www.headwayanimalhealth.com.au
info@theheadway.com.au
(+61)2 9896 0856

DERMASPORIN ORAL SOLUTION FOR CATS

For the treatment of allergic dermatitis in cats.

ACTIVE CONSTITUENT:

100 mg/mL Cyclosporin

NET CONTENTS: 17 mL

DIRECTIONS FOR USE

CONTRAINDICATIONS

This product is contraindicated for use in cats infected with FeLV or FIV.

This product is contraindicated for use in cats with a history of malignant disorders or progressive alignant disorders.

The efficacy and safety of cyclosporin has not been assessed in cats aged less than 6 months or weighing less than 2.3 kg. This product is contraindicated for use in cats aged less than 6 months or weighing less than 2.3 kg.

The safety of the drug has not been studied in male reproducing cats or in pregnant or lactating female cats. Cyclosporin was teratogenic in laboratory animals at maternally toxic doses, however, no teratogenic effects were observed in the well-tolerated dose range.

In laboratory animals, cyclosporin crosses the placenta barrier and is excreted via milk. A thorough risk/benefit analysis should be undertaken before using in reproducing, pregnant or lactating cats.

DOSAGE & ADMINISTRATION:

Oral doses to be administered once daily, with or without food.

The recommended dose of cyclosporin is 7 mg/kg body weight (0.07 mL of oral solution per kg). Use the contents within 10 weeks of first broaching of the vial. Discard the unused portion.

DERMASPORIN 100 mg/mL Oral Solution for Cats oral solution can be given either mixed with food or directly into the mouth. If given with food, the solution should be mixed with a small amount of food, preferably after a sufficient period of fasting to ensure complete consumption by the cat. When given directly into the mouth with the syringe, insert the syringe directly into the cat's mouth and deliver the entire dose.

DERMASPORIN 100 mg/mL Oral Solution for Cats oral solution should initially be given daily until a satisfactory clinical improvement is seen, usually within 4–8 weeks. Patients should be regularly re-evaluated and treatment options reviewed.

Once the clinical signs of allergic dermatitis are satisfactorily controlled, the product can then be given every second day. In some cases where the clinical signs are controlled with every second day dosing, the veterinarian can give DERMASPORIN 100 mg/mL Oral Solution for Cats every 3 to 4 days. Treatment may be stopped when the clinical signs are controlled. Upon recurrence of clinical signs, treatment should be resumed at daily dosing, and in certain cases, repeated treatment courses may be required.

Address: A9/20 Picrite Close, Pemulwuy, NSW-2145
Post Address: PO Box 465, Wentworthville, NSW-2145

www.headwayanimalhealth.com.au
info@theheadway.com.au
(+61)2 9896 0856

GENERAL DIRECTIONS:

Indications

DERMASPORIN 100 mg/mL Oral Solution for Cats is indicated for the treatment of chronic manifestations of allergic dermatitis in cats.

Allergic dermatitis in cats can have various manifestations, including eosinophilic plaques, head and neck excoriation, symmetrical alopecia and/or miliary dermatitis. Clinical signs of allergic dermatitis such as pruritus and skin inflammation are not specific for this disease. Other causes of dermatitis such as ectoparasitic infestations should be evaluated and eliminated. It is good practice to treat flea infestations before and during treatment of allergic dermatitis. A complete clinical examination should be performed prior to treatment. The immune status of the cats to FeLV and FIV infections should be assessed before treatment.

Pharmacological Properties

DERMASPORIN 100 mg/mL Oral Solution for Cats contains cyclosporin. Cyclosporin is a selective immunomodulator that acts specifically and reversibly on T-lymphocytes. Cyclosporin exerts anti-inflammatory and antipruritic effects in the treatment of allergic dermatitis. Cyclosporin has been shown to preferentially inhibit the activation of Tlymphocytes on antigenic stimulation by impairing the production of IL-2 and other T-cell derived cytokines. Cyclosporin also has the capacity to inhibit the antigen-presenting function of the skin immune system. It likewise blocks the recruitment and activation of eosinophils, the production of cytokines by keratinocytes, the functions of Langerhans cells, the degranulation of mast cells and therefore the release of histamine and pro-inflammatory cytokines.

Cyclosporin does not depress haematopoiesis and has no effect on the function of phagocytic cells.

Absorption

The bioavailability of cyclosporin is in the range of 24% to 29%. The peak plasma concentration is generally reached within 1 to 2 hours when given to fasted cats or mixed with food, and the drug is widely distributed into all tissues including skin. The absorption can be delayed by several hours when given after feeding.

Metabolism

Cyclosporin is metabolised mainly in the liver by cytochrome P450 (CYP 3A 4), but also in the intestine. Metabolism takes place essentially in the form of hydroxylation and demethylation, leading to metabolites with little or no activity.

Elimination is mainly via the faeces. A small proportion of the administered dose is excreted through urine as inactive metabolites.

A slight bioaccumulation related to the long half-life of the drug (approximately 24 h) is observed with repeated dosing. The steady state is reached within a week, with a bioaccumulation factor in the range of 2 to 3.

In the cat, there are large inter-individual variations in plasma concentrations. At the recommended dosage, cyclosporin plasma concentrations are not predictive of the clinical response, therefore monitoring of blood levels is not recommended.

Unscrew the screw cap from the bottle, remove the rubber stopper and assemble the dispensing system as described below. Take out the required volume of the medicinal product according to the weight of the cat by using the scale of the dispenser. For the dosing process, carefully follow the handling/dispensing instructions as described below.

