



Product Name: BRAVECTO 250 MG FLURALANER SPOT-ON SOLUTION FOR SMALL DOGS  
APVMA Approval No: 82797/106810

Label Name:	BRAVECTO 250 MG FLURALANER SPOT-ON SOLUTION FOR SMALL DOGS
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Signal Headings:	POISON KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS
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Constituent Statements:	280 mg/mL FLURALANER Also contains: 339 mg/mL DIMETHYLACETAMIDE (solvent)
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Claims:	<p>BRAVECTO Spot-on provides:</p> <ul style="list-style-type: none"><li>• Treatment and prevention of flea (<i>Ctenocephalides felis</i>) infestations for 6 months.</li><li>• Treatment and control of paralysis tick (<i>Ixodes holocyclus</i>) for 6 months.</li><li>• Treatment and control of brown dog tick (<i>Rhipicephalus sanguineus</i>) for 12 weeks.</li><li>• Rapid onset of action kills newly emerged adult fleas before they lay eggs.</li><li>• Control of flea allergy dermatitis (FAD).</li></ul> <p>BRAVECTO Spot-on contains fluralaner, a member of the antiparasitic class of isoxazoline-substituted benzamide derivatives. Fluralaner acts antagonistically on arthropods ligand-gated chloride channels (GABA-receptor and glutamate-receptor).</p> <p>BRAVECTO Spot-on is effective against fipronil-resistant strains of fleas.</p> <p>BRAVECTO Spot-on can be used in breeding, pregnant and lactating dogs.</p> <p><b>ONSET OF ACTION AND EFFICACY</b></p> <p>BRAVECTO Spot-on kills pre-existing and new infestations of paralysis ticks (<i>Ixodes holocyclus</i>) for 6 months.</p> <p>BRAVECTO Spot-on provides effective control of fleas on dogs within 8 hours of administration, and subsequently maintains persistent efficacy against flea re-infestations for 6 months following application.</p> <p>The flea life cycle can be broken by the rapid onset of action and the long-lasting efficacy against adult fleas on the dog. Newly emerged adult fleas on a dog are killed before viable eggs are produced.</p> <p>BRAVECTO Spot-on effectively controls environmental flea populations in areas to which the dog has access.</p>
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	Ixodes holocyclus ticks do not occur in Western Australia. In tick season daily searching for and removal of any ticks found is recommended.
Net Contents:	0.89 mL x 1 pipette 0.89 mL x 2 pipettes [Illegal to sell pipettes separately]
Directions for Use:	DIRECTIONS FOR USE
Restraints:	
Contraindications:	Contraindications BRAVECTO Spot-on must not be used in case of hypersensitivity to the active substance or to any of the excipients.
Precautions:	Precautions BRAVECTO Spot-on should not be used in puppies less than 8 weeks of age or weighing less than 2 kg.
Side Effects:	Side Effects Less than 1.5% of dogs treated in clinical trials developed mild and transient skin reactions such as erythema (reddened skin) or hair loss at the application site.
Dosage and Administration:	This section contains file attachment.
General Directions:	<p>General directions NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p> <p>MAKE NO ATTEMPT TO REMOVE CAP. CAP DOES NOT COME OFF. TWIST CAP AND USE.</p> <p>During laboratory and clinical field testing, no interactions between BRAVECTO Spot-on solution and routinely used veterinary medicines were observed.</p> <p>It is not recommended to wash or allow the dog to become immersed or swim in water within 3 days after treatment. Care should be taken to avoid contact with the eyes of the animal. It is recommended not to use directly on skin lesions.</p> <p>Fluralaner is readily systemically absorbed from the topical application site. The prolonged persistence and slow elimination from plasma and the lack of extensive metabolism provide effective concentrations of fluralaner for the duration of the inter-dosing interval.</p> <p>Fluralaner is part of the isoxazoline family of chemicals. Adverse reactions to this family of chemicals are rarely observed but may include vomiting, diarrhoea, lethargy, inappetence, itching and very rarely, seizures. Most adverse reactions are self-limiting and of short duration. If you have any concerns, please speak to your veterinarian.</p>

Fluralaner was well tolerated in Collies with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at 3 times the recommended dose (168 mg/kg bodyweight). No treatment-related clinical signs were observed.

