

For Veterinary Use Only.

CORTAL[®]

Suspension for Injection

Veterinary Systemic Antiinflammatory - Antiallergic

COMPOSITION

Cortal Suspension for Injection is a sterile, white crystalline suspension comprising 22,375 mg Prednisolon acetate equivalent to 20 mg prednizolon base per ml.

PHARMACOLOGICAL PROPERTIES

As a glucocorticoid used in horse, cattle, dog, and cats mainly Prednisolon is one of the synthetic analogues of cortisol. Cortal is a glucocorticosteroid with antiinflammatory and antiallergic efficiency. It has not any antibiotic activity, and organism should be used together with antibiotic in any acute microbial infection. On the other hand prednisolone is a significantly efficient drug when administered intraarticularly and intramuscularly in big and small animals. Dry eczema in summer, non-specific dermatitis, or acanthosis nigricans cases, and irritations calm down within 24-48 hours, and inflammation starts to be eliminated. Preoperative and postoperative stress conditions are to be prevented in order to acquire better results. Corticosteroids exist as bound or free in circulation. It exists as corticotropin bonding globulin for 75%, albumin for 10-15%, and free for 10-15%. They expose to biotransformation mainly in liver and also in other organ and tissues. Ineffective metabolites are generated by saturating double bond between C-4,5 in liver and other tissues. Afterwards they are excreted 75% through urination, and 25% through gall.

AREA OF USE/INDICATIONS

Cortal is indicated in therapies for a number of immune and non-immune inflammatory reactions as an antiinflammatory and antiallergic.

In metabolic diseases including ketosis in cattle (Asetonemia), pregnancy toxemia in sheep; all shocks (endotoxic, hemorrhagic, anaphylactic); all allergic reactions; skin diseases whose course is together with hepatic dystrophy, eczema and itchiness; urticaria; stress; ulcerative colitis, otoimmün haemolytic anaemia, cerebral oedema.

Locomotor System: Traumatic arthritis and myositis, bursitis, tendonitis, eosinophilic myositis, osteoarthritis, rheumatoid arthritis in dogs, laminitis.

Respiratory System; Allergic and non-allergic reactions, acute respiratory stress syndrome in cattle, chronic obstructive pulmonary disease in horses.

USAGE AND DOSAGE:

Unless recommended otherwise by veterinary surgeon;

through intramuscular injection:

Cattle and Horse 5-10 ml (100-200 mg/day)

Dog 0.5-1.5 ml (10-30 mg/day)

Cat 0.12-0.25 ml (2.5-5 mg/kg/day)

Intraarticular injection:

Synovial liquid is removed equivalent to injection volume under aseptic conditions in order to decrease or eliminate its systemic side effects, and a same amount of Cortal is injected.

2 – 4 ml in big animals

0.1 – 0.8 ml in small animals

Initial dose should be maximized or around maximum, dose should be decreased gradually after getting symptoms under control.

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR INTENDED SPECIES:

Pay attention when administering in very young or very old animals and the ones with renal, hepatic, and cardiovascular failure. Corticosteroids improve sensitivity against infections. Avoid using corticosteroids in bacterial, fungal, or parasitic skin diseases, and especially in mange cases.

UNDESIRE/SIDE EFFECTS

Serious complications might cause by long term corticosteroid therapy are as follows:

- 1) Hypokalemia and oedema
- 2) Its musculoskeletal effects characterized with osteoporosis and myopathy
- 3) Higher dose of systemic corticosteroid applications in last pregnancy periods may cause premature birth and abortion.

DRUG INTERACTIONS:

When using corticosteroids along with diuretics such as furosemide, and thiazide they improve calcium and potassium loss from body. In case of long term using along with salicylates and other pain killers they may cause peptic ulcer and increased acid release. Biotransformation of glucocorticoids is accelerated by drugs including phenytoin, rifampin, phenobarbital.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

Long term glucocorticoid use at high doses may arise symptoms including Cushing's syndrome, osteolysis, ulcer, delayed wound healing, improved tendency to blood clotting and thrombosis, failed wool and hair properties, calcium and potassium loss. Therefore short term high dose for acute cases, long term low dose for chronic cases are administered. No antidote is known.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP): Meat type animals should not be sent for slaughtering during treatment and before 8 days after the last drug administration. Any milk acquired during drug use or within 3 days (6 milking) after stopping its use should not be offered for human consumption.

CONTRAINDICATIONS:

Prednisolone and other glucocorticoids are not used in animals with diabetes mellitus because they are direct insulin antagonists. Avoid administration in acute infections because of its immunosuppressive effects. It could be used along with an appropriate antibacterial in non-acute infections. Its use is contraindicated in systemic viral infections, cornea ulcers (because of its effects on wound healing), last pregnancy periods (it may cause premature birth), hypertension, and renal and hepatic failures. Likewise intraarticular administration is contraindicated in sepsis condition in or around articular, intraarticular fractures, articular cartilage damage, degenerative bone lesions, and osteoporosis.

Use during pregnancy: In last terms of pregnancy it should not be administered because it may cause premature birth. Avoid administration in pregnant dogs because it may cause cleft palate and other anomalies in puppies.

GENERAL WARNINGS:

Subject to veterinary surgeon's prescription. Keep out of reach of children. Protect from light.
SHAKE SLIGHTLY BEFORE USE.

STORAGE CONDITIONS AND SHELF LIFE:

Shelf life is 2 years from manufacturing date when storing at room temperature (15-20°C) away from sunl ight.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE:

Presented to the market as 10, 20 and 50 ml colorless glass vials in cardboard boxes.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries.

APPROVAL DATE OF PACKAGE INSERT: 19.01.2009

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE - NO :
19.01.2009-21/004

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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