

DERMISOLONA® Oral suspension

ANTI-INFLAMMATORY - STEROIDAL ANTIALLERGIC



It is indicated as an aid in the treatment of inflammatory and allergic disorders in cats and dogs.

In dogs it is also indicated as an immunosuppressant in autoimmune diseases, as a therapy for chronic inflammatory bowel disease and in the treatment of hypoadrenocorticism.

Technical Specification

SPECIES

Dogs and cats.

DOSAGE FORM

Oral suspension

THERAPEUTIC ACTION

Anti-inflammatory - Steroidal antiallergic

COMPOSITION

Each mL of oral suspension contains:
Prednisolone Acetate 4.5 mg
(Equivalent to 4 mg of Prednisolone base)
Excipients q.s. 1 mL

INDICATIONS

It is indicated as an aid in the treatment of inflammatory and allergic disorders in cats and dogs.

In dogs it is also indicated as an immunosuppressant in autoimmune diseases, as a therapy for chronic inflammatory bowel disease and in the treatment of hypoadrenocorticism.

USE INSTRUCTIONS

Shake the suspension before use, then withdraw the product dose with the dosing syringe or dropper and administer directly into the oral cavity.

ROUTE OF ADMINISTRATION AND DOSAGE

Oral administration

	DOSE OF THE ACTIVE SUBSTANCE	PRODUCT DOSE (1 mL = 26 drops of product)
	DOGS	1,5 to 2,5 mL for each 10 Kg of weight, or 4 to 7 gotas for each Kg of weight,, for each 12 to 24 hours, for 3 to 5 days.
	CATS	1,5 to 2,5 mL for every 5 Kg of weight or 7 to 13 drops for each Kg of weight, every 12 to 24 hours, for 3 to 5 días.
ANTI-INFLAMMATORY AND ANTI-ALLERGIC	1 to 2 mg/Kg of weight, every 12 to 24 hours, for 3 to 5 days.	
In prolonged treatments, it is recommended to reduce to the lowest effective dose and administer on alternate days in the morning for dogs, and in the afternoon in cats (to respect the circadian rhythm).		
	DOGS	2.5 to 10 mL for every 10 Kg of weight per day, or 7 to 26 drops for each Kg of weight every 24 hours, for 2 to 14 days. Then, 1.3 to 5 mL for every 10 Kg of weight per day, or 4 to 13 drops for each Kg of weight every 24 hours, for 2 to 14 days. Then reduce the dose at regular intervals (2 to 6 weeks), until reaching the maintenance dose of 0.5 to 1 mg / Kg / every other day. (*)
IMMUNOSUPPRESSOR	1 to 4 mg / Kg / every 24 hours for 2 to 14 days. Then, 0.5 to 2 mg / Kg / every 24 hours, for 14 days. Then reduce the dose at regular intervals (2 to 6 weeks), until reaching the maintenance dose of 0.5 to 1 mg / Kg / every other day. (*)	2.5 to 10 mL for every 10 Kg of weight per day, or 7 to 26 drops for each Kg of weight, every 12 to 24 hours, for 2 to 4 weeks, then decrease the dose slowly at intervals of 10 days to 2 weeks depending on the clinical response, until reaching the maintenance dose of 1.5 to 2.5 mL for every 10 Kg of weight, or 4 to 7 drops for each Kg of weight, every other day . (*) (**)
	DOGS	2.5 to 10 mL for every 10 Kg of weight per day, or 7 to 26 drops for each Kg of weight, every 12 to 24 hours, for 2 to 4 weeks, then decrease the dose slowly at intervals of 10 days to 2 weeks depending on the clinical response, until reaching the maintenance dose of 1.5 to 2.5 mL for every 10 Kg of weight, or 4 to 7 drops for each Kg of weight, on alternate days. (*) (**)
CHRONIC INFLAMMATORY INTESTINAL DISEASE	1 to 4 mg / Kg of weight every 12 to 24 hours, for 2 to 4 weeks, then decrease the dose slowly at intervals of 10 days to 2 weeks depending on the clinical response, until reaching a maintenance dose of 0.5 to 1 mg / Kg every other day (*)	
	DOGS	

HYPOADRENOCORTICISM

0.2 to 0.4 mg / Kg of weight, every 24 hours, permanently.

0.5 to 1 mL per 10 Kg of weight or 2 to 3 drops per Kg of weight every 24 hours, permanently.

(*) The duration of therapy varies according to the intensity of the symptoms and the remission of symptoms, and can last for several weeks or months. In these cases, it is recommended to use the minimum

effective dose, every other day.

