

DORACIDE POUR-ON- doramectin solution
Bimeda, Inc.

DORACIDETM
(doramectin topical solution)
POUR-ON FOR CATTLE
Antiparasitic
0.5% Pour-On Solution for Cattle
5 mg/mL

PRODUCT DESCRIPTION:

Doracide Pour-On solution is a ready-to-use, systemically active, clear, light blue solution containing 0.5% w/v doramectin (5 mg/mL). It is formulated to deliver the recommended dosage of 500 mcg/kg (227 mcg/lb) of body weight when given by topical administration at the rate of 1 mL/22 lb (10 kg) of body weight.

PRODUCT CHARACTERISTICS:

Doracide Pour-On solution is a highly active, broad-spectrum parasiticide for topical administration to cattle. 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 Doracide Pour-On solution effectively treats and controls a wide range of roundworm and arthropod parasites that impair the health and productivity of cattle.

Studies have demonstrated the safety margin of doramectin. In USA trials, no toxic signs were seen in cattle given up to 25 times the recommended dose of doramectin injectable solution. A study using doramectin injectable solution also demonstrated safety in neonatal calves treated with up to 3 times the recommended dose. In breeding animals (bulls, and cows during folliculogenesis, organogenesis, implantation, and through gestation), a dose 3 times the recommended dose of doramectin injectable solution had no effect on breeding performance. A pharmacokinetic study demonstrated that systemic exposure to doramectin from doramectin pour-on was less than systemic exposure to doramectin from doramectin injectable solution.

PRODUCT INDICATIONS:

Doracide Pour-On solution is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, grubs (see PRECAUTIONS), biting and sucking lice, horn flies, and mange mites in cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Gastrointestinal roundworms

Ostertagia ostertagi (adults and L₄, including inhibited larvae)
O. lyrata (adults)

Haemonchus placei (adults and L₄)
Trichostrongylus axei (adults and L₄)
T. colubriformis (adults¹ and L₄)
Cooperia oncophora (adults¹ and L₄)
C. pectinata (adults)
C. punctata (adults and L₄)
C. surnabada (adults)
Bunostomum phlebotomum (adults)
Oesophagostomum radiatum (adults and L₄)
Trichuris spp. (adults)

¹ Efficacy below 90% was observed against adult *C. oncophora* in some clinical studies.

Lungworms (adults and fourth stage larvae)

Dictyocaulus viviparus

Eyeworms

Thelazia gulosa (adults)

T. skrjabini (adults)

Lice

Biting Lice

Bovicola (Damalinia) bovis

Sucking Lice

Haematopinus eurysternus

Linognathus vituli

Solenopotes capillatus

Grubs

Hypoderma bovis

H. lineatum

Horn Flies

Haematobia irritans

Mange Mites

Chorioptes bovis

Sarcoptes scabiei

Doramectin topical solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, and *Oesophagostomum radiatum* for 28 days; and *Cooperia punctata* and *Haemonchus placei* for 35 days after treatment.

Doramectin topical solution has been proved to effectively control infestations and to protect cattle from reinfestation with *Bovicola (Damalinia) bovis* for 77 days and *Linognathus vituli* for 42 days after treatment.

Management Considerations for Horn Flies

Doracide Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

DOSAGE:

Administer Doracide Pour-On solution to cattle topically at a dosage of 500 mcg doramectin per kg (227 mcg/lb) of body weight. Each mL contains 5 mg of doramectin, sufficient to treat 22 lb (10 kg) of body weight.

For the best results, Doracide Pour-On solution should be a part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult a veterinarian or an entomologist for information regarding the most effective timing of applications.

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:

Doracide Pour-On solution should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

Dosing Cup (1-L bottles)

A dosing cup is provided for use with Doracide Pour-On solution supplied in 1-L bottles. The Doracide Pour-On solution dosing cup should be installed by inserting the dip tube into the base of the measuring cap with slotted end going to the bottom of the container. Unscrew shipping cap from container.

Screw measuring cap onto container.

Select a dose [1 mL per 22 lb (10 kg) of body weight] by rotating the adjuster cap in either direction to position the dose indicator to the appropriate dose.

When body weight is between weight markings on the dosing cup, use the higher dose volume.

To fill the dosing reservoir, hold the bottle upright and squeeze it until a slight excess has been delivered as indicated by the calibration lines.

Release the pressure and excess will automatically drain from the reservoir and return to the bottle.

Tilt the bottle to deliver the dose. Doracide Pour-On solution should be delivered to cattle on the back in a single pass from the withers to the tailhead.

Applicators (2.5-L and 5-L backpacks)

Applicators are available for use with Doracide Pour-On solution supplied in 2.5-L and 5-L backpacks. Directions for 2 recommended applicators are provided below. Some applicators may be incompatible with this formulation.

Phillips Pour-on Applicator System

1. Replace the shipping cap on 2.5- or 5-L backpack with the draw-off cap provided and tighten firmly.
2. Thread the draw-off tubing through the anti-kink spring. Attach the tube to the draw-off cap. Screw the spring counter clockwise over the tubing and draw-off spigot.
3. Invert the backpack.

