

180.00 mm

For the use only of a Registered Veterinary Practitioner or a Hospital or a Laboratory or a Farm.

R_x
Cyclosporine Capsules IP 25 mg / 50 mg / 100 mg

VETOPIC[®] 25/50/100

व्हिटोपिक २५/५०/१००

An Immunosuppressant for use in dogs only.

VETOPIC[®] 25

COMPOSITION:

Each soft gelatin capsule contains:
 Cyclosporine IP.....25 mg
 Excipients.....q.s.
 Colour : Ferric Oxide (Red) USP-NF

VETOPIC[®] 50

COMPOSITION:

Each soft gelatin capsule contains:
 Cyclosporine IP.....50 mg
 Excipients.....q.s.
 Colour : Ferric Oxide (Red) USP-NF &
 Ferric Oxide (Black) USP-NF

VETOPIC[®] 100

COMPOSITION:

Each soft gelatin capsule contains:
 Cyclosporine IP.....100 mg
 Excipients.....q.s.
 Colour : Ferric Oxide (Red) USP-NF

INDICATIONS:

VETOPIC for Dogs is indicated for the control of atopic dermatitis (skin allergies) in dogs. Signs of skin allergies include itching, scratching, licking, gnawing, chewing, skin infections, hair loss, terrible odor, and sleepless nights.

DOSAGE AND ADMINISTRATION:

The recommended initial dose is 5 mg/kg / day as a single daily dose for 30 days.
 Following initial daily treatment, the dose can be decreased to every other day or twice weekly to maintain the desired therapeutic effect. It should be given at least one hour before or two hours after a meal. If a dose is missed, the next dose should be administered (without doubling) as soon as possible, but dosing should be no more frequent than once daily.

Weight of dog (Kg)	Dose 5mg/Kg
4 to < 7.5 Kg	25 mg Capsule
7.5 to < 15 Kg	50 mg Capsule
15 to < 29 Kg	100 mg Capsule
29 to < 36 Kg	100 mg + 50 mg Capsule
36 to < 56 Kg	2 x 100 mg Capsule

Dogs weighing over 56 kg bodyweight:
 Use the appropriate Dosage or as directed by the veterinarian.

CAPSULE SHOULD BE SWALLOWED WHOLE AND NOT TO BE OPENED, CHEWED OR CRUSHED

TARGET SPECIES: Dogs

PHARMACOLOGICAL PROPERTIES:

Pharmacotherapeutic group: Selective immunosuppressive agents
 ATCvet code: QL04AD01.

PHARMACODYNAMIC PROPERTIES:

Ciclosporin (also known as cyclosporin, cyclosporine, cyclosporine A, CsA) is a selective immunosuppressor. It is a cyclic polypeptide consisting of 11 amino acids, has a molecular weight of 1203 daltons and acts specifically and reversibly on T lymphocytes. Ciclosporin exerts anti-inflammatory and antipruritic effects in the treatment of atopic dermatitis. Ciclosporin has been shown to preferentially inhibit the activation of T-lymphocytes on antigenic stimulation by impairing the production of IL-2 and other T-cell derived cytokines. Ciclosporin also has the capacity to inhibit the antigen-presenting function on 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. Ciclosporin does not depress haematopoiesis and has no effect on the function of phagocytic cells.

PHARMACOKINETICS:

Absorption: The bioavailability of ciclosporin is about 35%. The peak plasma concentration is reached within 1 to 2 hours. The bioavailability is better and less subject to individual variations if ciclosporin is administered to fasted animals rather than at mealtimes.

Distribution: In dogs, the volume of distribution is about 7.8 L/kg. Ciclosporin is widely distributed to all tissues. Following repeated daily administration to dogs ciclosporin concentration in the skin is several times higher than in blood.

Metabolism: Ciclosporin 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. Unchanged ciclosporin represents about 25% of circulating blood concentrations in the course of the first 24 hours.

Elimination: Elimination is mainly via the faeces. Only 10% is excreted in the urine, mostly in the form of metabolites. No significant accumulation was observed in blood of dogs treated for one year

WARNING & PRECAUTIONS:

- For use only in dogs.
- Capsules should not be broken or opened. Wear gloves during administration.
- Wash hands after administration. In case of accidental ingestion, seek medical advice immediately and provide the package insert or the label to the physician.
- It is recommended to clear bacterial and fungal infections before administering the veterinary medicinal product. However, infections occurring during treatment are not necessarily a reason for drug withdrawal, unless the infection is severe.
- Closely monitor creatinine levels in dogs with severe renal insufficiency.
- Treatment with the veterinary medicinal product may interfere with vaccination efficacy. In the case of inactivated vaccines, it is not recommended to vaccinate during treatment or within a two-week interval before or after administration of the product.

CONTRAINDICATIONS:

- Hypersensitivity to any of the Ingredients.
- Do not administer to animals other than those for which it is indicated.
- Do not vaccinate with a live vaccine during treatment or within a two-week interval before or after treatment.
- Do not use in cases with a history of malignant disorders or progressive malignant disorders.
- For all capsule strengths, do not use in dogs less than six months of age or less than 2 kg in weight.

ADVERSE EFFECTS:

The occurrence of adverse reactions is uncommon. The most frequently observed undesirable effects are gastrointestinal disturbances such as vomiting, mucoid or soft faeces and diarrhoea. They are mild and transient and generally do not require the cessation of the treatment.

Other undesirable effects may be observed infrequently: lethargy or hyperactivity, anorexia, mild to moderate gingival hyperplasia, skin lesions such as verruciform lesions or change of hair coat, red and swollen pinnae, muscle weakness or muscle cramps. These effects generally resolve spontaneously after treatment is stopped.

STORAGE: Store below 30°C in a dry place, protected from moisture .

CONTAINER DISPOSAL: Any unused product or waste material should be disposed of in accordance with local requirements.

PRESENTATION:

1 Alu / Alu Blisters containing 6 soft gelatin capsules is packed in a Carton along with the Pack Insert.

**FOR VETERINARY USE.
 FOR ANIMAL TREATMENT ONLY.
 NOT FOR HUMAN USE.
 FOR ORAL ADMINISTRATION ONLY.**

KEEP OUT OF REACH OF CHILDREN & PETS, AWAY FROM FOOD.

Veko

Manufactured For:
VEKO CARE PVT. LTD.
 Room No. 1, Ground Floor, Plot No. E - 47, M.I.D.C., Ranjangaon, Shirur,
 Tal. Shirur (Pune - Zone 4)-412220,India
 Customer care : care@vekocare.com ©: Registered Trade Mark of Vekocare

Mfd. by : Rivpra Formulation Pvt. Ltd.
 Plot No. 7, Sector-6A, I.I.E., SIDCUL,
 Haridwar-249 403 (U.K.)
 A unit of Rivpra Formulation Pvt. Ltd.
(WHO-cGMP Certified Company)
 Plot No. 8, Sector-6A, I.I.E., SIDCUL,
 Haridwar-249 403 (U.K.)



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