Preparing the dispensing system

The dispensing system consists of three parts:

www.headwayanimalhealth.com.au
info@theheadway.com.au
(+61)2 9896 0856

1. A bottle containing the medicine, with rubber stopper and a child-resistant screw cap to close the bottle after use.

2. A plastic adapter with dip tube that you push into the neck of the bottle. The adapter must always remain in the bottle after first use.

3. An oral dosing syringe that fits into the plastic adapter to withdraw the prescribed dose of medicine from the bottle.

• Push and turn the child-resistant screw cap to open the bottle.

• Remove and dispose of the rubber stopper.

• Hold the open bottle upright on a table and push the plastic adapter firmly into the neck of the bottle as far as possible, then close the bottle with the child-resistant screw cap.

Preparing a dose of medicine

1. Push and turn the child-resistant cap to open the bottle. NOTE: Always close the bottle with the child-resistant screw cap after use.

2. Check that the plunger of the syringe is pushed all the way down.

3. Keep the bottle upright and insert the syringe firmly into the plastic adapter.

4. Slowly pull the plunger up so that the syringe fills with the medicine.

5. Withdraw the prescribed dose of medicine. NOTE: If the prescribed dose is more than the maximum volume marked on the syringe, the syringe will need to be reloaded to withdraw the full dose.

6. Remove the syringe by gently twisting it out of the plastic adapter.

The entire dose can then be pushed out of the syringe, either directly into the mouth of the cat or onto the cat's food.

PRECAUTIONS:

Cyclosporin may cause elevated levels of blood glucose. The effect of cyclosporin in cats with diabetes has not been evaluated. Cyclosporin should be used with caution in cats with diabetes mellitus. While cyclosporin does not induce tumours, it does inhibit Tlymphocytes and therefore treatment with cyclosporin may lead to an increased incidence of clinically apparent malignancy. If lymphadenopathy is observed in cats being treated with cyclosporin, further clinical investigations are recommended and treatment discontinued if necessary.

Cats that are seronegative for T. gondii may be at risk of developing clinical toxoplasmosis if they become infected while under treatment. In rare cases this can be fatal. Potential exposure of seronegative cats to toxoplasma should therefore be minimised (e.g. keep indoors, avoid raw meat or scavenging). Cyclosporin was shown to not increase T. gondii oocyte shedding in a controlled laboratory study. In cases of clinical toxoplasmosis or other serious systemic illness, stop treatment with cyclosporin and initiate appropriate therapy. As cyclosporin is immunosuppressive, any infections should be properly treated before initiation of treatment. Infections occurring during treatment are not necessarily a reason for drug withdrawal, unless the infection is severe.

It is not recommended to use other immunosuppressive agents concomitantly. Interaction with other veterinary medicinal products and other forms of interaction Various substances are known to competitively inhibit or induce the enzymes involved in the metabolism of cyclosporin, in particular cytochrome P450 (CYP 3A 4). The compound class of azoles is known to increase the blood concentration of cyclosporin in cats, which is considered to be clinically relevant. Macrolides such as erythromycin may increase the plasma levels of cyclosporin up to twofold. Certain inducers of cytochrome P450,

anticonvulsants and antibiotics (e.g. trimethoprim/sulfadimidine) may lower the plasma concentration of cyclosporin.

Cyclosporin is a substrate and an inhibitor of the MDR1 P-glycoprotein transporter. Therefore, the co-administration of cyclosporin with P-glycoprotein substrates such as macrocyclic lactones could decrease the efflux of such drugs from blood-brain barrier cells, potentially resulting in signs of CNS toxicity. In clinical studies with cats treated with cyclosporin and selamectin or milbemycin, there did not appear to be an association between these drugs' concomitant use and neurotoxicity. Cyclosporin can increase the nephrotoxicity of aminoglycoside antibiotics and trimethoprim. The concomitant use of cyclosporin is not recommended with these active ingredients.

Treatment with DERMASPORIN 100 mg/mL Oral Solution for Cats oral solution may result in decreased immune response to vaccination. It is recommended not to vaccinate during treatment or within a two-week interval before or after administration of the product.

Overdosage

Under laboratory conditions, no undesirable effects have been observed following single oral doses of up to 40 mg/kg (more than 5x the recommended dose).

The following adverse events were seen in the case of repeated administration for 56 days at 24 mg/kg (more than 3x the recommended dose) or for 6 months at up to 40 mg/kg (more than 5x the recommended dose): loose/soft faeces, vomiting, mild to moderate increases in absolute lymphocyte counts, fibrinogen, activated partial thromboplastin time (APTT), slight increases in blood glucose and reversible gingival hypertrophy.

The frequency and severity of these signs were generally dose and time dependent. There is no specific antidote and in case of signs of overdose the cat should be treated symptomatically.

SIDE EFFECTS:

Clinical studies in cats have shown that decreased appetite and weight loss may occur during cyclosporin treatment. Monitoring of body weight is recommended. Significant reduction in body weight may result in hepatic lipidosis. If persistent, progressive weight loss occurs during treatment, it is recommended to discontinue treatment until the cause has been identified.

FIRST AID INSTRUCTIONS:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

DISPOSAL

Dispose of container by wrapping in paper and putting in the garbage.

STORAGE

Store below 30°C (room temperature). Do not store below 15°C. Do not refrigerate. Keep the vial in the outer carton.

APVMA Approval No. 90969/135591