

NDC 30798-545-17



Doramectin

(doramectin injection)

Antiparasitic

1% injectable solution
for cattle and swine

10 mg/mL

Approved by FDA under ANADA # 200-750

Net
Contents:
500 mL
(16.91 fl oz)



INDICATIONS: Cattle: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. Doramectin Injectable Solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

Swine: For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites. See package insert for complete indications and directions for use.

RECOMMENDED DOSE: Cattle: 1 mL (10 mg doramectin) per 110 lb of body weight (200 mcg/kg) administered by subcutaneous (SC) or intramuscular (IM) injection in the neck region. Beef Quality Assurance guidelines recommend SC administration as the preferred route. Swine: 1 mL (10 mg doramectin) per 75 lb of body weight (300 mcg/kg) administered by IM injection only.

RESIDUE WARNINGS: Cattle: Do not slaughter for human consumption within 35 days of treatment.

Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Swine: Do not slaughter for human consumption within 24 days of treatment.

PRECAUTIONS: For SC injection in cattle only. For IM injection in swine and cattle.

Store at 20°C to 25°C (68°F to 77°F), with an excursion permitted between 15°C and 30°C (between 59°F and 86°F).

Use within 90 days of first puncture, no more than 141 punctures.

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.

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

Not for human use.

Restricted Drug (CA) Use only as directed.

Manufactured for:

Durvet, Inc.
Blue Springs, MO 64014
www.durvet.com
Contact No: 1-800-821-5570
Code: 4206162/TS/DRUGS/2023
LC54517-00
Made in India REV. 06/24

Lot:

Exp:

UNVARNISH ZONE
Coding Area (29.5x18.7 mm)





Un Varnished area
70.04x28.50 mm

Exp:
Lot:

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10 mg/mL

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Net Contents:
500 mL (16.91 fl oz)

Each mL of Doramectin Injectable Solution contains 10 mg of doramectin, 2.5 mg of phenol, and 215 mg of ethyl oleate in a sesame oil vehicle.

INDICATIONS: *Cattle:* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. Doramectin Injectable Solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment. *Swine:* For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites. See package insert for complete indications and directions for use.

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Antiparasitic

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for cattle and swine

10 mg/mL

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Net Contents:
500 mL (16.91 fl oz)

PRECAUTION: For SC injection in cattle only. For IM injection in swine and cattle.

Store at 20°C to 25°C (68°F to 77°F), with an excursion permitted between 15°C and 30°C (between 59°F and 86°F). See USP controlled room temperature.

Use this product within 90 days of the first puncture and maximum allowable punctures of 141 times. If more than the maximum number of punctures is anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16-gauge, discard any product remaining in the vial 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.

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

Not for human use.

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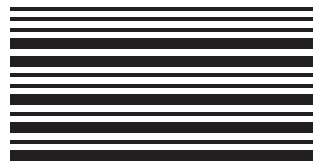
Made in India
REV. 06/24

Code: 4206162/TS/DRUGS/2023

CC54517-00



Doramectin
(doramectin
injection)



Doramectin
(doramectin
injection)

**Doramectin
(doramectin injection)**

Antiparasitic

**1% injectable solution for cattle and swine
10 mg/mL**

PRODUCT DESCRIPTION:

Doramectin Injectable Solution is a ready-to-use, colorless to pale yellow, sterile solution containing 1% w/v doramectin (10 mg/mL). In cattle, Doramectin Injectable Solution is formulated to deliver the recommended dosage (200 mcg/kg of body weight) when given by subcutaneous (SC) or intramuscular (IM) injection at the rate of 1 mL/110 lb of body weight. In swine, Doramectin is formulated to deliver the recommended dosage (300 mcg/kg of body weight) when given by IM injection at the rate of 1 mL/75 lb of body weight.

PRODUCT CHARACTERISTICS:

Doramectin Injectable Solution is a highly active, broad-spectrum parasiticide for parenteral administration to cattle and swine. It contains doramectin, a novel fermentation-derived macrocyclic lactone. Doramectin is isolated from fermentations of selected strains derived from the soil organism *Streptomyces avermitilis*.

