



DEXAFLAM

REGISTRATION NUMBER Q-7972-109

Corticosteroid; long acting antiallergic and anti-inflammatory.

FORMULATION:

Dexamethasone 21 sodium phosphate 2 mg
Vehicle q.s.1 mL.

DOSAGE SIZE AND FORM: 100 mL

VETERINARY USE

SOLUTION FOR INJECTION

DEXAMETHASONE 21 PHOSPHATE

STEROIDAL ANTI-INFLAMMATORY AGENT

INDICATIONS:

DEXAFLAM is a potent glucocorticoid with anti-allergic and anti-inflammatory activity. It acts directly on the musculoskeletal system.

Dexamethasone is a synthetic corticosteroid that comes as a white or slightly yellow crystalline powder. It is highly soluble in water and is extremely hygroscopic. Its molecular weight is 516.41 Da. It is chemically designated as 9-fluoro-11 β ,17-dihydroxy-16-methyl-21-(phosphonooxi) pregna-1,4-dien-3,20-dione disodium salt. The structural chemical formula is: $C_{22}H_{28}FNa_2O_8P$.

As a glucocorticoid, **dexamethasone** is about 30 times more potent than hydrocortisone and 5 to 7 times more potent than prednisone. In addition, it is one of the most long-acting corticosteroids, with minimal mineralocorticoid activity.

MECHANISM OF ACTION

Glucocorticoids are natural hormones that prevent or suppress immune and inflammatory responses when administered at certain pharmacological doses. Free glucocorticoids easily cross cell membranes and bind





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to specific cytoplasmic receptors, inducing a series of responses that modify transcription and therefore protein synthesis. These responses are the inhibition of leukocyte infiltration at the site of inflammation, interference with mediators of inflammation, and suppression of immune responses. The glucocorticoid anti-inflammatory action involves proteins that inhibit phospholipase A2, the so-called lipocortins. In turn, lipocortins control the biosynthesis of a number of powerful inflammation mediators such as prostaglandins and leukotrienes. Some of the responses of glucocorticoids are edema reduction and a general suppression of the immune response. It stabilizes cell membranes and inhibits the proliferation of fibroblasts, macrophages, lymphocyte sensitization and mediating cells. Increases potassium and calcium excretion, and reabsorption of sodium and chlorine. It decreases the response to pyrogens and at the hematopoietic level increases the number of platelets, neutrophils and circulating erythrocytes. It prevents vasoconstriction and increases hepatic glycogen stores because it stimulates gluconeogenesis.

PHARMACOKINETICS

The time of action of **Dexflam®** depends on the route of administration type (intravenous, intramuscular, or intra-articular route) and irrigation at the injection site. In intramuscular administration the drug is rapidly absorbed circulating in plasma bound to plasma proteins at 90%, the portion not fixed to proteins being active. It is quickly and completely absorbed from the administration site, reaching a relevant concentration in blood at 30 minutes, with a peak maximum concentration at 60 minutes. It has a plasma half-life of 3 +/- 0.8 hours and a biological half-life of 36 to 54 hours. The drug is quickly distributed in kidneys, intestines, liver, skin, and muscles. Like other corticosteroids, it crosses the placental barrier and is excreted in breast milk. Dexamethasone is metabolized in the liver producing inactive products that are eliminated in the urine.

IMPORTANCE.

The main advantage of **Dexflam®** is linked to the pharmacological properties of Dexamethasone, which is approximately 3000 times more soluble and 25- to 30 times more potent than hydrocortisone. At equivalent doses, in relation to the anti-inflammatory potency, Dexamethasone almost completely lacks the mineralocorticoid property of retaining water and sodium that hydrocortisone and its derivatives possess.

PHARMACODYNAMICS

Corticosteroids bind to specific receptor proteins in target tissues located in the cytoplasm to regulate the expression of genes responding to corticosteroids, modifying the amount and variety of proteins synthesized by different tissues. As a result of the time required to modulate gene expression and protein synthesis, most of the effects of corticosteroids are only visible after several hours of being administered. This is clinically important because it explains the delayed corticosteroid therapy beneficial effects.

DRUG-THERAPEUTIC PROPERTIES:



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Dexamethasone is a synthetic glucocorticoid with anti-inflammatory and immunosuppressive actions by:

- Inhibition of leukocyte infiltration at the site of inflammation.
- Interference in inflammatory response mediators function.
- Suppression of the humoral immune response.

INDICATIONS:

It is indicated in the treatment of muscular and articular inflammatory processes and in allergic syndromes in cattle, swine, equines, canines, and felines.

- **CATTLE:** It is used as an anti-inflammatory, antiallergic and adjuvant in the treatment of anaphylactic shock.
- **SWINE:** It is used as an anti-inflammatory and in allergic reactions.
- **EQUINES:** It is used in anaphylactic shock, septic shock, and allergies, in the treatment of acute musculoskeletal inflammations such as: arthritis, bursitis, tendosynovitis, traumatic myositis and as an adjuvant in the improvement and reduction of claudication.
- **CANINES:** in anaphylactic shock, septic shock, allergies, dermatitis, eczema, otitis, myositis, arthritis, spondylitis, lameness and in the treatment of vertebral disc inflammation.
- **FELINES:** in anaphylactic and septic shock, allergies, eczema, dermatitis, arthritis, arthrosinovitis in conjunction with antibiotic therapy, otitis, and lameness.

