RLP
APPROVED

Product Name: BRAVECTO QUANTUM FLURALANER 150 mg/mL INJECTABLE SUSPENSION FOR DOGS
APVMA Approval No: 91883 / 133781

Label Name:	BRAVECTO QUANTUM FLURALANER 150 mg/mL INJECTABLE SUSPENSION FOR DOGS

Signal Headings:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS

Constituent Statements:	[Powder vial] 1000 mg/g FLURALANER Contains 150 mg/mL FLURALANER when suspended with vehicle according to directions.

Claims:	For use only by or under supervision of a veterinarian. BRAVECTO Quantum provides • Treatment and prevention of flea (Ctenocephalides felis) infestations for 12 months (1 year). • Control of paralysis tick (Ixodes holocyclus) for 12 months (1 year). • Control of brown dog tick (Rhipicephalus sanguineus) for 11 months. • Control of flea allergy dermatitis (FAD). A single BRAVECTO Quantum injection will control flea infestations on the dog within 2 days of treatment. From Day 6, newly emerged adult fleas are killed before they lay eggs, for a full year. Long-lasting efficacy controls newly emerged fleas before viable eggs are produced; effectively controlling flea populations in the dog's environment. BRAVECTO Quantum is effective against fipronil-resistant strains of fleas. Ixodes holocyclus ticks do not occur in Western Australia. BRAVECTO Quantum takes 3 days to exert its full effect, so it should be applied at least 3 days before the dog is exposed to paralysis ticks. Ticks already on dogs prior to applying BRAVECTO Quantum will not be killed immediately after injection. For paralysis tick control it is recommended that the product be used in conjunction with daily searching for, and removal of any ticks found, as the risk of tick paralysis cannot be entirely eliminated. Veterinarian should give dog owners the advice on tick searching and removal techniques.

Net Contents:	1, 2, 5 or 10 [vial(s) containing 2.51 g fluralaner powder].

	1, 2, 5 or 10 [vial(s) containing 16 mL sterile vehicle].

Directions for Use:	

Restraints:	

Contraindications:	Not to be used in animals with hypersensitivity to the active substance.

Precautions:	The safety of this product has not been established for use in breeding, pregnant or lactating dogs. Not recommended for use in dogs under 6 months of age, as the use of this product has not been evaluated.

Side Effects:	BRAVECTO Quantum is well tolerated with the only treatment-related finding limited to transient, non-painful injection site swellings that resolved over time, with no further treatment required. 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.

Dosage and Administration:	This section contains file attachment.

General Directions:	NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION. BRAVECTO Quantum takes 3 days to exert its full effect, so it should be applied at least 3 days before the dog is exposed to paralysis ticks. BRAVECTO Quantum demonstrated >95% efficacy against paralysis ticks at 72 hours after new tick infestations for 12 months (1 year). Ticks already on dogs prior to applying BRAVECTO Quantum will not be killed immediately after injection. These ticks should be removed, and the risk of tick paralysis cannot be entirely eliminated. Fluralaner was well tolerated in Collies with a deficient multidrug-resistance protein 1 (MDR1 -/-) following single oral administration at 3 times the maximum recommended oral dose (168 mg/kg body weight). No treatment-related clinical signs were observed.

Withholding Periods:	

Trade Advice:	

Safety Directions:	Wash hands after use.

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

First Aid Warnings:	

Additional User Safety:	Care should be taken to avoid accidental self-injection when administering this product. In the event of accidental self-injection, seek medical advice immediately.

Environmental Statements:	

Disposal:	Dispose of container by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled ‘sharps’ container.

Storage:	Store below 30 °C (room temperature). Product suspended for injection as directed may be stored for up to 3 months at room temperature (below 30 °C). Discard the unused suspension after 3 months.

Dosage and Administration

In-use shelf life
Product suspended for injection as directed may be stored for up to 3 months at room temperature (below 30°C). Use this product within 3 months of the first puncture and puncture a maximum of 20 times. Discard the unused suspension after 3 months.