Withholding Periods:

Trade Advice:

Safety Directions:

**SAFETY DIRECTIONS**

May irritate the eyes. Avoid contact with eyes. Wash hands after use.

First Aid Instructions:

**FIRST AID**

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

If skin contact occurs, remove contaminated clothing and wash skin thoroughly.

First Aid Warnings:

Additional User Safety:

**ADDITIONAL USER SAFETY INFORMATION**

Rehandling statements

Do not contact the application area until dry. Where possible, apply to the animal in the evening.

Environmental Statements:

Disposal:

**DISPOSAL**

Dispose immediately of empty pipette, sachet and carton by wrapping in paper and putting in garbage.

Storage:

**STORAGE**

Store below 30°C (room temperature). The pipettes should be kept in the sachets to prevent solvent loss or moisture uptake. The sachets should only be opened immediately prior to use.

## Dosage and Administration

**BRAVECTO Spot-on** for dogs is available in five sizes. The following table indicates the size of pipette to be used according to the body weight of the dog (equivalent to 25 - 56 mg fluralaner/kg body weight).

Body weight (kg) of dog	Administration guide: (volume and number of pipettes)				
	Bravecto 112.5 mg for Very Small Dogs	Bravecto 250 mg for Small Dogs	Bravecto 500 mg for Medium Dogs	Bravecto 1000 mg for Large Dogs	Bravecto 1400 mg for Very Large Dogs
	0.4 mL / pipette	0.89 mL / pipette	1.79 mL / pipette	3.57 mL / pipette	5.0 mL / pipette
2 – 4.5	1				
>4.5 - 10		1			
>10 - 20			1		
>20 -40				1	
>40 - 56					1

For dogs above 56 kg body weight, use a combination of two pipettes that most closely matches the body weight.

Puppies should be weighed regularly. Fast growing puppies may outgrow the initial weight band during the inter-dosing interval. Treatment may be appropriately adapted by the veterinarian to suit the individual weight changes.

**BRAVECTO Spot-on** should not be administered at intervals shorter than 8 weeks as the safety at shorter intervals has not been tested.

### Method of administration:

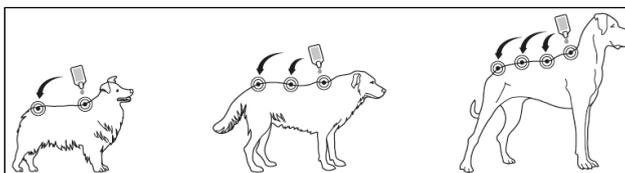
**Step 1:** Immediately before use, open the sachet and remove the pipette. The pipette should be held by the base or by the upper rigid portion below the cap in an upright position (tip up) for opening it. The **twist-and-use cap** should be rotated clockwise or counter clockwise one full turn. **The cap will stay on the pipette; it is not possible to remove it.** The pipette is open and ready for application when the breaking of the seal is felt.



**MAKE NO ATTEMPT TO REMOVE CAP.  
CAP DOES NOT COME OFF.  
TWIST CAP AND USE.**

**Step 2:** The dog should be standing or lying with its back horizontal during application. Part the hair and place the pipette tip vertically against the skin between the shoulder blades of the dog.

**Step 3:** Part hair, squeeze the pipette gently and apply the entire contents directly to the dog's skin in one spot (when volume is small) or several spots along the dog's dorsal line from the shoulder to the base of the tail. Avoid the application of an excessive amount of solution in any one spot as it could cause some of the solution to run or drip off the dog.



### Treatment schedule:

For optimal control of **paralysis tick** and **flea infestation**, the product should be administered at intervals of **6 months**. For optimal control of brown dog tick, the product should be administered at intervals of 12 weeks.

**BRAVECTO Spot-on** can be used year round.

The dog's coat at the treatment application site may appear damp, greasy and mildly clumped.