



Australian Pesticides &
Veterinary Medicines Authority

Product Name: Owtbac Doramate Pour-On Endectocide
APVMA Approval No: 95335/145315

Label Name:	Owtbac Doramate Pour-On Endectocide
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Signal Headings:	POISON KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS BEFORE OPENING OR USING
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Constituent Statements:	5 mg/mL Doramectin
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Claims:	<p>For the treatment and control of doramectin sensitive internal and external parasites of cattle.</p> <p>Owtbac Doramate Pour-On Endectocide is for the treatment and persistent control of gastrointestinal round worms, lungworms and buffalo fly in cattle. Control of eye worms, sucking and biting lice, mange mites and cattle ticks.</p> <p>Owtbac Doramate Pour-On Endectocide contains doramectin, a member of the macrocyclic lactone family of chemicals.</p> <p>Owtbac Doramate Pour-On Endectocide is highly effective in the treatment and control of the following species:</p> <p>Gastrointestinal Roundworms (adults and fourth stage larvae) Ostertagia ostertagi1 – Small brown stomach worm Haemonchus placei – Barber’s pole worm Trichostrongylus axei – Stomach hair worm T. colubriformis – Black scour worm Cooperia spp.1 – Small intestinal worm Cooperia oncophora1 Bunostomum phlebotomum – Hook worm2 Oesophagostomum radiatum – Nodule worm Nematodirus spathiger – Thin necked intestinal worm2 Thelazia spp. – Eye worm2 Trichuris spp. – Whipworm</p> <p>1 Including inhibited larvae 2 Adults only</p> <p>Adult and Immature Lungworm Dictyocaulus viviparus</p>
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	<p>Sucking Lice Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus</p> <p>Biting Lice Bovicola bovis</p> <p>Buffalo Fly Haematobia irritans exigua</p> <p>Cattle Tick³ Boophilus microplus</p> <p>Mange Mites Chorioptes bovis, Sarcoptes scabiei var. bovis</p> <p>3 Engorged female ticks that drop off for up to 3 days after treatment may lay viable eggs.</p> <p>Worm parasites may develop resistance to any anthelmintic. If this is suspected please contact your local veterinary practitioner or advise the manufacturer.</p>
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Net Contents:	1 L, 2.5 L, 5 L, 20 L, 22 L
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Directions for Use:	
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Restrains:	Re-treatment interval: DO NOT re-treat animals for 56 days (8 weeks) after last treatment.
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Contraindications:	
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Precautions:	
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Side Effects:	
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Dosage and Administration:	<p>DOSE: 1 mL of solution / 10 kg bodyweight.</p> <p>Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. For external use only.</p> <p>Use the dose rate, according to the weight of the animal, given in the tables below. The dose rate should be based on the heaviest member in the weight range (given under the heading 'weight (kg)'). Cattle should be weighed with either scales or a weighband.</p> <p>Table 1:</p>
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Dose rate: 1 mL per 10 kg bodyweight.

Weight (kg)	Dose (mL)
40-50	5
51-75	7.5
76-100	10
101-150	15
151-200	20
201-250	25
251-300	30
301-350	35
351-400	40
401-450	45
451-500	50
501-550	55
551-600	60
601-650	65

Cattle whose weight is in excess of 650 kg should be dosed at 1 mL per 10 kg bodyweight.

Treatment of very young animals (less than 40 kg bodyweight) is generally not warranted.

ADMINISTRATION: Using the Pour-On Applicator

Attach the open end of the draw-off tubing to the Pour-On applicator. Attach draw-off tubing to the draw-off cap stem. Replace shipping cap with the draw-off cap and tighten the draw-off cap. Invert the backpack. Gently prime the applicator whilst checking for leaks. Follow manufacturer's directions for correct use and care of equipment.

The Owtbac Doramate Pour-On Endectocide applicator is recommended for use with this product. Some applicators may not be suitable for use with this formulation. If unsure, check with the manufacturer, or your supplier.

Directions for 22 litre Container

Attach internal tube to internal tube barb on draw-off cap provided. Remove shipping cap from container and replace with draw-off cap.