4. Set the dose to maximum (50 mL). Gently prime the applicator, checking for leaks. To prime, place the nozzle into a clean, dry receptacle and depress lever fully. Pump 3–4 short strokes ensuring that the piston reaches the end of the cylinder, and then release the lever completely to fill the cylinder. A small air bubble may appear within the cylinder. This will not affect the dosing accuracy.
5. Set the required dose and administer.
6. To disconnect the system, proceed as follows:
 - a) Set backpack in upward position.
 - b) Discharge residual material from the applicator and draw-off tubing into a separate, clean, dry receptacle.
7. Follow the manufacturer's recommendation for care and maintenance of the dosing applicator.
8. Remove the draw-off cap. Replace with the original cap and tighten firmly.

Syrvet Pour-on Applicator System

1. Replace the shipping cap on the 2.5- or 5-L backpack with the draw-off cap provided and tighten firmly.
 2. Thread the draw-off tubing through the anti-kink spring. Attach the tube to the draw-off cap. Screw the spring clockwise over the tubing and draw-off spigot.
 3. Invert the backpack.
 4. Set the dose at the maximum (50 mL) by unscrewing the adjuster at the base of the handle. Gently prime the applicator, checking for leaks. To prime, point the nozzle into a clean, dry receptacle and gently pump the lever back and forth to expel air from the system. When the barrel completely fills after every priming stroke, set the dose.
 5. Set the dose as follows:
 - a) Use the handle to align the middle of the blue plunger ring with the chosen mark on the barrel. Tighten the adjuster screw against the handle.
 - b) Secure the dose with the adjuster screw locknut.
- Note:** Dose accuracy can be checked by dispensing a known number of set doses into a measuring cylinder. Correct any inaccuracy by adjusting the dose setting screw. Repeat this procedure until desired accuracy is achieved.
6. Administer each dose by fully depressing the handle so that the plunger travels its entire set length. Release the handle and the applicator will automatically refill.
 7. To disconnect the system proceed as follows:
 - a) Set backpack in upward position.
 - b) Discharge residual material from the applicator and draw off tubing into a separate, dry receptacle.
 8. Follow the manufacturer's recommendation for care and maintenance of the dosing applicator.
 9. Remove the draw-off cap. Replace with the original cap and tighten firmly.

WARNING:

Flammable! Keep away from heat, sparks, open flame, and other sources of ignition. Not for human use. Keep out of 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 www.fda.gov/reportanimalae

Doracide Pour-On solution for cattle may be irritating to human skin and eyes, and users should be careful not to apply it to themselves or to other persons. Operators should wear protective clothing including a long-sleeved shirt, protective gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

RESIDUE WARNING:

Cattle must not be slaughtered for human consumption within 45 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.

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 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:

Doracide Pour-On solution has been developed specifically for use in cattle only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

This product is to be applied to skin surface only. Do not administer orally or parenterally.

Do not apply to areas of skin which are caked with mud or manure.

Wash hands after use.

Do not smoke or eat while handling the product.

Cloudiness in the formulation may occur when Doracide Pour-On solution is stored at temperatures below 0°C (32°F). Allowing to warm to room temperature will restore the

normal appearance without affecting efficacy.

Doracide Pour-On solution is highly effective against 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 Doracide Pour-On solution, but can occur with any successful treatment of grubs. Cattle should be treated either before or after the migratory phase of grub development. Consult your veterinarian concerning the proper time for treatment.

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

USE CONDITIONS:

Varying weather conditions, including rainfall, do not affect the efficacy of Doracide Pour-On.

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 cattle to enter lakes, streams or ponds for at least 6 hours after treatment. 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.

STORE BELOW 25°C (77°F)

PROTECT FROM LIGHT

HOW SUPPLIED: Doracide Pour-On solution is available in 1-L, 2.5-L, and 5-L multi-dose containers.

Approved by FDA under ANADA # 200-636

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

Not for human use.

Restricted Drug (California) - Use Only as Directed

Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058
www.bimeda.com

NDC# 61133-4004-4

DORACIDE

(doramectin topical solution)

POUR-ON FOR CATTLE

Antiparasitic

0.5% Pour-On Solution for Cattle
5 mg/mL

For Treatment and Control of Gastrointestinal Roundworms, Lungworms, Eyeworms, Grubs, Biting and Sucking Lice, Horn Flies, and Mange Mites in Cattle.

WARNING: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

NOT FOR HUMAN USE

Restricted Drug (California) - Use Only as Directed

Approved by FDA under ANADA # 200-636




Net Contents:
5 L (169 fl oz)

1.02-4003 8005005 Rev. 05/24

Manufactured by:
Bimeda, Inc.
La Sueur, MN 56058
www.bimeda.com

LOT:
EXP:

 **Bimeda**

DORACIDE POUR-ON

doramectin solution

Product Information

Product Type

OTC ANIMAL DRUG

Item Code (Source)

NDC:61133-4004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| DORAMECTIN (UNII: KGD7A54H5P) (DORAMECTIN - UNII:KGD7A54H5P) | DORAMECTIN | 5 mg in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:61133-4004-2 | 1000 mL in 1 BOTTLE | | |
| 2 | NDC:61133-4004-3 | 2500 mL in 1 BOTTLE | | |
| 3 | NDC:61133-4004-4 | 5000 mL in 1 BOTTLE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200636 | 04/08/2022 | |

Labeler - Bimeda, Inc. (060492923)

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Bimeda, Inc.