(**) 1 mL of DERMISOLONA® Oral suspension is equivalent to 26 drops of product.

DRUG INTERACTIONS

It is recommended to avoid the concomitant administration of Prednisolone with:

- Amphotericin B or caluuretic diuretics (furosemide, thiazides), as hypokalemia may occur. Digitalis may increase the possibility of toxicity, if hypokalemia is generated.
- Phenytoin, phenobarbital and rifampicin, because they can increase the metabolism of corticosteroids.
- Cyclosporine, because the blood levels of both drugs can be increased with mutual inhibition of liver metabolism.
- With ulcerogenic drugs (for example, non-steroidal anti-inflammatory drugs) since the risk of gastrointestinal ulceration can be increased.
- Cyclophosphamide, as corticosteroids can inhibit hepatic chemotherapy metabolism.
- Patients treated with corticosteroids at immunosuppressive doses generally should not receive live attenuated virus vaccines, because viral replication may be enhanced.
- Insulin requirements may be increased in patients receiving glucocorticoids.

CONTRAINDICATIONS

- Do not use in animals with Cushing's syndrome.
- Do not use in patients with systemic fungal infections or viral infections.
- Do not use in animals with peptic or corneal ulcers.
- Do not administer to pregnant females.
- Do not use in animals hypersensitive to any of the components of this product.
- Do not administer in conjunction with vaccines.

SPECIAL PRECAUTIONS FOR USE

- In case of prolonged treatments with Prednisolone, a higher protein intake must be provided to keep the animal in a positive nitrogen balance.
- No delayed effect on wound healing has been described, however, such a possibility should be considered when used in surgery.
- Prolonged glucocorticoid therapy can suppress adrenocortical activity, so discontinuation should be done gradually to ensure gradual return of ACTH and endogenous corticosteroid functions.
- Administer with caution in animals that have diabetes, osteoporosis, or are recovering from a bone fracture, predisposition to thrombophlebitis, hypertension, congestive heart failure, kidney failure, or active tuberculosis.
- The anti-inflammatory effects can mask signs of infection.
- Administer with caution in growing animals as it may cause delay.
- Administer with caution in animals with liver failure.

SPECIAL PRECAUTIONS FOR THE OPERATOR

- Wash hands after administering the product.
- In case of skin contact, it is recommended to wash your hands with soap and plenty of water. If irritation develops and persists, see a doctor.

- In the case of contact with the eyes, it is recommended to wash with plenty of water for 15 minutes. If irritation develops and persists, see a doctor.
- In case of ingestion, do not induce vomiting. Get medical help.

WARNINGS

Keep out of the reach of children.

ADVERSE EFFECTS

- Administered in the short term, Prednisolone is unlikely to cause harmful effects, even in massive doses. Adverse effects are generally associated with chronic therapies, especially at high doses or if an alternate day regimen is not followed.
- The most frequent adverse effects are polyuria, polydipsia and polyphagia; and they are preferably associated with anti-inflammatory doses.
- With regard to immunosuppressive doses and extensive treatments, adverse reactions are more likely to appear and are potentially more pronounced. These effects, rarely observed, are manifested as symptoms of hyperadrenocorticism (Cushing's syndrome): opaque and dry fur, weight gain, panting, vomiting, diarrhea, hepatomegaly with the consequent alteration of the concentration of liver enzymes in the serum, pancreatitis, gastrointestinal ulceration (particularly when used with NSAIDs), lipidemias, alteration of insulin requirements, activation or intensification of Diabetes Mellitus, muscle wasting and changes in behavior (depression, lethargy, vices).
- In prolonged treatments, an increase in the incidence of osteoporosis is described, especially in elderly dogs.

OBSERVATIONS

Overdose:

Given in the short term, glucocorticoids are unlikely to cause harmful effects, even in massive doses. Adverse effects are generally associated with chronic therapies, especially at high doses or if an alternate day regimen is not followed.

Special precautions for the disposal of unused product or waste material:

Discard the remains of unused product in its original container. Do not throw the empty container or with product remains, in rivers, lakes or streams of natural water. Dispose of this product with caution with household waste.

CONSERVATION

Store in a cool and dry place, at a temperature between 2 and 30° C.
Once the bottle is opened, use within 30 days.

CONDITION OF SALE

Sale with Veterinary Medical prescription only

PRESENTATION

Bottle with 30 mL

PREPARED BY

Laboratorio Drag Pharma.

RECORDS

Reg. SAG N° 2281

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