



Australian Pesticides &
Veterinary Medicines Authority

Product Name: Owtbac Moxidone Long Acting Injection for Sheep
APVMA Approval No: 95510/145911

Label Name:	Owtbac Moxidone Long Acting Injection for Sheep
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Signal Headings:	CAUTION KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
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Constituent Statements:	20 g/L MOXIDECTIN
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Claims:	<p>For the treatment and control of roundworms, nasal bot and itch mite in sheep.</p> <p>For protection against severe challenge by <i>Haemonchus contortus</i> (Barber's Pole Worm) for up to 4 months.</p> <p>Owtbac Moxidone Long-Acting injection for Sheep contains moxidectin, a second generation of the macrocyclic lactone family. It is effective against sensitive strains of the following parasites and provides protection against severe challenge by <i>Haemonchus contortus</i> (Barber's Pole Worm) for up to 4 months.</p> <p>Internal Parasites:</p> <ul style="list-style-type: none">Mature (adult) and immature (L4)<i>Haemonchus contortus</i> (Barber's Pole Worm)<i>Trichostrongylus</i> spp. (Black Scour Worm)<i>Trichostrongylus axei</i> (Stomach Hair Worm)<i>Trichostrongylus colubriformis</i><i>Teladorsagia</i> (<i>Ostertagia</i>) spp. (Small Brown Stomach Worm)<i>Teladorsagia</i> (<i>Ostertagia</i>) <i>circumcincta</i><i>Ostertagia lyrata</i><i>Cooperia</i> spp. (Small Intestinal Worm)<i>Cooperia oncophora</i><i>Nematodirus</i> spp. (Thin Necked Intestinal Worm)<i>Nematodirus battus</i><i>Nematodirus filicollis</i><i>Nematodirus spathiger</i><i>Strongyloides papillosus</i> (Intestinal Threadworm)<i>Oesophagostomum columbianum</i> (Nodule Worm)<i>Chabertia ovina</i> (Large Mouthed Bowel Worm)<i>Dictyocaulus filaria</i> (Large Lungworm) <p>Adult Nematodes:</p> <ul style="list-style-type: none"><i>Trichostrongylus rugatus</i><i>Trichostrongylus vitrinus</i>
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Ostertagia trifurcata
 Cooperia curticei
 Nematodirus abnormalis
 Nematodirus helvetianus
 Oesophagostomum venulosum (Large Bowel Worm)
 Trichuris ovis

External Parasites:
 Psorobia ovis (Itch mite)
 Oestrus ovis (Nasal Bot)

PROTECTION PERIOD

When Owtbac Moxidone Long-Acting injection for Sheep is used at the recommended dose rate as a single subcutaneous injection, it prevents reinfection of sheep with nematodes as in the following table:

Protection	<i>H. contortus</i>	<i>T. (O.) circumcincta</i>	<i>T. colubriformis</i>
Prevents reinfection of sheep with worms	Not less than 91 days	Not less than 91 days	Up to 49 days

Owtbac Moxidone Long-Acting injection for Sheep is effective against benzimidazole and levamisole resistant strains of *H. contortus*, *T. colubriformis* and *T. (O.) circumcincta*.

Owtbac Moxidone Long-Acting injection for Sheep has shown efficacy against a number of avermectin resistant strains of *H. contortus* and *Teladorsagia (Ostertagia) spp.* However, as Owtbac Moxidone Long-Acting injection for Sheep shares a similar mechanism of action to the avermectins, it SHOULD NOT be used where avermectin resistance is present, except where specifically recommended by an advisor.

RESISTANCE AND WORM CONTROL PROGRAMS

Resistance may develop to any anthelmintic chemical. Ask your local veterinary practitioner or animal health adviser for recommended parasite management practices for your area to reduce development of resistance. It is advisable that a resistance test be conducted before any parasite treatment is used.

Net Contents:	200 mL, 500 mL, 550 mL
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Directions for Use:	
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Restraints:	DO NOT USE in ewes which are producing or may in the future produce milk that may be used or processed for human consumption. DO NOT USE in lambs less than 20 kg Re-treatment interval: DO NOT RE-TREAT sheep for 91 days after last treatment.
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Contraindications:	Not recommended in goats as safety and efficacy have not been evaluated.
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Precautions:	
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Side Effects:	
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Dosage and Administration:	This section contains file attachment.
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General Directions:	<p>Owtbac Moxidone Long-Acting injection for Sheep has a wide margin of safety when used as recommended.</p> <p>Owtbac Moxidone Long-Acting injection for Sheep is safe to use concurrently with other treatments including mineral supplements and vaccines. It is recommended that vaccines are injected on the opposite side of the neck to Owtbac Moxidone Long-Acting injection for Sheep.</p> <p>Caution: avoid carcass damage.</p> <ul style="list-style-type: none"> •rinse all injection syringes, ensure needles and draw off tubes are free of dirt and unused product before and after use; •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; •maintain cleanliness at all times; •keep needles sharp and clean, replace frequently; •avoid injection of animals during wet weather or under dusty conditions as far as possible; •inject the product under the skin, NOT into the muscle tissue; •inject at the base of the ear or high on the neck behind the ear.
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Withholding Periods:	MEAT: DO NOT USE less than 91 days before slaughter for human consumption.
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Trade Advice:	EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 133 days before slaughter for export. Before using this product, confirm the current ESI from the distributor 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>If self-injection occurs, seek medical advice as soon as possible.</p> <p>Accidental self-injection may cause a persistent inflammatory or an allergic response. Medical advice should be sought as soon as possible on the management of all instances of self-injection, especially deep injections, those near a joint or those associated with bruising. The application of gentle pressure with absorbent material, eg. facial tissues, to the needle puncture area will swab up unabsorbed product. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a suitable antiseptic applied.</p>
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Environmental Statements:	ENVIRONMENTAL PROTECTION Extremely toxic to aquatic species. Do not contaminate dams, rivers, streams or other waterways with the chemical or used container.
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Disposal:	Dispose of container by wrapping with paper and putting in garbage. Discarded needles/ sharps should immediately be placed in a designated and appropriately labelled 'sharps' container.
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Storage:	Store below 30 °C (room temperature). Protect from light.
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DOSAGE AND ADMINISTRATION

Use the contents within 6 months of first broaching the vial. Discard the unused portion.

DOSE RATE

1 mg moxidectin/kg liveweight (1 mL/20 kg liveweight).

Owtbac Moxidone Long-Acting injection for Sheep must be administered by subcutaneous (under the skin) injection at the base of the ear or high on the neck behind the ear.

The product is ready to use. Administer the dose according to the dosage table using an appropriate sheep injector gun. DO NOT use any other injector. Check dose rates and equipment before treatment commences. Sheep should be weighed prior to dosing and treated according to the weight range bracket in the dosage table below. DO NOT underdose.

DOSAGE TABLE:

Weight range (kg)	Dose volume (mL)
20*	1
21-30	1.5
31-40	2
41-50	2.5
51-60	3
61-70	3.5
71-80	4
81-90 ⁺	4.5

*DO NOT use in LAMBS less than 20 kg

⁺Animals heavier than 90kg should be dosed at 0.5 mL per 10 kg

A representative sample of animals should be weighed before treatment. Dose the mob to the heaviest animal by live weight in each group (ewes, wethers, rams, lambs). Where there is a large variation in size within the group, dose rate should be based on the label directions for each weight range. DO NOT underdose. Drafting into two or more lines may be appropriate, to avoid excessive overdosing.