Place the external draw-up hose onto the external hose barb, positioned on the outside (top) of the draw-off cap. Screw the anti-kink spring over the hose and hose barb.

Attach the other end of the hose to the hose barb on the Pour-On applicator. Screw the anti-kink spring over the hose and gun's hose barb. Set the applicator to the maximum dose. Prime the applicator. Check for leaks, or any air bubbles entering the hose. Place the nozzle of the applicator into a clean, dry receptacle and depress finger grip, pump these grips until the cylinder is full of product and the air is removed. A small bubble may appear in the cylinder. This will not affect dosing accuracy.

Select the desired dose and administer product. To disconnect the system, proceed as follows:

- a) Carefully unscrew the breather cap from the container. Lift the internal draw tube until it is clear of Owtbac Doramate Pour-On Endectocide in the 22-L container.
- b) Place the nozzle of the gun back into the 22-L container and squeeze the finger grips until all product is removed from the tube and applicator.
- c) Replace original shipping cap onto the 22-L container.

Follow manufacturer's recommendation for care and storage of the dosing applicator.

Using the dosing cup (1 litre)

Refer to instructions on the inner carton.

Treatments per pack

As a quick reference, treatments per pack are tabled below.

<Insert Table 2.>

This section contains file attachment.

General Directions:

Owtbac Doramate Pour-On Endectocide is a ready-to-use, pale blue solution containing doramectin 5 mg/mL. It is formulated to deliver the recommended dosage of 500 g/kg bodyweight when given by topical administration at the rate of 1 mL/10 kg bodyweight.

For best results, DO NOT treat cattle when their hide or hair is wet.

DO NOT apply to areas of skin which are contaminated with mud or manure.

PRODUCT CHARACTERISTICS

Owtbac Doramate Pour-On Endectocide is a highly active broad spectrum parasiticide for topical administration to cattle. It contains doramectin, a member of the macrocyclic lactone family of chemicals. Doramectin is isolated from fermentation of selected strains derived from the soil organism *Streptomyces avermitilis*.

The primary mode of action of doramectin is to modulate chloride ion channel activity in the nervous system of nematodes and arthropods. Doramectin binds to receptors that increase membrane permeability to chloride ions, inhibiting the electrical activity of nerve cells in nematodes and muscle cells in arthropods, causing paralysis and death of the parasites. In mammals the neuronal receptors to which doramectin binds are localised within the central nervous system (CNS), a site reached by only negligible concentrations of doramectin.

Broad-spectrum: a single treatment with Owtbac Doramate Pour-On Endectocide effectively treats and controls a wide range of internal parasites (roundworms) and external parasites (arthropods) that impair the health and productivity of cattle.

Persistent action: the persistent drug concentrations that result from the product's unique pharmacokinetics enable it to protect cattle against parasite infection and reinfection for extended periods following treatment.

Safety: Owtbac Doramate Pour-On Endectocide has a wide margin of safety in all classes of cattle. Its broad spectrum of activity, favourable pharmacokinetics and exceptional toleration make it an ideal product for application as an antiparasitic for cattle.

Rainfast: the efficacy of Owtbac Doramate Pour-On Endectocide is not adversely affected if applied when the hide is wet or if rain falls shortly after treatment. However, treatment of animals with wet hides or when rain threatens should be avoided as it is not good agricultural practice.

Persistent Protection

Extensive studies have also demonstrated the following levels of persistent protection against reinfection from important worm species.

Species Period of Protection Following Treatment

Ostertagia ostertagi Up to 35 days

Haemonchus placei Up to 35 days

Trichostrongylus axei Up to 35 days

Cooperia spp. Up to 35 days

Cooperia oncophora Up to 21 days

Dictyocaulus viviparus Up to 28 days

Oesophagostomum radiatum Up to 21 days

Bunostomum phlebotomum Up to 21 days

Owtbac Doramate Pour-On Endectocide controls buffalo flies (*Haematobia irritans exigua*) for up to 14 days after treatment.