SPECIES:

Cattle, meat, and milk, equines (not intended for human consumption), swine, sheep, goats, felines, and canines.

DOSE:

Cattle, meat, and milk: 0.06 mg per kg of equivalent weight 2.5 to 10 mL (5-20 mg total dose).

Equines (not intended for human consumption): 0.06 mg per kg of equivalent weight 2.5 to 5 mL (5-10 mg total dose).

Swine: 0.06 mg per kg of equivalent weight 1 to 5 mL (2-10 mg total dose).

Sheep and Goats: 0.06 mg per kg of equivalent weight 1 to 2 mL (2-4 mg total dose).

Canines and felines: 0.1 mg per kg of equivalent weight 0.25 to 0.5 mL (0.5-1 mg total dose).

SUGGESTED DOSES:

Equines: Parenterally 0.05 to 0.2 mg per kg every 24 hours (1 to 4 mL per 40 kg of weight) or 2.5 to 20 mg total dose per animal per day.

Orally the dose is 0.05 to 0.2 mg per kg of body weight, every 24 hours (1 to 4 mL per 40 kg of weight).

As an anti-inflammatory and antiallergic agent:

- **Cattle:** 5 to 40 mg as a single dose per day.
- **Swine:** 1 to 10 mg per animal (0.5 to 5 mL per animal) once a day.



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As an adjuvant in the treatment of anaphylactic shock, intravenously:

- **Cattle:** 1 to 4 mg per kg of body weight (0.5 to 2 mL/kg) every 4 hours.
- **Canines and felines:** 4 to 6 mg per kg of body weight (2 to 3 mL/kg) once a day.
- **Canines:** As an anti-inflammatory 0.1 to 1 mg per kg of body weight IM or IV, every 24 hours, as an immunosuppressant 0.3-0.6 mg per kg in two IV or IM administrations.
In patients with acute intervertebral disc disease, administer 2 mg per kg of body weight, via IV every 8 hours, for a period not exceeding 5 days.
In enterotoxemia by dilation or gastric volvulus administer 5 mg per kg of body weight slowly, via IV.
- **Felines:** for endotoxic or septicemic shock: 5 mg per kg of body weight, via IV.
In neoplasms of lymphoma and leukemia or mastocytoma administer 2 to 6 mg per m² every 24 to 48 hours, via SC or IV, for acute asthma 1 mg per kg, via IV.

WITHDRAWAL TIME:

Do not use this product 8 days before the slaughter of animals intended for human consumption. Do not use the milk of treated animals for human consumption until 72 hours after the last administration.

In equines: 24 days.

ROUTE OF ADMINISTRATION:

Intramuscular and intravenous.

PRECAUTIONS:

In **dogs** it can cause slight polydipsia, polyphagia, and polyuria, they are short-term adverse effects, as well as with maintenance therapy on alternate days especially on days when the drug product is administered. Other adverse effects in dogs may include dull and dry fur, weight gain, panting, vomiting, diarrhea, elevated liver enzymes, pancreatitis, gastrointestinal ulcers, lipidemias, activation or worsening of diabetes mellitus, muscle atrophy and behavioral changes (depression, lethargy). Gradual decrease in corticosteroid may be necessary and may be switched to another steroid such as prednisone to avoid other problems (iatrogenic Cushing syndrome). With the exception of polydipsia, polyphagia and polyuria, adverse effects associated with steroidal anti-inflammatory drug treatment at recommended doses are relatively rare.

Cats usually require higher doses than dogs to have a good clinical effect, and they tend to present fewer adverse effects. Occasionally, polydipsia, polyuria, polyphagia with weight gain, diarrhea, or depression may be observed.

In **horses** the administration of dexamethasone or triamcinolone may play an important role in laminitis development.

DRUG-DRUG INTERACTIONS

Co-administration of dexamethasone and amphotericin B or diuretics (furosemide, thiazides) may cause hypokalemia. Like with co-administration with digitalis, there is an increased risk of digitalis poisoning that induces hypokalemia. Insulin requirements may increase in patients taking glucocorticoids. Concomitant administration of glucocorticoids and cyclosporine may increase the blood levels of each, by mutual



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inhibition of hepatic metabolism. Glucocorticoids can also inhibit the hepatic metabolism of cyclophosphamide, so the dose of this oncological product must be adjusted. Patients taking corticosteroids at immunosuppressive doses should not receive live virus vaccines attenuated by virus replication. In addition, low immune response.

WARNINGS AND/OR RESTRICTIONS:

"Do not administer this product to equines intended for human consumption". Do not use this product 8 days before the slaughter of animals intended for human consumption, neither use the milk of treated animals 72 hours after product administration.

Dexamethasone administered by any route in pregnant females can induce labor.

Keep in a cool, dry place, in a range within 15-30 °C and protected from direct sunlight. Keep out of reach of children and pets. Product for exclusive use in Veterinary Medicine.

Consult a Doctor of Veterinary Medicine

Available by prescription only

Exclusive literature for Veterinary Doctors

Responsible for content: Technical Department