dexamethasone Sterile Injection

Veterinary Multiple Dose Vial KEEP OUT OF REACH OF CHILDREN

NOT FOR USE IN HUMANS

Approved by FDA under ANADA # 200-324

Net Contents: 100 mL

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



Manufactured for: Clipper Distributing Company, LLC St. Joseph, MO 64507

Each mL contains: 2 mg dexamethasone; 500 mg polyethylene glycol 400; 9 mg benzyl alcohol, 1.8 mg methylparaben, and 0.2 mg propyl-paraben as preservatives; 4.75% alcohol; HCl to adjust pH to approximately 4.9; water for injection qs.



Trademarks are property of Clipper Distributing Company, LLC

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

Rev. 02-24

D-2953-04

pregnancy and may precipitate parturition followed by dystocia, fetal death, retained placenta, and metritis.

oparoca, tetat death, retained placerta, and metritis.
Additionally, corticosteroids administered to dogs, rabbits, and todents during pregnancy have produced cleft palate. Other congenital anomalies including deformed forelegs phocometia, and ansasca have been reported in oilspring of dogs which received corticosteroids during pregnancy.

A withdrawal period has not been established for this product in pre-rumineting calves. Do not use in calves to be processed for yeal.

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

hing's syndrome in dogs has been reported in ociation with prolonged or repeated steroid

Corticosteroids reportedly cause laminitis in horses.

CONTACT INFORMATION: To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Sparhawk Laboratories Inc. at 1600-256-6386 or 1913-863-790. For additional information about adverse due prepietors reporting for arimal drugs, contact FDA at 1-868-FDA-VETS or http://www.fdA.gov/reportarimal.com/

HOW SUPPLIED
DE XAMETHASONE INJECTION 2 mg/mL, 100 ml. multiple dose vial.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 36°F). Protect from freezing

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

Approved by FDA under ANADA # 200-324

Each mL contains: 2 mg dexameth-asone; 500 mg polyethylene glycol 400; 9 mg benzyl alcohol, 1.8 mg methylparaben, and 0.2 mg propyl-paraben as preservatives; 4.75% alcohol; HCl to adjust pH to approximately 4.9; water for injection qs.

TAKE TIME OBSERVE LABEL DIRECTIONS

Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA

D-2953-04

DEXAMETHASONE INJECTION 2 mg/mL

Solution for intravenous or intramuscular injection

Intramuscular injection
Veterinary
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 ficensed veterinarian.

order of a Scensed veterinarian.

DEXAMETHASONE BLECTION 2 mg/ml. is a synthetic analogue of predissionies, having similar but more potent anti-inflammatory, therapeute action and obversified bornmant and instabolic effects. Modification of the base control structure as achieved in DEXAMETHASONE INJECTION 2 mg/ml. offers adhanced anti-inflammatory effect by the production of the producti

DEXAMETHASONE INJECTION 2 mg/ml. is not species specific; however, the veterinarian should read the sections on MDICATIONS, DOSAGE, SIDE EFFECTS, CONTRAINDICATIONS, PRECAUTIONS, and WARNINGS before this drug is used.

OPEN HERE

and warefules Gender this drug is used.

DEXAMETHASONE BLECTION 2 might, is intended for infraenous or infransous administration. Each not contains 2 mg decamethasone, 500 mg polyethylene glyock 400, 9 mg benzyl alcohol, 1.8 mg polyethylene glyock 400, 9 mg benzyl alcohol, 1.8 mg polyethylene and 0.2 mg propylgrashen as presidentally, 95% action, 101 to adjust pH to approximately 4.9 water for integration qu.

approximately 43, water for injection q.s. EVERDIMENTAL STUBES Experimental airmal studies on documental scene have revealed it possesses greater anti-inflammatory activity than many storoids. Vetorinary clinical evidence includes documentalises the asprovimately trends to the second production of the control produiscitors and seventy to ediply times that of control the second production of the control of the control documentalisms. The control is decarred to the control of produiscitors and carried to the control of produiscitors. In reference to mineral coorticol activity, decarmed has one 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.

RIDGATIONS

RIDCATIONS

RIDCATIONS

RIDCATIONS

RIDCATIONS

DEXAMETHASONE INJECTION 2 mgimL is indicated for the treatment of primary bovine states and a martin inflammatory agent in the bowine and equine.

