EPRIGARD POUR-ON FOR BEEF AND DAIRY CATTLE- eprinomectin solution
Aurora Pharmaceutical, Inc.

EpriGard™
Pour-On for Beef and Dairy Cattle
(eprinomectin)

Parasiticide

Contains 5 mg eprinomectin/mL

Not for use in calves to be processed for veal.

INTRODUCTION

EpriGard Pour-On delivers effective internal and external parasite control in one application. EpriGard Pour-On contains eprinomectin, a unique avermectin. Its broad-spectrum efficacy in a weatherproof formulation, margin of safety, zero slaughter withdrawal and zero milk discard, make it a convenient product for parasite control in beef and dairy cattle, including lactating dairy cattle.

MODE OF ACTION

Eprinomectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells.

This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

INDICATIONS

EpriGard (eprinomectin) Pour-On is indicated for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, sucking and biting lice, chorioptic and sarcoptic mange mites, and horn flies in beef and dairy cattle of all ages, including lactating dairy cattle.

Applied at the recommended dose volume of 1 mL/10 kg (22 lb) body weight, to achieve a dose level of 500 mcg eprinomectin/kg body weight, EpriGard Pour-On is indicated for the effective treatment and control of the following parasites.

Gastrointestinal Roundworms

Haemonchus placei	(adults and L4)
Ostertagia ostertagi (including inhibited L4)	(adults and L4)
Trichostrongylus axei	(adults and L4)
Trichostrongylus colubriformis	(adults and L4)
Trichostrongylus longispicularis	(adults only)
Cooperia oncophora	(adults and L4)
Cooperia punctata	(adults and L4)
Cooperia surnabada	(adults and L4)
Nematodirus helvetianus	(adults and L4)
Oesophagostomum radiatum	(adults and L4)
Bunostomum phlebotomum	(adults and L4)
Strongyloides papillosus	(adults only)
Trichuris spp.	(adults only)

Lungworms

Dictyocaulus viviparus	(adults and L4)

Cattle Grubs (all parasitic stages)

Hypoderma lineatum, Hypoderma bovis

Lice

Damalinia bovis, Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

Mange Mites

Chorioptes bovis, Sarcoptes scabiei

Horn Flies

Haematobia irritans

Persistent Activity

EpriGard (eprinomectin) Pour-On for Beef and Dairy Cattle has been proved to effectively control infections and to protect cattle from re-infection with Dictyocaulus viviparus for 21 days after treatment and Haematobia irritans for 7 days after treatment.

Use Conditions

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

Management Considerations for Treatment of External Parasites

For best results EpriGard Pour-On should be applied to all cattle in the herd. Cattle introduced to the herd later should be treated prior to introduction. Consult your veterinarian or an entomologist for the most effective timing of applications for the control of external parasites.

Chorioptic Mange: In clinical studies evaluating the efficacy of eprinomectin Pour-On against chorioptic mange mites, mites were not recovered from skin scrapings taken 8 weeks after treatment; however, chronic skin lesions were still present on some animals.

Horn flies: For optimal control of horn flies, as EpriGard Pour-On provides 7 days of persistent activity against horn flies, the product should be used as part of an integrated control program utilizing other control methods to provide extended control.

DOSAGE

The product is formulated only for external application to beef and dairy cattle. The dose rate is 1 mL/10 kg (22 lb) of body weight. The product should be applied topically along the backline in a narrow strip extending from the withers to the tailhead.

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

Metering Cup with Measure-Squeeze-Pour System

250 mL (8.5 fl oz) Container with 25 mL Metering Cup

This pack contains 1 Metering Cup and 1 dip tube

1. Insert the dip tube into base of the Metering Cup. Leave the "slotted end" of the dip tube exposed in the bottom of the container.

2. Unscrew shipping cap from container top.

3. Screw the Metering Cup onto container top.

4. **Measure:** To select the correct dose rate, rotate the adjuster cap (top) in either direction to position the dose indicator to the weight of the animal you want to treat. When body weight is between markings, use the higher setting.

5. **Squeeze** the container gently to fill the Metering Cup to the required dose. Release your grip and any excess will return to the container.

6. **Pour:** Apply the full dose by tipping and pouring along the backline of the animal until the Metering Cup is empty.

7. **Storage:** The Metering Cup should not remain attached to the container when not in use. Detach the Metering Cup after each use and replace the shipping cap to close the container top.

