

MOXIDECTIN- moxidectin injection, solution

Durvet

Moxidectin Injection **(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

Moxidectin Injection (moxidectin) 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. Moxidectin Injection 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

Moxidectin Injection, 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

Ostertagia ostertagi - Adults and L4 (including inhibited Larvae)

Haemonchus placei - Adults

Trichostrongylus axei - Adults and L4

Trichostrongylus colubriformis - Adults and L4

Cooperia oncophora - Adults

Cooperia pectinata - Adults

Cooperia punctata - Adults and L4

Cooperia spatulata - Adults

Cooperia surnabada - Adults and L4

Nematodirus helvetianus - Adults

Oesophagostomum radiatum - Adults and L4

Trichuris spp. - Adults

Lungworms

Dictyocaulus viviparus - Adults and L4

Cattle Grubs

Hypoderma bovis
Hypoderma lineatum

Mites

Psoroptes ovis
(*Psoroptes communis* var. *bovis*)

Lice

Linognathus vituli
Solenopotes capillatus

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, Moxidectin Injection (moxidectin) 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 Moxidectin Injection in your location to effectively control external parasites.

DOSAGE

The recommended rate of administration for Moxidectin Injection 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

Moxidectin Injection 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 Moxidectin.

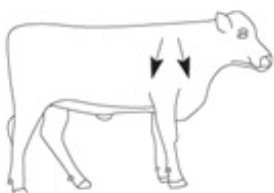


Figure 1. Sites for administration of Moxidectin Injection

HUMAN WARNINGS

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

CONTACT INFORMATION:

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. 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

Moxidectin Injection (moxidectin) 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.

Moxidectin Injection is effective against the migrating stage of cattle grubs (*Hypoderma*

larvae). Treatment with Moxidectin Injection (moxidectin) 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 Moxidectin Injection 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 Moxidectin Injection.

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 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F). Use within 28 days of first puncture and puncture a maximum of 30 times with a needle or 5 times with a dosage delivery device. When using a draw-off spike or needle larger than 4-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

Moxidectin Injection is available in 500 mL plastic, multi-dose bottles.

Restricted Drug (CA) - Use Only As Directed.

Approved by FDA under ANADA # 200-788

**Manufactured for
Durvet, Inc.
Blue Springs, MO 64014**

www.durvet.com

Made in Canada

Rev. 07/24

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DOSAGE: The recommended rate of administration for Moxidectin Injection 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. Be careful not to overdose animals; estimate animal's weight as closely as possible or weigh animals individually.

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.

PRECAUTIONS: This product is intended for subcutaneous use in cattle only and should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

STORAGE: Store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F). Use within 28 days of first puncture and puncture a maximum of 30 times with a needle or 5 times with a dosage delivery device. When using a draw-off spike or needle larger than 4-gauge, discard any remaining product immediately after use.

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NDC 30798-314-17

durvet

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Injectable Solution for Beef and Nonlactating Dairy Cattle

Antiparasitic

**Sterile
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

Approved by FDA under ANADA # 200-788

**Net Contents:
500 mL**



Read accompanying package insert carefully before use.

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

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Durvet, Inc.
Blue Springs, MO 64014
www.durvet.com
Made in Canada

1MOX040 8MOX040
Rev. 07/24

MOXIDECTIN

moxidectin injection, solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:30798-314
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:30798-314-17	500 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200788	10/02/2024	

Labeler - Durvet (056387798)

Registrant - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda-MTC Animal Health		256232216	manufacture

Revised: 10/2024

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