

TAURAMOX- moxidectin injection, solution
Norbrook Laboratories Limited

Tauramox™
(moxidectin)
Injectable Solution for Beef
and Nonlactating Dairy Cattle

Antiparasitic

Contains 10 mg moxidectin/mL

Not for use in female dairy cattle 20 months of age or older (including dry dairy cows), veal calves, and calves less than 8 weeks of age. For Treatment of Infections and Infestations Due to Internal and External Parasites of Cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

PRODUCT DESCRIPTION

Tauramox™ Injectable Solution is a ready-to-use, sterile solution containing 1% moxidectin. Moxidectin is an endectocide in the milbemycin chemical class which shares the distinctive mode of action characteristic of macrocyclic lactones. Tauramox™ Injectable is specially formulated to allow moxidectin to be absorbed from the site of injection and distributed internally to the areas of the body affected by endo- and/or ectoparasitism. Moxidectin binds selectively and with high affinity to glutamate-gated chloride ion channels which are critical to the function of invertebrate nerve and muscle cells. This interferes with neurotransmission resulting in paralysis and elimination of the parasite.

INDICATIONS

Tauramox™ Injectable, when administered at the recommended dose level of 0.2 mg/2.2 lb (0.2 mg/kg) body weight, is effective in the treatment and control of the following internal and external parasites of cattle:

Gastrointestinal Roundworms	Lungworms
<i>Ostertagia ostertagi</i> - Adults and L4 (including inhibited Larvae)	<i>Dictyocaulus viviparus</i> - Adults and L4
<i>Haemonchus placei</i> - Adults	Cattle Grubs
<i>Trichostrongylus axei</i> - Adults and L4	<i>Hypoderma bovis</i>
<i>Trichostrongylus colubriformis</i> - Adults and L4	<i>Hypoderma lineatum</i>
<i>Cooperia oncophora</i> - Adults	Mites
<i>Cooperia pectinata</i> - Adults	<i>Psoroptes ovis</i> (<i>Psoroptes communis</i> var. <i>bovis</i>)
	Lice

<i>Cooperia punctata</i> - Adults and L4 <i>Cooperia spatulata</i> - Adults <i>Cooperia surnabada</i> - Adults and L4 <i>Nematodirus helvetianus</i> - Adults <i>Oesophagostomum radiatum</i> - Adults and L4 <i>Trichuris</i> spp.- Adults	<i>Linognathus vituli</i> <i>Solenopotes capillatus</i>
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Persistent Activity: Moxidectin Injectable has been proven to effectively protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 42 days after treatment, *Haemonchus placei* for 35 days after treatment, and *Ostertagia ostertagi* and *Trichostrongylus axei* for 14 days after treatment.

Management Considerations for External Parasites:

For most effective external parasite control, Tauramox™ Injectable should be administered to all cattle in the herd. Cattle entering the herd following this administration should be treated prior to introduction. Consult your veterinarian or a livestock entomologist for the most appropriate time to administer Tauramox™ Injectable in your location to effectively control external parasites.

DOSAGE

The recommended rate of administration for Tauramox™ Injectable is 1 mL for each 110 lb (50 kg) body weight to provide 0.2 mg moxidectin/2.2 lb (0.2 mg/kg) body weight. The table below will assist in the calculation of the appropriate volume of injectable which must be administered based on the weight of animal being treated. Be careful not to overdose animals; estimate animal's body weight as closely as possible or weigh animals individually.

Weight (lb)	165	220	330	440	550	660	770	880	990	1100
Weight (kg)	75	100	150	200	250	300	350	400	450	500
Dose (mL)	1.5	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0

- Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

ADMINISTRATION

Tauramox™ Injectable should be administered by subcutaneous injection under the loose skin in front of or behind the shoulder (Figure 1). Needles 1/2 to 3/4 inch in length and 16 to 18 gauge are recommended for subcutaneous injections. Use sterile, dry equipment and aseptic procedures when withdrawing and administering Tauramox™.