	<p>To obtain optimal benefit from the persistent-action of Owtbac Doramate Pour-On Endectocide against internal parasites, it is recommended that cattle which are set-stocked should be treated twice at 8-week intervals.</p> <p>Used in this way Owtbac Doramate Pour-On Endectocide will reduce the build-up of infective larvae on pasture and protect such animals from parasitic gastro-enteritis and parasitic bronchitis by reducing pasture larval challenge.</p> <p>NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.</p>
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Withholding Periods:	<p>Meat – DO NOT USE less than 42 days before slaughter for human consumption.</p> <p>Milk – NIL</p>
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Trade Advice:	<p>EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 42 days before slaughter for export. Before using this product, confirm the current ESI from The United Animal Healthcare (Inner Mongolia) Co., Ltd. on 1300 646 614 or the APVMA website (apvma.gov.au/residues).</p>
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Safety Directions:	<p>Poisonous if swallowed. May irritate the eyes and skin. Avoid contact with skin and eyes. When using the product, wear face shield or goggles. If product in eyes, wash it out immediately with water. Wash hands after use. After each day's use, wash face shield or goggles.</p>
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First Aid Instructions:	<p>If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.</p>
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First Aid Warnings:	
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Additional User Safety:	<p>Use only in well-ventilated surroundings.</p> <p>Flammable—Keep away from heat, sparks, open flame and other sources of ignition.</p> <p>Additional information is listed in the Material Safety Data Sheet.</p>
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Environmental Statements:	<p>ENVIRONMENTAL PROTECTION</p> <p>Very toxic to aquatic life. Do not contaminate wetlands or watercourses with this product or used containers.</p> <p>Toxic to dung fauna. However, use of the product as directed is not expected to have long-term adverse effects on dung fauna or dung degradation.</p>
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Disposal:	<p>[1 L] Dispose of container by wrapping with paper and putting in garbage.</p> <p>[2.5 L, 5 L, 20 L, 22 L] Triple-rinse container and dispose of rinsate in compliance with relevant local, state or territory government regulations. Do not dispose of undiluted chemicals on-site. If recycling, replace cap and return clean container to recycler or designated collection point. If the container has the drumMUSTER logo visible, and has been thoroughly cleaned and dried, and is free of any visible residues, it can be recycled at any drumMUSTER collection or similar container management program site. The cap</p>
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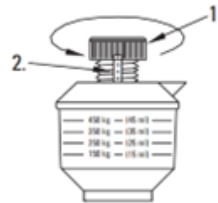
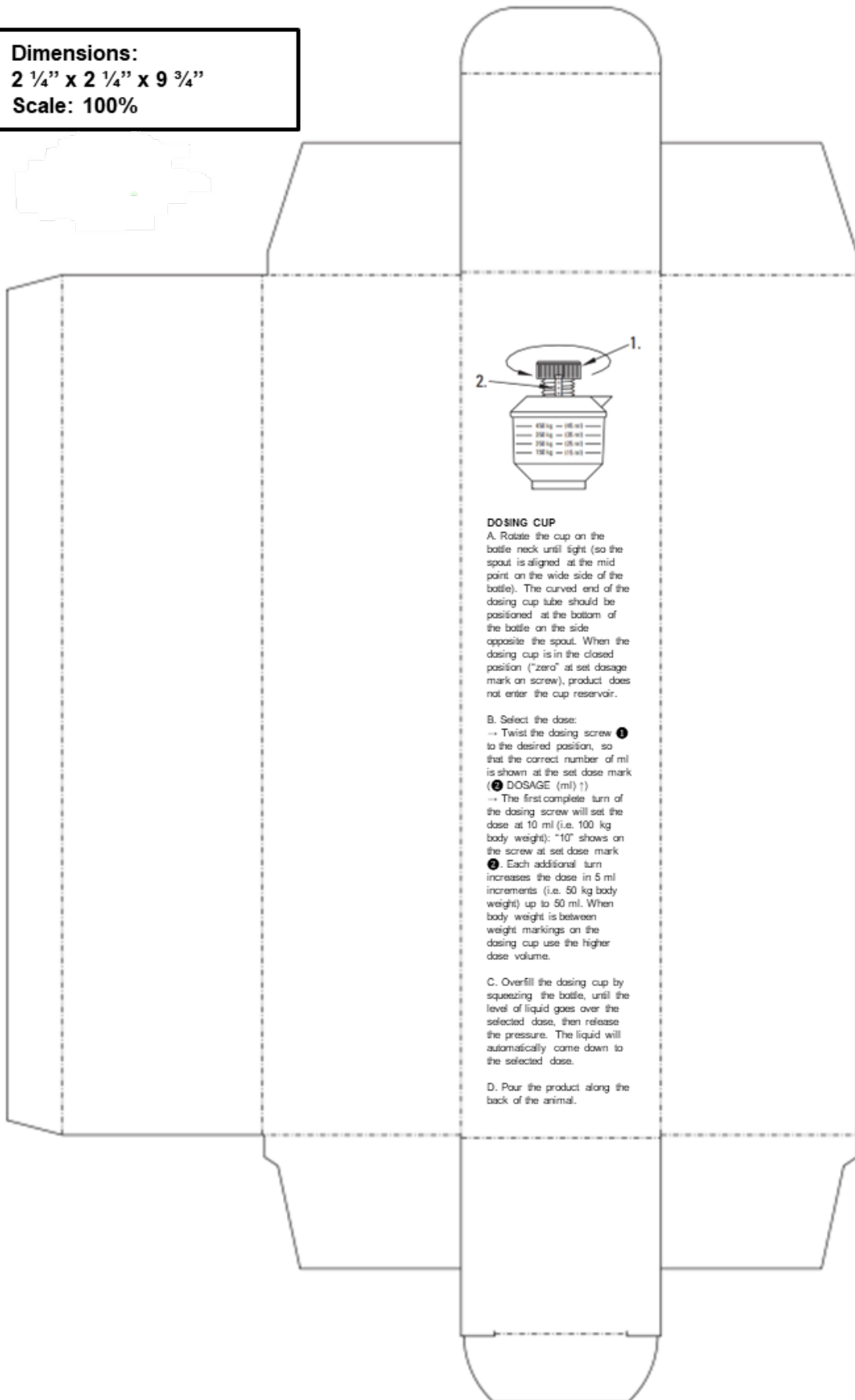
	should not be replaced, but may be recycled separately with the container. If not recycling, break, crush, or puncture container and deliver to an approved waste management facility. If an approved waste management facility is not available, bury the broken, crushed or punctured containers 500 mm below the surface in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and tree roots, in compliance with relevant local, state or territory government regulations. Do not burn empty containers or product.
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Storage:	Store below 30°C (room temperature). Protect from direct sunlight.
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Table 2: Treatments per pack.