A primary mode of action of macrocyclic lactones is to modulate chloride ion channel activity in the nervous system of nematodes and arthropods. Macrocyclic lactones bind to receptors that increase membrane permeability to chloride ions. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods and causes paralysis and death of the parasites. In mammals, the neuronal receptors to which macrocyclic lactones bind are localized within the central nervous system (CNS), a site reached by only negligible concentrations of doramectin.

One dose of Doramectin Injectable Solution effectively treats and controls a wide range of roundworm and arthropod parasites that impair the health and productivity of cattle and swine.

Studies have demonstrated the safety margin of doramectin injection in cattle and swine. In USA trials, no toxic signs were seen in cattle given up to 25 times the recommended dose, or in swine given up to 10 times the recommended dose. Studies also demonstrated safety in neonatal calves and piglets treated with up to 3 times the recommended dose. In males (bulls and boars) and females (cows and sows during folliculogenesis, implantation, organogenesis, and through gestation), a dose 3 times the recommended dose had no effect on breeding performance.

PRODUCT INDICATIONS:

Cattle: Doramectin Injectable Solution is indicated for the treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, grubs (see PRECAUTIONS), sucking lice (see PRECAUTIONS), and mange mites. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Gastrointestinal Roundworms (adults and fourth stage larvae)	Lungworms (adults and fourth stage larvae)
<i>Ostertagia ostertagi</i>	<i>Dictyocaulus viviparus</i>
(including inhibited larvae)	Eyeworms (adults)
<i>O. lyrata</i>	<i>Thelazia</i> spp.
<i>Haemonchus placei</i>	Grubs (parasitic stages)
<i>Trichostrongylus axei</i>	<i>Hypoderma bovis</i>
<i>T. colubriformis</i>	<i>H. lineatum</i>
<i>T. longispicularis</i> ¹	Sucking Lice
<i>Cooperia oncophora</i>	<i>Haematopinus eurysternus</i>
<i>C. pectinata</i> ¹	<i>Linognathus vituli</i>
<i>C. punctata</i>	<i>Solenopotes capillatus</i>
<i>C. surnabada</i> (syn. <i>mcmasteri</i>)	Mange Mites
<i>Bunostomum phlebotomum</i> ¹	<i>Psoroptes bovis</i>
<i>Strongyloides papillosus</i> ¹	<i>Sarcoptes scabiei</i>
<i>Oesophagostomum radiatum</i>	¹ adults
<i>Trichuris</i> spp. ¹	

Doramectin Injectable Solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

Swine: Doramectin Injectable Solution is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, kidney worms, sucking lice (see PRECAUTIONS), and mange mites. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Gastrointestinal Roundworms
(adults and fourth stage larvae)

- Ascaris suum*
- Oesophagostomum dentatum*
- Oesophagostomum quadrispinulatum*¹
- Strongyloides ransomi*¹
- Hyostrongylus rubidus*¹

¹ adults

DOSAGE:

Cattle: Administer Doramectin Injectable Solution at the recommended dosage of 200 mcg doramectin per kg (91 mcg/lb) of body weight. Each mL of doramectin contains 10 mg of doramectin, 2.5 mg of phenol, and 215 mg of ethyl oleate in a sesame oil vehicle, sufficient to treat 110 lb (50 kg) of body weight.

Body Weight (lb)	Dose (mL)
110	1
220	2
330	3
440	4
550	5
660	6
770	7
880	8
990	9
1,100	10

Swine: Administer Doramectin Injectable Solution at the recommended dosage of 300 mcg doramectin per kg (136 mcg/lb) of body weight. Each mL of doramectin contains 10 mg of doramectin, 2.5 mg of phenol, and 215 mg of ethyl oleate in a sesame oil vehicle, sufficient to treat 75 lb (34 kg) of body weight.

Body Weight (lb)	Dose (mL)
15	0.2
30	0.4
45	0.6
60	0.8
75	1.0
150	2.0
225	3.0
300	4.0
375	5.0
450	6.0

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.

