

Product Name: ADVOCATE FOR DOGS 4-10 KG  
APVMA Approval No: 55321/131617



Label Name:	ADVOCATE FOR DOGS 4-10 KG
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Signal Headings:	CAUTION KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS
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Constituent Statements:	100 g/L IMIDACLOPRID 25 g/L MOXIDECTIN
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Claims:	<p>Fleas, Heartworms &amp; Worms Once a month topical flea, heartworm and worm treatment Doesn't rely on fleas having to bite to be killed Treatment and control of intestinal worms and worm larvae Prevents heartworm and oesophageal worm Water resistant, convenient, easy to apply</p> <p>FOR: Treatment and prevention of fleas (<i>Ctenocephalides</i> spp.). Reduces the incidence of Flea Allergy Dermatitis (FAD). Larval flea stages are killed in the surroundings of ADVOCATE treated dogs. Aid in the prevention of the flea tapeworm (<i>Dipylidium caninum</i>) through effective flea control. Prevention of heartworm (<i>Dirofilaria immitis</i>) and oesophageal worm (<i>Spirocerca lupi</i>).</p> <p>FOR THE TREATMENT AND CONTROL OF: roundworms: (<i>Toxocara canis</i>, <i>Toxascaris leonina</i>), kills larval (L4) , immature adult (L5) and adult worms; hookworms: (<i>Ancylostoma caninum</i>, <i>Ancylostoma braziliense</i> (this hookworm is usually restricted to tropical areas in Australia), <i>Ancylostoma ceylanicum</i>, <i>Uncinaria stenocephala</i>), kills larval (L4), immature adult (L5) and adult worms of all species; whipworm: (<i>Trichuris vulpis</i>); generalised demodicosis (<i>Demodex canis</i>); sarcoptic mange (<i>Sarcoptes scabiei</i>); ear mites (<i>Otodectes cynotis</i>); lice (<i>Trichodectes canis</i>, <i>Linognathus setosus</i>) for up to 6 weeks; in dogs.</p> <p>One application lasts for a month. Advocate contains imidacloprid (a neonicotinoid) and moxidectin (a macrocyclic lactone). If problems persist, consult a veterinarian.</p>
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Net Contents:	<p>1 x 1 mL  2 x 1 mL  3 x 1 mL  6 x 1 mL  pipettes</p> <p>It is illegal to sell pipettes separately.</p>
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Directions for Use:	
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Restraints:	
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Contraindications:	
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Precautions:	<p>Use with caution in sick, debilitated or underweight animals. Take care to avoid the product coming into contact with the eyes or mouth of the pet. Ingestion by the recipient or in-contact animals should be prevented.</p> <p><b>PREGNANCY AND LACTATION</b>  No primary embryo-toxic, teratogenic or reproductive toxic effects have been observed with imidacloprid or moxidectin in laboratory species. Evidence suggests that no adverse effects are to be expected in pregnant and lactating dogs. However, the safety of ADVOCATE has not been established during pregnancy and lactation.</p>
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Side Effects:	Neurological signs such as ataxia and muscle tremor (most of which are transient) may be observed in very rare cases.
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Dosage and Administration:	<p>Consult a veterinarian before use.</p> <p><b>FOR EXTERNAL USE ONLY</b>  <b>DO NOT GIVE THIS PRODUCT BY MOUTH (include pictogram)</b>  <b>DO NOT use in cats.</b></p> <p>One tube treats dogs 4 - 10 kg. Apply to the skin in one spot between the shoulder blades, once a month.  Treatment for heartworm should occur regularly at monthly intervals.</p> <p><b>DOSAGE</b>  For animals of this type: Use 1 TUBE from this pack colour  Dogs up to 4 kg dark green  Dogs 4-10 kg turquoise</p> <ol style="list-style-type: none"> <li>1. Remove required tube(s) from the package.</li> <li>2. Hold tube upright and pull off the cap.</li> <li>3. Reverse the cap and push cap back on tube.</li> <li>4. Twist cap to break seal, then remove cap from tube</li> <li>5. If applying ADVOCATE to a dog wearing a SERESTO® collar, there is no need to remove the SERESTO collar, however remove any other collar prior to application, and replace when product is dry.</li> <li>6. The dog should be standing for easy application. Part the hair until the skin is visible. Place the tip of the tube on the skin and squeeze the tube firmly twice to apply the solution directly on the skin. Avoid pet's eyes or mouth.</li> <li>7. Record treatment date and repeat monthly or as directed.</li> </ol>
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ADVOCATE remains efficacious following shampoo treatment, swimming or exposure to rain. If you wash your dog between treatments, always use a soap-free shampoo. Occasionally, hair loss may occur at the application site. This is usually a single occurrence and hair will grow back uneventfully.

General Directions:

FLEA CONTROL AND PREVENTION

ADVOCATE kills fleas quickly, within 20 minutes of contacting treated dogs. Fleas stop feeding in 3–5 minutes, and don't need to bite dogs to be killed. ADVOCATE breaks the flea life cycle by killing fleas on the dog and the flea larval stages in the dogs' environment. Registered flea house sprays or bombs can also be useful to help clean-up heavy environmental flea infestations. The feeding activity of fleas on pets exposing them to fleas' saliva may elicit a hypersensitivity skin disorder known as Flea Allergy Dermatitis (FAD), that can cause intense scratching, reddened skin and hair loss. FAD is common in dogs. By killing fleas and their larvae, ADVOCATE reduces the incidence of this condition. For ongoing flea prevention, treat all dogs in same environment monthly with ADVOCATE for dogs and all cats with ADVOCATE for cats.