As supportive therapy, DEXAMETHASONE INJECTION 2 mgimL may be used in the management of various rheumatic, allergic, dermatologic, and other diseases known to be responsive to anti-inflammatory continuated to the continuation of the contin

Immediate hormonia response is required.

Bodies Récoss

DEXAMETHASIONE INJECTION 2 mg/ml. is offered

DEXAMETHASIONE INJECTION 2 mg/ml. is offered

Judicioneogenic effects of DEXAMETHASIONE

NUCCTION 2 mg/ml., when administered

intramiscularly, are operatly noted within the first of

10 27 hours. When DEXAMETHASIONE PARCTION 2

mg/mL is used intravenously, the effects may be noted sooner. Blood sugar levels rise to normal levels rapidly and perentally rise to above normal levels within 12 to 24 hours. Aestone bodies are reduced to normal constitutions usually within 24 hours. The commitment constitution within 24 hours. The DECAME HASCONE 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 surpses provious peaks. The recovery process usually takes from 50°7 days.

Suporties Therapy E INJECTION 2 mg/mL may be DEXAMETHASONE INJECTION 2 mg/mL 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 erhances 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 lever, pneumonia, laminitis, and retained placenta. Egize

DEVAMETHASONE INJECTION 2 mg/mL is indicated
for the treatment of acute musculcokedetal
for the treatment of acute musculcokedetal
tendonitis, myonits, and sprains. If boney changes
exist in any of the conditions, joints, or accessor,
service in the conditions, joints, or accessor,
MECTION 2 mg/mL carnot be opposed, of andition,
DEVAMETHASONE INJECTION 2 mg/mL may be
used as supportive therapy in futique, heat
provided myonitis, and relation placents
provided myonitis and tendonic placents
provided myonitis and tendonic placents.

ADMINISTRATION AND DOSAGE
Therapy with DEXAMETHASONE INJECTION 2
mgml, 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.

tolerance for steroid excess.

Treatment may be changed over to
DEXAMETHASONE INJECTION 2 mg/ml. from any
other glucocorticoid with proper reduction or
objects to descent other glucocorticoid with adjustment of dosage.

Boxine - 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.

CONTRAINDCATIONS
Except for emergency therapy, do not use in animals with chroric nephritis and hypercorticalism (Cushing's syndrome). Existence of congestive heart failure, diabetes, and osteoprorosis are relative contraindications. Do not use in viral inflections during the viernic estate.

the virenic stage.

PRECAUTIONS

Animals receiving DEXAMETHASONE NAECTION 2

Animals receiving DEXAMETHASONE NAECTION 2

rights should no under close observation. Because
rights of infection may be masked and it may be
signs of infection may be masked and it may be
rocessary to stop treatment until a further diagnosis is
made. Overdosage of some glucocorticoids may

6

DEXAMETHAS ONE

sult in sodium retention, fluid retention, potassium s, 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 chemothorapeutic 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.

Des of cottosteroids, depending on dose, duration, and specific steroid, may result in inhibition of nedequarts as teroid production following of an endogenous steroid production following of undergonous withdrawas. In patients presently receipting or recently withdrawas from systemic corticosteroid resuments, steroid production of the control of th

2 mg in 1 mL

Strength

DEXAMETHASONE

dexamethasone injection, solution

Product Information

Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:57319-519

Route of Administration INTRAMUSCULAR, INTRAVENOUS

DEXAMETHASONE (UNII: 7S5I7G3JQL) (DEXAMETHASONE - UNII:7S5I7G3JQL)

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength

Inactive Ingredients

Ingredient Name BENZYL ALCOHOL (UNII: LKG8494WBH)

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57319-519-05	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200324	01/18/2008		

Labeler - Clipper Distributing Company, LLC (150711039)

Registrant - Sparhawk Laboratories, Inc. (147979082)

Establishment			
Name	Address	ID/FEI	Business Operations
Sparhawk Laboratories, Inc.		147979082	analysis, manufacture

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharmacia & Upjohn Company LLC		618054084	api manufacture	

Revised: 5/2024 Clipper Distributing Company, LLC