DERMISOLONA® Oral tablets

ANTI-INFLAMMATORY – STEROIDAL ANTI-ALLERGIC.

It is indicated as an aid in the treatment of non-infectious inflammatory disorders, non-septic arthropathies and in the treatment of allergic dermatitis; in chronic inflammatory bowel disease and as an immunosuppressant in tumor states.

Technical Specification

SPECIES

Dogs and cats.

DOSAGE FORM

Oral tablet.

THERAPEUTIC ACTION

Anti-inflammatory – Steroidal anti-allergic.

COMPOSITION

Each Tablet contains:
Prednisolone base.....20 mg
Excipients q.s.p.....1 tablet

INDICATIONS

It is indicated as an aid in the treatment of non-infectious inflammatory disorders, non-septic arthropathies and in the treatment of allergic dermatitis; in chronic inflammatory bowel disease and as an immunosuppressant in tumor states.

ROUTE OD ADMINISTRATION AND DOSAGE

Oral administration.

Active ingredient dose:

- **For anti-inflammatory and anti-allergic treatment:** 0.5 to 1 mg/Kg in dogs and 1 to 2 mg/Kg in cats, every 12 or 24 hours for 3 to 5 days. In the event of prolonged treatment, it is recommended to reduce to the lowest effective dose and give in the regime of alternated days in the morning for dogs and in the afternoon in cats (to respect the circadian rhythm).

- **As immunosuppressant:** 2.2 to 3.3 mg/Kg of weight for two consecutive days and then 2-4 mg/Kg every 48 hours. Evaluate the duration of the treatment according to the intensity and remission of the symptoms.
- **Chronic inflammatory bowel disease:** 1-2 mg/Kg of weight once a day for 2 to 4 weeks.

Product dose:

- **As anti-inflammatory and anti-allergic:**
  Dogs: ¼ - ½ tablet/10 Kg of weight every 12 or 24 hours for 3 to 5 days.
  Cats: ¼-½ Tablet /5 Kg of weight every 12 or 24 hours for 3 to 5 days.
- **As immunosuppressant:** 1 - 1 ½ tablet/10 Kg of weight for two consecutive days and then 1 - 2 tablets/10 Kg of weight, every 48 hours. Evaluate the duration of the treatment according to intensity and remission of the symptoms.
- **Chronic inflammatory bowel disease:** ½ - 1 tablet/10 Kg of weight once a day for 2 to 4 weeks.

DRUG INTERACTIONS

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

- Amphotericin B or caliuretic 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 patients with systemic fungal infections or viral infections.
- Systemic therapy with Prednisolone is contraindicated in animals with peptic ulcer, corneal ulcer, and Cushing's syndrome.
- Do not administer to pregnant animals.
- Do not use in animals hypersensitive to some of the components of this product.

SPECIAL PRECAUTIONS FOR THE OPERATOR

Wash hands after administering the product

WARNINGS

Special warnings and 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 in a graduated manner 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.
- 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.
- Prednisolone passes into milk and may induce negative effects in infants, but only if the mother receives high doses for prolonged periods.
- Keep out of the reach of children.

SIDE EFFECTS

- Therapeutic use of Prednisolone is unlikely to cause metabolic-like effects associated with glucocorticoids. An effect of delayed wound healing has not been described, however, such a possibility should be considered when used in surgery.
- Long-term treatment describes an increase in the incidence of osteoporosis, especially in older dogs. Its use is not recommended during the recovery phase of a bone fracture.
- The most frequent adverse effects are polyuria, polydipsia and polyphagia; and they are preferably associated with anti-inflammatory doses.
- Regarding immunosuppressive doses and extensive treatments, adverse reactions are more likely to occur and are potentially more pronounced. Such effects, which are 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, altered insulin requirements, activation or intensification of diabetes mellitus, muscle wasting, and behavioral changes (depression, lethargy, vices).

OBSERVATIONS

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 together with household waste.
- Contact the manufacturing company or companies specialized in waste disposal, to receive recommendations on the disposal of expired or unused products.

CONSERVATION

Store at a temperature between 15 and 30°C, protected from light.

CONDITION OF SALE

To be supply only on veterinary prescription.

PRESENTATION

Box containing 10 tables.

PREPARED BY

Drag Pharma Laboratory.

RECORDS

Chile: Reg. SAG N° 1745
Bolivia: Reg. SENASAG PUV-F-N° 005507/13

COUNTRIES WHERE IT IS MARKETED

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