

DECTOGARD POUR-ON- doramectin solution
Aurora Pharmaceutical, Inc.

DectoGard™

(doramectin topical solution) Pour-On

Antiparasitic

0.5% pour-on solution for cattle

5 mg/mL

PRODUCT DESCRIPTION:

DectoGard 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:

DectoGard Pour-On solution is a highly active, broad-spectrum parasiticide for topical administration to cattle. It contains doramectin, a novel fermentation-derived macrocyclic lactone discovered by Pfizer Inc. 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 DectoGard 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 topical solution was less than systemic exposure to doramectin from doramectin injectable solution.

PRODUCT INDICATIONS:

DectoGard 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 (adults 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)

Lungworms (adults and fourth stage larvae)

Dictyocaulus viviparus

Eyeworms	Grubs
<i>Thelazia gulosa</i> (adults)	<i>Hypoderma bovis</i>
<i>T. skrjabini</i> (adults)	<i>H. lineatum</i>
Lice	Horn Flies
Biting Lice	<i>Haematobia irritans</i>
<i>Bovicola (Damalinia) bovis</i>	Mange Mites
Sucking Lice	<i>Chorioptes bovis</i>
<i>Haematopinus euryesternus</i>	<i>Sarcoptes scabiei</i>
<i>Linognathus vituli</i>	
<i>Solenopotes capillatus</i>	

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.

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

Management Considerations for Horn Flies

DectoGard 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 Dectogard 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, Dectogard 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:

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

Applicators (1-L, 2.5-L and 5-L bottles)

Applicators are available for use with Dectogard Pour-On solution supplied in 1-, 2.5- and 5-L bottles. Directions for use with compatible applicators are provided below. Some applicators may be incompatible with this formulation.

- 1) Replace the shipping cap on 1-, 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 bottle.
- 4) Set the dose to maximum (50 mL). Gently prime the applicator, checking for leaks.
- 5) Follow the dosing applicator manufacturer's directions to 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.

WARNING:

Flammable! Keep away from heat, sparks, open flame, and other sources of ignition. Not for human use. Keep out of reach of children. The Safety Data

Sheet (SDS) contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain an SDS, call 1-888-215-1256.

DectoGard 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.

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.

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.

PRECAUTIONS:

DectoGard 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 DectoGard 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.

Dectogard 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 Dectogard 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 Dectogard Pour-On solution after the end of heel fly season may be re-treated with Dectogard 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 DectogardPour-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 30°C (86°F)

Protect From Light

HOW SUPPLIED:

Dectogard Pour-On solution is available in 1-L, 2.5-L, and 5-L multi-dose containers.

Approved by FDA under ANADA # 200-738

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 by:

Aurora Pharmaceutical, Inc.