Weight (kg)	Treatments Per Pack				
	1 L	2.5 L	5 L	20 L	22 L
50	200	500	1000	4000	4400
75	133	333	666	2660	2926
100	100	250	500	2000	2200
150	66	166	333	1320	1452
200	50	125	250	1000	1100
250	40	100	200	800	880
300	33	83	166	660	726
350	28	71	142	560	616
400	25	62	125	500	550
450	22	55	111	440	484
500	20	50	100	400	440
550	18	45	90	360	396
600	16	41	83	320	352
650	15	38	76	300	330

Dimensions:
2 1/4" x 2 1/4" x 9 3/4"
Scale: 100%



DOSING CUP

A. Rotate the cup on the bottle neck until tight (so the spout is aligned at the mid point on the wide side of the bottle). The curved end of the dosing cup tube should be positioned at the bottom of the bottle on the side opposite the spout. When the dosing cup is in the closed position ("zero" at set dosage mark on screw), product does not enter the cup reservoir.

B. Select the dose:

→ Twist the dosing screw ① to the desired position, so that the correct number of ml is shown at the set dose mark ② (DOSAGE (ml) †)

→ The first complete turn of the dosing screw will set the dose at 10 ml (i.e. 100 kg body weight); "10" shows on the screw at set dose mark ②. Each additional turn increases the dose in 5 ml increments (i.e. 50 kg body weight) up to 50 ml. When body weight is between weight markings on the dosing cup use the higher dose volume.

C. Overfill the dosing cup by squeezing the bottle, until the level of liquid goes over the selected dose, then release the pressure. The liquid will automatically come down to the selected dose.

D. Pour the product along the back of the animal.