

# Atopica

## Introduction



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## Presentation

Soft capsules containing 10 mg, 25 mg, 50mg or 100 mg cyclosporine A. The capsules bear the imprint: S in a triangle and are labelled with the amount of active ingredient. They are coloured:

Atopica 10 mg: yellow-white oval capsule  
Atopica 25 mg: blue-grey oval capsule  
Atopica 50 mg: yellow-white oblong capsule  
Atopica 100 mg: blue-grey oblong capsule

## Uses

Treatment of chronic manifestations of atopic dermatitis in dogs.

## Dosage and administration

The mean recommended dose of cyclosporine is 5 mg/kg body weight according to the tabulated dosage scheme.

### Atopica dosage scheme:

Body weight of dog	Number of capsules given to obtain recommended dose			
	Atopica 10 mg	Atopica 25 mg	Atopica 50 mg	Atopica 100 mg
2 to < 3 kg	1 capsule			
3 to < 4 kg	2 capsules			
4 to < 7.5 kg		1 capsule		
7.5 to < 15 kg			1 capsule	
15 to < 29 kg				1 capsule
29 to < 36 kg			3 capsules	
36 to 55 kg				2 capsules

Atopica will initially be given daily until a satisfactory clinical improvement is seen. This will generally be the case within 4 weeks. If no response is obtained within the first 8 weeks, the treatment should be stopped.

Once the clinical signs of atopic dermatitis are satisfactorily controlled, the preparation can then be given every other day as a maintenance dose. The veterinary surgeon should perform a clinical assessment at regular intervals and adjust the frequency of administration to the clinical response obtained.

In some cases where the clinical signs are controlled with every-other-day dosing, the veterinary surgeon can decide to give Atopica every 3 to 4 days.

Adjunct treatment (e.g. medicated shampoos, fatty acids) may be considered before reducing the dosing interval.

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.

Atopica should be given at least 2 hours before or after feeding. Insert the capsule directly into the dog's mouth.

## Contra-indications, warnings, etc

Do not use in cases of hypersensitivity to cyclosporine or one of the excipients.

Do not use in dogs less than 6 months of age or less than 2 kg in weight.

Do not use in cases with a history of malignant disorders or progressive malignant disorders.

Do not vaccinate with a live vaccine during treatment or within a 2-week interval before or after treatment.

### Undesirable effects

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: anorexia, mild to moderate gingival hyperplasia, verruciform lesions of the skin or change of hair coat, red and swollen pinnae, muscle weakness or muscle cramps. These effects resolve spontaneously after treatment is stopped.

### Special precautions for use

Clinical signs of atopic dermatitis such as pruritus and skin inflammation are not specific for this disease and therefore other causes of dermatitis such as ectoparasitic infestations, other allergies which cause dermatological signs (e.g. flea allergic dermatitis or food allergy) or bacterial and fungal infections should be ruled out before treatment is started. It is good practice to treat flea infestations before and during treatment of atopic dermatitis.

It is recommended to clear bacterial and fungal infections before administering Atopica. However, infections occurring during treatment are not necessarily a reason for drug withdrawal, unless the infection is severe.

A complete clinical examination should be performed before treatment. As cyclosporine inhibits T-lymphocytes and though it does not induce tumours, it may lead to increased incidences of clinically apparent malignancy. Lymphadenopathy observed on treatment with cyclosporine should be regularly monitored.

In laboratory animals, cyclosporine is liable to affect the circulating levels of insulin and to cause an increase in glycaemia. In the presence of suggestive signs of diabetes mellitus, the effect of treatment on glycaemia must be monitored. The use of cyclosporine is not recommended in diabetic dogs.

Closely monitor creatinine levels in dogs with severe renal insufficiency.

Particular attention must be paid to vaccination. Treatment with Atopica may interfere with vaccination efficacy. In the case of inactivated vaccines, it is not recommended to vaccinate during treatment or within a 2-week interval before or after administration of the product.

It is not recommended to use other immunosuppressive agents concomitantly.

### Use during pregnancy and lactation

The safety of the drug has neither been studied in breeding male dogs nor in pregnant or lactating female dogs. In the absence of such studies in the dog, it is recommended to use the drug in breeding dogs only upon a positive risk/benefit assessment by the veterinary surgeon. Cyclosporine passes the placenta barrier and is excreted via milk. Therefore the treatment of lactating bitches is not recommended.

### Interactions with other medication

Various substances are known to competitively inhibit or induce the enzymes involved in the metabolism of cyclosporine, in particular cytochrome P450 (CYP 3A 4). In certain clinically justified cases, an adjustment of the dosage of Atopica may be required. Ketoconazole at 5-10 mg/kg is known to increase the blood concentration of cyclosporine in dogs up to five-fold, which is considered to be clinically relevant. During concomitant use of ketoconazole and cyclosporine the veterinary surgeon should consider as a practical measure to halve the dose or to double the treatment interval if the dog is on a daily treatment regime.

Macrolides such as erythromycin may increase the plasma levels of cyclosporine up to two-fold.

Certain inducers of cytochrome P450, anticonvulsants and antibiotics (e.g. trimethoprim/sulfadimidine) may lower the plasma concentration of cyclosporine.

Cyclosporine is a substrate and an inhibitor of the MDR 1 P-glycoprotein transporter. Therefore, the co-administration of cyclosporine with P-glycoprotein substrates such as macrocyclic lactones (e.g. ivermectin and milbemycin) could decrease the efflux of such drugs from blood-brain barrier cells, potentially resulting in signs of CNS toxicity.

Cyclosporine can increase the nephrotoxicity of aminoglycoside antibiotics and trimethoprim. The concomitant use of cyclosporine is not recommended with these active ingredients.

## Pharmaceutical precautions

Do not store above 25°C.

Keep the medicinal product in the blister pack. Keep the blister pack in the outer carton.

### Disposal

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

## Legal category

POM-V (previously POM)

## Packaging Quantities

Box containing 15 capsules in 3 aluminium/aluminium blister packs.

## Further information

Nil.

## Marketing authorisation number

Atopica 10 mg Vm 12501/4144.

Atopica 25 mg Vm 12501/4145.

Atopica 50 mg Vm 12501/4146.

Atopica 100 mg Vm 12501/4147.