RECOMMENDED TREATMENT PROGRAM FOR SWINE:

To effectively initiate control of mange and sucking lice in swine, it is important to treat all animals in the herd. After initial treatment, use Doramectin Injectable Solution regularly as follows:

Breeding Animals:

Sows: Treat 7-14 days prior to farrowing to minimize exposure of piglets to mites and sucking lice.

Gilts: Treat 7-14 days prior to breeding. Treat 7-14 days prior to farrowing.

Boars: Treat a minimum of 2 times per year.

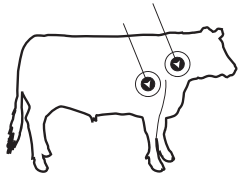
Feeder Pigs: Treat any new feeder pigs upon arrival at farm or before placement in clean quarters.

Weaners, Growers, Finishers: Weaners and grow-out/finisher pigs should be treated before placement in clean quarters.

For effective mange elimination, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities.

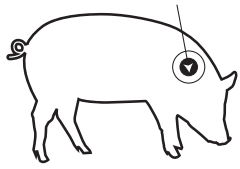
ADMINISTRATION:

Dry, sterile equipment and aseptic procedures should be used when withdrawing and administering Doramectin Injectable Solution. For multiple treatments either automatic injection equipment or an aspirating needle should be used.



Cattle:

Administer Doramectin Injectable Solution by SC or IM route. Injections should be made using a 16 gauge needle for adult cattle or an 18 gauge needle for young animals. Needles 1/2-3/4" in length are suggested for SC administration. A 1-1/2" needle is suggested for IM administration. SC injections should be administered under the loose skin in front of or behind the shoulder. IM injections should be administered into the muscular region of the neck. Beef Quality Assurance guidelines recommend SC administration as the preferred route.



Swine:

Administer Doramectin Injectable Solution by the IM route. Inject in the neck region using an 18 gauge x 1" needle for young animals; a 16 gauge x 1-1/2" needle for sows and boars. To accurately meter doses administered to piglets, use of a tuberculin syringe and 20 gauge x 1" needle is recommended.

WARNINGS:

Not for human use. Keep out of reach of children. To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Durvet, Inc. at 1-800-821-5570.

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.

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 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 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.

RESIDUE WARNINGS:

Cattle: Do not slaughter for human consumption within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in prerinuating calves. Do not use in calves to be processed for veal. Swine: Do not slaughter for human consumption within 24 days of treatment.

PRECAUTIONS:

Doramectin Injectable Solution has been developed specifically for use in cattle and swine only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

For SC injection in cattle only. For IM injection in swine and cattle. This product is approved for the treatment and control of sucking lice. For treatment of biting lice in cattle, use of doramectin topical solution is recommended.

Doramectin Injectable Solution is highly effective against all stages of cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble) season.

Destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *H. lineatum* when it is in the tissue surrounding the gullet may cause bloat; Killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with Doramectin Injectable Solution, but can occur with any successful treatment of grubs. Cattle should be treated either before or after these stages of grub development. Consult your veterinarian concerning the proper time for treatment.

Cattle treated with Doramectin Injectable Solution after the end of the heel fly season may be re-treated with Doramectin Injectable Solution during the winter for internal parasites, mange mites, or sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

ENVIRONMENTAL SAFETY:

Studies indicate that when doramectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free doramectin may adversely affect fish and certain aquatic organisms. Do not permit water runoff from feedlots to enter streams or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, doramectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

STORAGE CONDITIONS:

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Use this product within 90 days of the first puncture and maximum allowable punctures are given in the below table.

If more than the maximum number of punctures is anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16-gauge, discard any product remaining in the vial immediately after use.

Fill Volume	Allowable Punctures
100 mL	28
250 mL	70
500 mL	141

HOW SUPPLIED:

Doramectin Injectable Solution is available in 100-mL, 250-mL, and 500-mL multi-dose, rubber-stoppered glass vials.

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Not for human use.

Restricted Drug (CA) Use only as directed.

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Durvet, Inc.

Blue Springs, MO 64014

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Contact No: 1-800-821-5570

Code: 4206162/TS/DRUGS/2023

PC545-00

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REV. 06/24

TAKE TIME



OBSERVE LABEL DIRECTIONS

01

durvet