Mixing directions
To be suspended with **ONLY 15 mL** sterile vehicle for **BRAVECTO Quantum** to give 150 mg/mL FLURALANER.

Items needed to constitute **BRAVECTO Quantum**
- Fluralaner powder vial – included.
- Sterile vehicle vial – included.
- Vent needle (25 G) – included. Not intended to be used for administration.
- Sterile transfer needle (18 G) – not included.
- Sterile 20 mL syringe for transfer – not included.

USE ONLY 15 ML OF STERILE VEHICLE WHEN SUSPENDING TO ENSURE ACCURATE DOSING.

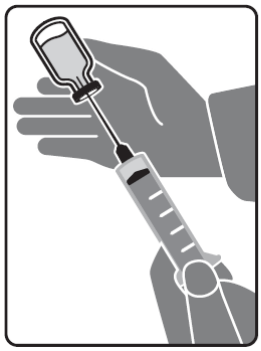

Image A

Image B

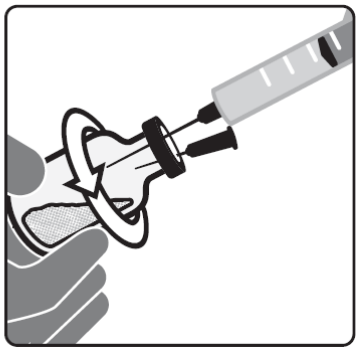

Image C

Step by step mixing instructions
1. **Shake the fluralaner powder vial** to break up any aggregates prior to constitution.
2. Prior to use, invert the vehicle vial **at least 3 times** until visibly uniform. The vehicle solution may be clear to cloudy in appearance.
3. Using an 18 G needle and syringe, first inject up to 14 mL of air into the vehicle vial, then **withdraw 15 mL of the vehicle** from the vial (**Image A**). **There is more vehicle supplied in the vial than required for constitution.**
4. Insert a 25 G vent needle into the top of the fluralaner powder vial (**Image B**).
5. While **rotating the vial horizontally** in hand, slowly transfer the vehicle into the fluralaner powder vial to ensure complete wetting of the powder (**Image C**).
6. Once the vehicle has been added, remove the vent and transfer needles from the fluralaner powder vial. Discard needles.
7. **Shake the vial vigorously** for **at least 30 seconds** until a thoroughly mixed suspension of the fluralaner powder and vehicle is produced.

Administration directions
For subcutaneous injection only. Do not inject suspended product intravenously.
Dose rate of suspended product: 0.1 mL/kg BW.

Administer 0.1 mL of the constituted suspension per kg body weight subcutaneously between the shoulder blades (dorsoscapular region) of the dog to provide a dose of 15 mg fluralaner per kg body weight. The dog should be weighed at the time of dosing to calculate an accurate dose. The following table provides a guide to weight specific dose volumes.

Guide to weight specific dose volumes	
Body weight* (kg)	Dose volume (mL)
1	0.1
5	0.5
10	1.0
15	1.5
20	2.0
25	2.5
30	3.0
35	3.5
40	4.0
45	4.5
50	5.0
55	5.5
60	6.0
All dogs should be dosed at 0.1 mL suspension/kg body weight.	

*For use in dogs from 6 months of age only.

Step by step administration instructions

1. The fluralaner powder will separate out of suspension upon standing. **Before every use, shake the constituted vials vigorously for 30 seconds to achieve a uniform suspension.**
2. Determine dose to be administered according to the directions under **Dosage and administration.**
3. Use a sterile syringe and an 18 G needle for dosing. It may be necessary to inject air into the vial prior to dosing. To maintain a uniform suspension and accurate dosing, the **dose should be administered within 5 minutes** after drawing into dosing syringe.
4. **Use a new needle.** Inject the product **subcutaneously in the dorsoscapular region.**
5. Discard constituted vials after 20 punctures to the stopper, or if product has been suspended for more than 3 months.