



Australian Pesticides &
Veterinary Medicines Authority

Product Name: Owtbac Moxidone Long Acting Injection for Cattle

APVMA Approval No: 96833/150797

Label Name:	Owtbac Moxidone Long Acting Injection for Cattle
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Signal Headings:	POISON KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
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Constituent Statements:	100 mg/mL MOXIDECTIN
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Claims:	<p>For the treatment and control of moxidectin sensitive internal and external parasites in cattle.</p> <p>Owtbac Moxidone Long Acting Injection for Cattle contains moxidectin, a second-generation member of the macrocyclic lactone family of chemicals. It is effective against sensitive strains of the following parasites:</p> <p>Internal Parasites: Mature (adult) and immature (L4): Haemonchus placei (Barber's pole worm) Haemonchus contortus Ostertagia ostertagi / Ostertagia lyrata (including inhibited larvae) Trichostrongylus spp. (Black scour worms) Trichostrongylus axei Cooperia oncophora (Small intestinal worm) Cooperia pectinata Cooperia punctata Oesophagostomum radiatum (Nodule worm) Bunostomum phlebotomum (Hookworm) Trichuris discolor (Whipworm) Trichuris ovis Dictyocaulus viviparus (Lungworm)</p> <p>Adult Nematodes: Nematodirus spathiger Nematodirus helvetianus</p> <p>External Parasites:</p> <p>Lice (Sucking lice): Linognathus vituli Haematopinus eurysternus Solenopotes capillatus</p>
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Aids in the control of *Bovicola bovis* (biting lice).

Mites:
Chorioptes bovis

Ticks:
Rhipicephalus (Boophilus) microplus

PROTECTION PERIOD

When Owtbac Moxidone Long Acting Injection for Cattle is used at the recommended dose rate as a single subcutaneous injection, it prevents re-infection of cattle with parasites as in the following table:

Table 1

Parasite species	Persistent protection period
<i>Ostertagia</i> spp.	112 days
<i>Haemonchus</i> spp.	120 days
<i>Trichostrongylus axei</i>	72 days
<i>Cooperia</i> spp.	21 days
<i>Dictyocaulus viviparus</i>	120 days
<i>Oesophagostomum radiatum</i>	120 days
<i>Linognathus vituli</i>	133 days

Owtbac Moxidone Long Acting Injection for Cattle is effective for treatment and control of cattle tick, including strains resistant to organophosphates, synthetic pyrethroids and amidines. The persistent activity of Owtbac Moxidone Long Acting Injection for Cattle prevents the development of viable cattle tick (*Rhipicephalus (Boophilus) microplus*) for at least 51 days and prevents egg production for at least 65 days after treatment. Some engorged females containing viable eggs may continue to drop for up to 4 days after treatment. This should be taken into account when planning a strategic treatment program.

Resistance may develop to any chemical.

Net Contents: 500 mL

Directions for Use:

Restrains:

DO NOT USE in cattle that may be exported live for slaughter. Use is permitted in cattle that may be exported live for breeding.

DO NOT USE in lactating cows or within 80 days of calving where milk may be used or processed for human consumption.

INJECT ONLY by subcutaneous injection into the back of the ear (as directed below). DO NOT inject anywhere else in the animal. Injection sites anywhere else on the animal may result in injection site residues that exceed approved limits at the Withholding Period or Export Slaughter Interval.

RE-TREATMENT INTERVAL: DO NOT RE-TREAT animals for 56 days after administration.

Contraindications:

Precautions:	
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Side Effects:	
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Dosage and Administration:	<p>Use the contents within 6 months of first broaching the vial. Discard the unused portion.</p> <p>Dose Rate: 1 mg moxidectin/kg liveweight (1 mL/100 kg liveweight).</p> <p>Owtbac Moxidone Long-Acting Injection for Cattle must be administered by subcutaneous (under the skin) injection into the back of the ear towards its base. DO NOT administer anywhere else on the animal. Avoid intravascular (into a blood vessel) injection. Some injection site reactions or generalised reactions are possible. Treat as appropriate. The animal must be confined in a restraint mechanism (head bail). Using a 5 mL injector gun fitted with a 16 or 18 gauge, 12 to 18 mm needle, inject into the back of the ear towards its base. To accomplish this the needle should be inserted at the point indicated by the 'X' in the illustration, all the way up to the hub. Inject slowly and after injection withdraw the needle and place finger pressure on the site for a few seconds.</p> <p>Diagram 1. Injection site at back of ear</p> <p>Any potential site reactions may be minimised by attention to injection hygiene. If any generalised reactions such as ataxia (staggering), lying down or excess salivation occur, seek veterinary advice.</p> <p>The product is ready to use. Administer the dose according to the dosage table using an appropriate 5 mL injector gun. DO NOT use any other injector. Check dose rates and equipment before treatment commences. Cattle should be weighed prior to dosing and treated according to the weight range bracket in the dosage table below. DO NOT underdose.</p> <p>A maximum of 5 mL can be injected into one site. Hence, for cattle above 500 kg, half of the total dose volume should be injected into the back of one ear towards its base and the other half of the total dose should be injected into the back of the other ear towards its base (for example, 600 kg cattle receive a total dose of 6 mL, with 3 mL injected into the back of each ear near its base).</p> <p>Table 2. Dose rate table:</p> <p>A representative sample of animals should be weighed before treatment either with scales or a weighband. Dose rate to be based on heaviest cattle in each group (bulls, cows, steers, calves, etc.). DO NOT underdose. Where there is a large variation in size within a group, draft into two or more lines based on bodyweight, to avoid excessive overdosing.</p> <p>This section contains file attachment.</p>
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General Directions:	<p>Owtbac Moxidone Long Acting Injection for Cattle has a wide margin of safety when used as recommended.</p> <p>Owtbac Moxidone Long Acting Injection for Cattle is safe to use concurrently with other treatments including mineral supplements and vaccines.</p> <p>Caution: Avoid Carcass Damage</p>
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	<ol style="list-style-type: none"> 1. Rinse all injection syringes and ensure needles and draw off tubes are free of dirt and unused product before and after use. 2. Sanitise plastic injection apparatus by immersing in 500 mL of water plus 20 mL of household bleach (4% w/v available chlorine) for 1 hour. Flush with cool boiled water before use. 3. Maintain cleanliness at all times. 4. Keep needles sharp and clean. Replace frequently. 5. As far as possible, avoid injection of animals during wet weather or under dusty conditions. 6. This product should be injected only under the skin into the back surface of the ear. It should be injected in the third of the ear closest to the head. DO NOT inject at any other site. <p>EFFECT ON DUNG BEETLES</p> <p>When applied as directed, the levels of Owtbac Moxidone Long Acting Injection for Cattle in the faeces of treated cattle are not likely to have any significant adverse effect on the following dung beetles: Onthophagus gazella, O. taurus, Euoniticellus intermedius and E. fulvus. Effects on other dung beetle species have not been fully evaluated.</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:	Meat: DO NOT USE less than 56 days before slaughter for human consumption.
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Trade Advice:	EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 108 days before slaughter for export. Before using this product, confirm the current ESI from the distributor on 1300 646 614 or the APVMA website (www.apvma.gov.au/residues).
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Safety Directions:	
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First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.
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First Aid Warnings:	
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Additional User Safety:	<p>WARNING: AVOID SELF-INJECTION.</p> <p>Accidental self-injection may cause an inflammatory or allergic response and medical advice should be sought in these cases. Deep injections, particularly if they are near a joint or associated with local bruising may require medical management. In most circumstances application of gentle pressure with absorbent material, e.g. facial tissues, to the needle puncture area to swab up unabsorbed product followed by cleaning of the damaged area with a suitable disinfectant will be sufficient to prevent problems.</p> <p>Additional information is listed in the safety data sheet (SDS).</p>
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Environmental Statements:	<p>ENVIRONMENTAL PROTECTION</p> <p>Moxidectin is extremely toxic to aquatic species. DO NOT contaminate dams, rivers, streams or other waterways with the chemical or used containers.</p>
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Disposal:	Dispose of container by wrapping with paper and putting in garbage.
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Discarded needles should immediately be placed in a designated and appropriately labelled "sharps" container. The container should be of a type to reduce the possibility of injury to handlers during collection and disposal. Incineration is the preferred method of disposal, otherwise sharps should be buried at a suitable site, such as an on-farm chemical disposal pit located away from water courses.

Storage:	Store below 30°C (room temperature). Protect from light.
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DOSAGE AND ADMINISTRATION

Diagram 1. Injection site at back of ear

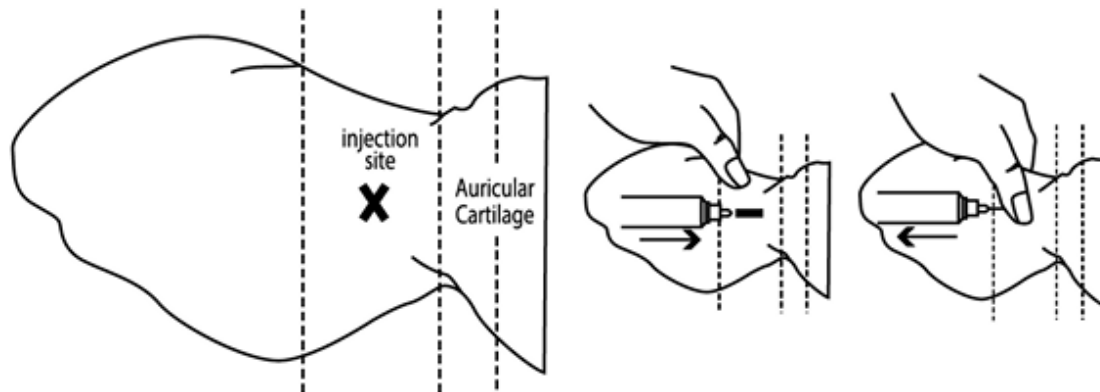


Table 2. Dose rate table:

Weight range (kg)	Total Dose volume (mL)	Dose volume per ear (mL)
100*	1	
101 - 150	1.5	
151 - 200	2	
201 - 250	2.5	
251 - 300	3	
301 - 350	3.5	
351 - 400	4	
401 - 450	4.5	
451 - 500	5	
501 - 550	5.5	2.75
551 - 600	6	3
601 - 650	6.5	3.25
651 - 700	7	3.5
701 - 750	7.5	3.75
751 - 800	8	4
801 - 850	8.5	4.25
851 - 900	9	4.5
901 - 950	9.5	4.75
951 - 1000*	10	5

*DO NOT use in cattle less than 100 kg

*DO NOT use in cattle greater than 1000 kg