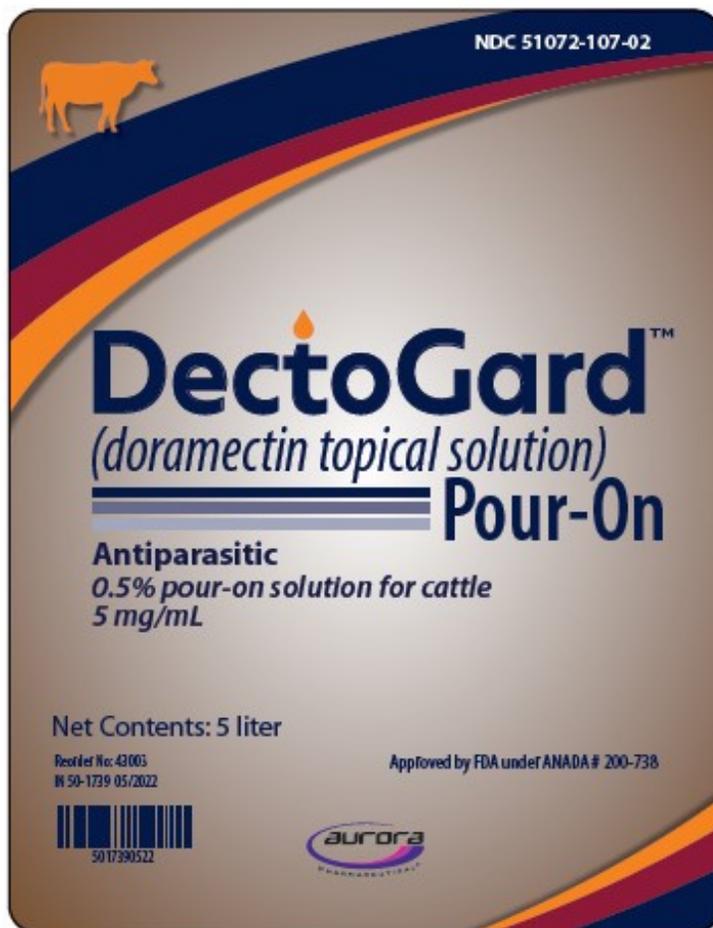
Northfield, MN 55057



PRINCIPAL DISPLAY PANEL - 5 L Bottle front and back

IN 50-1739

rev 05/2022



IN 50-1741

rev 05/2022

DectoGard™ (doramectin topical solution) Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Indications:

For treatment and control of gastrointestinal roundworms, lungworms, eye worms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. See package insert for complete indications and directions for use.

Doramectin topical solution has been proved to effectively control infestations and to protect cattle from reinfection with *Cooperia oncophora*, *Dicrocoelium viviparum*, *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 reinfection with *Bovicola (Dermatobia) bovis* for 77 days and *Limnognathus vituli* for 42 days after treatment.

Management Consideration For Horn Flies
DectoGard™ 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.

Recommended Dose:

1 mL (5 mg of doramectin) per 22 lb (10 kg) of body weight administered by the topical route.



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Lot:
Exp:

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

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 pre-ruminating calves. Do not use in calves to be processed for veal.

Precaution:

For topical use in cattle only

Store Below 30°C (86°F)
Protect From Light

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 by: Aurora Pharmaceutical, Inc.
Northfield, Minnesota 55057

DectoGard™ is a trademark of Aurora Pharmaceutical, Inc.

IN 50-1741 05/2022

TAKE TIME  OBSERVE LABEL DIRECTIONS



PRINCIPAL DISPLAY PANEL - 5 L Carton

IN 40-1744

rev 11/2022

NDC 51072-107-02



DectoGard™

(doramectin topical solution)

Pour-On

Antiparasitic
0.5% pour-on solution for cattle
5 mg/mL

Treats 200
550-lb cattle

Net Contents: 5 liter
Reorder No: 43003
Approved by FDA under ANADA # 200-738



Dosage and Administration:
Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. Dosing guidelines are provided in the following table:

Body Weight (lb)	Dose (mL)
Up to 110	5 mL*
111-220	10 mL
221-330	15 mL
331-440	20 mL
441-550	25 mL
551-660	30 mL
661-770	35 mL
771-880	40 mL
881-990	45 mL
991-1100	50 mL

* Administer using an appropriate dosing gun.

For animals heavier than 1100 lb, increase the dose by 5 mL for each additional 1-110 lb of body weight.

DECTOGARD POUR-ON

doramectin solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:51072-107
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

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51072-107-00	1 in 1 CARTON		
1		1000 mL in 1 BOTTLE		
2	NDC:51072-107-01	1 in 1 CARTON		
2		2500 mL in 1 BOTTLE		
3	NDC:51072-107-02	1 in 1 CARTON		
3		5000 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200738	02/20/2023	

Labeler - Aurora Pharmaceutical, Inc. (832848639)

Establishment

Name	Address	ID/FEI	Business Operations
Aurora Pharmaceutical, Inc.		832848639	manufacture

Revised: 11/2023

Aurora Pharmaceutical, Inc.