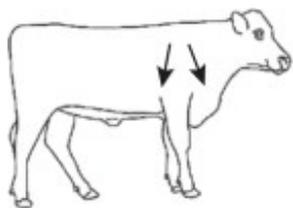


Figure 1. Sites for administration of Tauramox™ Injectable

HUMAN WARNINGS

Not For Use in Humans. Keep this and all drugs out of the reach of children.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Norbrook at 1-866-591-5777. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

RESIDUE WARNINGS

Cattle must not be slaughtered for human consumption within 21 days of treatment. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

ANIMAL SAFETY WARNINGS

Do not use in sick, debilitated, or underweight animals. In foreign countries there have been reports of adverse effects, including death. This product should not be used in calves less than 8 weeks of age because safety testing has not been done in the U.S. in calves less than 8 weeks of age.

ENVIRONMENTAL WARNINGS

Studies indicate that when moxidectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive. Free moxidectin may adversely affect fish and certain aquatic organisms. Do not contaminate water by direct application or by improper disposal of drug containers.

OTHER WARNINGS

- Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.
- Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.
- Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd/flock, prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count

reduction test or another appropriate method).

- A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

PRECAUTIONS

Tauramox™ Injectable has been formulated specifically for subcutaneous injection in cattle and should not be given by other routes of administration. Subcutaneous injection can cause transient local tissue reaction that may result in trim loss of edible tissue at slaughter if animals are slaughtered within 35 days after treatment. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Tauramox™ Injectable is effective against the migrating stage of cattle grubs (*Hypoderma* larvae). Treatment with Tauramox™ Injectable during the period when grubs are migrating through vital areas may cause undesirable host-parasite reactions. Killing *H. lineatum* when they are located in peri-esophageal tissues may cause bloat. Killing *H. bovis* when they are in the vertebral canal may cause staggering or hindlimb paralysis. Cattle should be treated as soon as possible after heel fly (warble fly) season to avoid this potential problem. Cattle treated with Tauramox™ Injectable at the end of fly season can be retreated during the winter without danger of grub-related reactions. Consult your veterinarian for more information regarding these secondary grub reactions and the correct time to treat with Tauramox™ Injectable.

ANIMAL SAFETY

U.S. tolerance and toxicity studies have demonstrated that moxidectin injectable has an adequate margin of safety for use in cattle 8 weeks of age and older. No toxic signs were seen in growing cattle given up to 5 times the recommended dose. Calves as young as 8 weeks of age showed no toxic signs when treated with up to 3 times the recommended dose while nursing from cows concurrently treated with the recommended dose level of moxidectin injectable. Mild, transient ataxia was noted in growing cattle receiving 10 times the recommended dose and in bulls treated at 4.5 times the recommended dose. In breeding animals (bulls and cows in estrous and during early, mid and late pregnancy), treatment with at least 3 times the recommended dose had no effect on breeding performance.

Signs of toxicity include ataxia, excessive salivation, depression, and mydriasis. These signs usually occur within 12 to 48 hours post-treatment.

STORAGE

Store at 59° to 77°F (15° to 25°C). Exposure to temperature up to 104°F (40°C) may be tolerated provided the mean kinetic temperature does not exceed 77°F (25°C). Use within 3 months of first puncture and puncture a maximum of 56 times. If more than 56 punctures are anticipated, the use of multi-dosing equipment is recommended. If using a needle or draw-off spike larger than 16 gauge, discard any remaining product immediately after use.

DISPOSAL

Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

PACKAGE INFORMATION

Tauramox™ Injectable is available in 250 and 500 mL amber glass bottles.

Restricted Drug (CA) - Use Only As Directed

Approved by FDA under ANADA # 200-746

Tauramox™ is a trademark of
Norbrook Laboratories Limited.

Manufactured by:
Norbrook Laboratories Limited,
Newry, BT35 6QQ, Co. Down, Northern Ireland