HEARTWORM PREVENTION

Treatment with ADVOCATE should start one month before the first exposure to mosquitoes, which transmit heartworm (*Dirofilaria immitis*) between dogs. ADVOCATE must be applied at one-month intervals during the time of the year when mosquitoes are present. In many areas of Australia continuous, year-round heartworm prevention is recommended. To establish a routine, it is recommended that the same day or date be used each month to administer ADVOCATE. When replacing another heartworm preventive product with ADVOCATE, talk to an Animal Health Consultant at Elanco on 1800 995 709 for advice. ADVOCATE may be safely applied to heartworm infected dogs, therefore there is no absolute requirement for a heartworm test before commencing treatment. However, a diagnostic test for heartworm prior to commencement of treatment is recommended to ensure the optimum health of dogs.

INTESTINAL WORM CONTROL

ADVOCATE kills larval (L4), immature adult (L5) and adult stages of roundworms and hookworms. Larval stages are prevented from migrating around the body of your dog. ADVOCATE treats and controls adult whipworm. Dogs may be regularly re-infested with roundworms, hookworms and whipworms from the environment, but monthly use of ADVOCATE provides continuous protection. The flea tapeworm (*D. caninum*) is transmitted by fleas. Dogs are infected by ingesting adult fleas infected with the immature stages of this tapeworm. Effective flea control with ADVOCATE aids in the prevention of flea tapeworm infestation. In order to control other tapeworms treat with a tapewormer as directed by your veterinarian. If worm problems persist, consult a veterinarian.

TREATMENT AND CONTROL OF GENERALISED DEMODICOSIS

ADVOCATE has been shown to be highly effective in the treatment of generalised demodicosis when administered at monthly intervals for 2 to 4 treatments. In a laboratory study performed on dogs naturally infested with *Demodex canis*, treatment with ADVOCATE resulted in a decrease in the occurrence of erythema, casts, scales, crusts and alopecia and a significant reduction (97.84%) in mite numbers found on skin scrapings. In a field study, all dogs enrolled in the study were 100% cured of *Demodex* mites.

TREATMENT AND CONTROL OF SARCOPTIC MANGE

ADVOCATE has been shown to eliminate 100% of sarcoptic mites (*Sarcoptes scabiei*) after a single dose. A second dose of ADVOCATE a month later will result in continued improvement of the clinical signs associated with sarcoptic mange. Monthly application of ADVOCATE will control any subsequent sarcoptic mite infestation.

TREATMENT AND CONTROL OF EAR MITES

For the treatment of ear mites (*Otodectes cynotis*), ADVOCATE is highly efficacious as a single dose. Monthly application of ADVOCATE will control any subsequent ear mite infestation. To maximise efficacy, thorough cleaning of the ear canal is recommended with a product that is registered for that purpose or as directed by a veterinarian.

PREVENTION OF OESOPHAGEAL WORM INFECTION

The oesophageal worm (*Spirocerca lupi*) forms nodules in the oesophagus of dogs. Infection may be asymptomatic, or may cause regurgitation, vomiting, weight loss and occasionally death. Monthly application of ADVOCATE prevents spirocercosis.

#### PUPPIES

Puppies may be treated with ADVOCATE from 7 weeks of age. If puppies younger than 7 weeks require flea control, they may be safely treated with ADVANTAGE for Dogs. For control of roundworms and hookworms puppies require worming fortnightly starting from 2 weeks to 8 weeks of age. When worming puppies prior to commencing ADVOCATE, use a specific worming agent such as MILBEMAX. Once treatment with ADVOCATE every month is commenced worms will be continuously controlled.

#### PHARMACOLOGICAL PROPERTIES

ADVOCATE has two active constituents, imidacloprid and moxidectin. After topical administration of the product, imidacloprid rapidly distributes over the dogs' skin within one day of application and can be found on the body surface throughout the treatment interval. Moxidectin rapidly enters the skin, and is then distributed systemically throughout the dog's body tissues, concentrating mainly in fat due to its lipophilicity. Maximum plasma concentrations are reached approximately 4 - 9 days after application. It is slowly eliminated from the plasma as manifested by detectable moxidectin concentrations in plasma throughout the treatment interval of one month. The half-life (T<sub>1/2</sub>) in dogs is approximately 35 days, and steady state serum levels are achieved following 4 - 5 consecutive monthly treatments in dogs.

#### ADDITIONAL INSTRUCTIONS

ADVOCATE has no strong chemical smell. The liquid vehicle in ADVOCATE may discolour or damage certain surfaces and fabrics e.g. polished floorboards, leather. Exclude the animal from contact with such surfaces until the product dries on the animal's coat.

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

Withholding Periods:

Trade Advice:

Safety Directions:

Harmful if swallowed. Will damage the eyes. Repeated exposure may cause allergic disorders. Avoid contact with the eyes. If product in eyes, wash it out immediately with water. Wash hands after use.

First Aid Instructions:

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

First Aid Warnings:

Additional User Safety:

Environmental Statements:

Disposal:	Dispose of used pipettes and foil blisters by wrapping with paper and putting in the garbage. Recycle cardboard carton and leaflet.
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Storage:	Store below 25°C (Air Conditioning).
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