Revised February 2023

015670I01



Norbrook®

Principal Display Panel - 500 mL Carton Label

NDC 55529-192-05

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(moxidectin)**

**Injectable Solution for Beef
and Nonlactating Dairy Cattle**

Antiparasitic

Sterile

**Contains 10 mg moxidectin/mL
(5,000 mg/500 mL)**

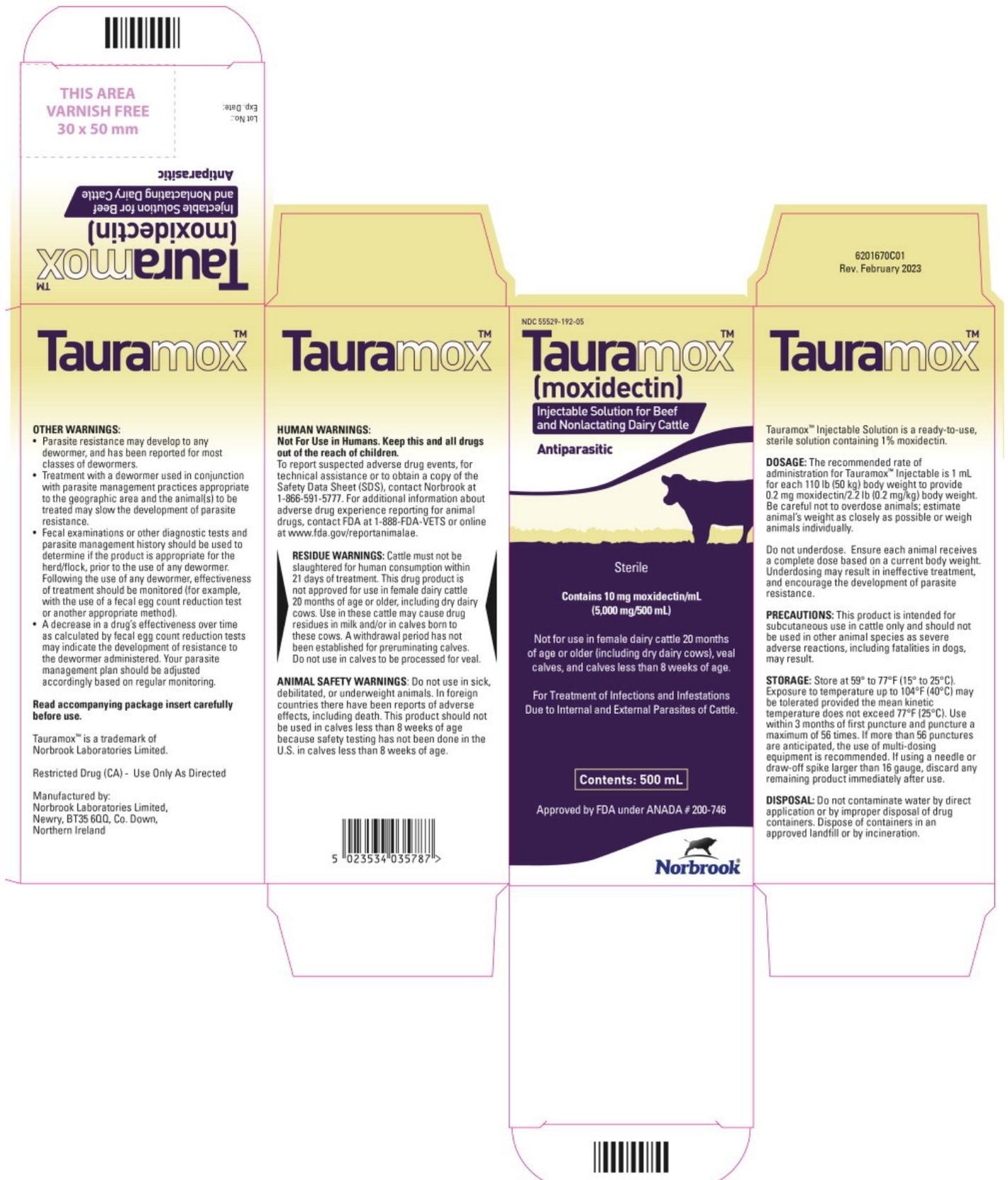
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STERILE
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Lot No.:
Exp. Date:

012670L01
Rev. February 2023

TAURAMOX

moxidectin injection, solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:55529-192
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MOXIDECTIN (UNII: NGU5H31YO9) (MOXIDECTIN - UNII:NGU5H31YO9)	MOXIDECTIN	10 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55529-192-04	1 in 1 CARTON		
1		250 mL in 1 VIAL, GLASS		
2	NDC:55529-192-05	1 in 1 CARTON		
2		500 mL in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200746	04/24/2023	

Labeler - Norbrook Laboratories Limited (214580029)**Establishment**

Name	Address	ID/FEI	Business Operations
Norbrook Laboratories Limited		211218325	MANUFACTURE, PACK, LABEL, ANALYSIS

Revised: 5/2023

Norbrook Laboratories Limited