Backpack (1 L/33.8 fl oz, 2.5 L/84.5 fl oz, and 5 L/169 fl oz Packs) and 10 L/338 fl oz Pack

Connect the dosing applicator and draw-off tubing to the backpack as follows:

Attach the open end of the draw-off tubing to an appropriate dosing applicator. Attach draw-off tubing to the cap with the stem that is included in the pack. Replace the shipping cap with the cap having the draw-off tubing.

Gently prime the dosing applicator, checking for leaks. Follow the dosing applicator manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing applicator and draw-off tubing.

ANIMAL SAFETY

Tolerance and toxicity studies have demonstrated the margin of safety for eprinomectin in cattle. In toxicity studies, application of 3 times the recommended dose had no adverse effects on neonatal calves, and application of up to 5 times the recommended dose 3 times at 7 day intervals had no adverse effects on 8 week old calves. In the tolerance study, one of 6 cattle treated once at 10 times the recommended dose showed clinical signs of mydriasis. Application of 3 times the recommended dose had no adverse effect on breeding performance of cows or bulls.

Residue Warnings: When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk discard time is required, therefore, meat and milk from cattle treated with EpriGard (eprinomectin) Pour-On may be used for human consumption at any time following treatment. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

WARNING:

Keep this and all drugs out of the reach of children.

NOT FOR USE IN HUMANS.

As with any topical medication intended for treatment of animals, skin contact should be avoided. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water. The Safety Data Sheet (SDS) contains more detailed occupational safety information.

To report suspected adverse drug events, for technical assistance, or to obtain a copy of the SDS, contact Aurora Pharmaceutical at 1-888-215-1256 or www.aurorapharmaceutical.com. 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.

PRECAUTIONS

This product is for topical application only. Do not administer orally or by injection.

Do not apply to areas of the backline covered with mud or manure.

EpriGard Pour-On is not recommended for use in species other than cattle. Severe adverse reactions have been reported in other species treated with products containing compounds of this class.

Restricted Drug (California) - Use only as directed.

When to Treat Cattle with Grubs

EpriGard Pour-On is effective against all stages of cattle grubs. However, proper timing of treatment is important. For the most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season. While this is not peculiar to eprinomectin, destruction of *Hypoderma* larvae (cattle grubs) at the period

when these grubs are in vital areas may cause undesirable host-parasite reactions. Killing *Hypoderma lineatum* when it is in the esophageal tissues may cause bloat; killing *H.bovis* when it is in the vertebral canal may cause staggering or paralysis. Cattle should be treated either before or after these stages of grub development.

Cattle treated with EpriGard Pour-On at the end of the fly season may be re-treated with EpriGard Pour-On during the winter without danger of grub-related reactions. For further information and advice on a planned parasite control program, consult your veterinarian.

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.

Environmental Safety

Studies indicate that when eprinomectin comes in contact with soil, it readily and tightly binds to the soil and becomes inactive over time. Free eprinomectin 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, eprinomectin 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.

ADVERSE REACTIONS

No adverse reactions were observed during clinical trials.

STORAGE CONDITIONS

Store bottle or pack in the carton to protect from light and at temperatures up to 86°F/30°C. Storage at temperatures up to 104°F/40°C is permitted for a short period of time, however, such exposure should be minimized. Do not freeze.

For the 250 mL/8.5 fl oz bottle with a measure-squeeze-pour system, the Metering Cup should not remain attached to the container when not in use. Detach the Metering Cup after each use and replace the shipping cap to close the container top.

HOW SUPPLIED

EpriGard (eprinomectin) Pour-On for Beef and Dairy Cattle is available in a 250 mL/8.5 fl oz bottle with a measure-squeeze-pour system, or in a 1L/33.8 fl oz, 2.5 L/84.5 fl oz, or 5 L/169 fl oz backpack, or 10 L/338 fl oz pack, intended for use with appropriate automatic dosing equipment.

Approved by FDA under ANADA # 200-741

Manufactured by: **Aurora Pharmaceutical, Inc.**

Northfield, Minnesota 55057

Principal Display Panel - 5000 mL Bottle Carton

EpriGard™

Pour-On for Beef
and Dairy Cattle
(eprinomectin)

Parasiticide
Contains 5 mg eprinomectin/mL

For Treatment and Control of Internal and External Parasites

Residue Information:
Not for use in calves to be processed for veal.
Zero Slaughter Withdrawal
Zero Milk Discard

Contains 200 Doses (550 lb)

Approved by FDA under ANADA # 200-741

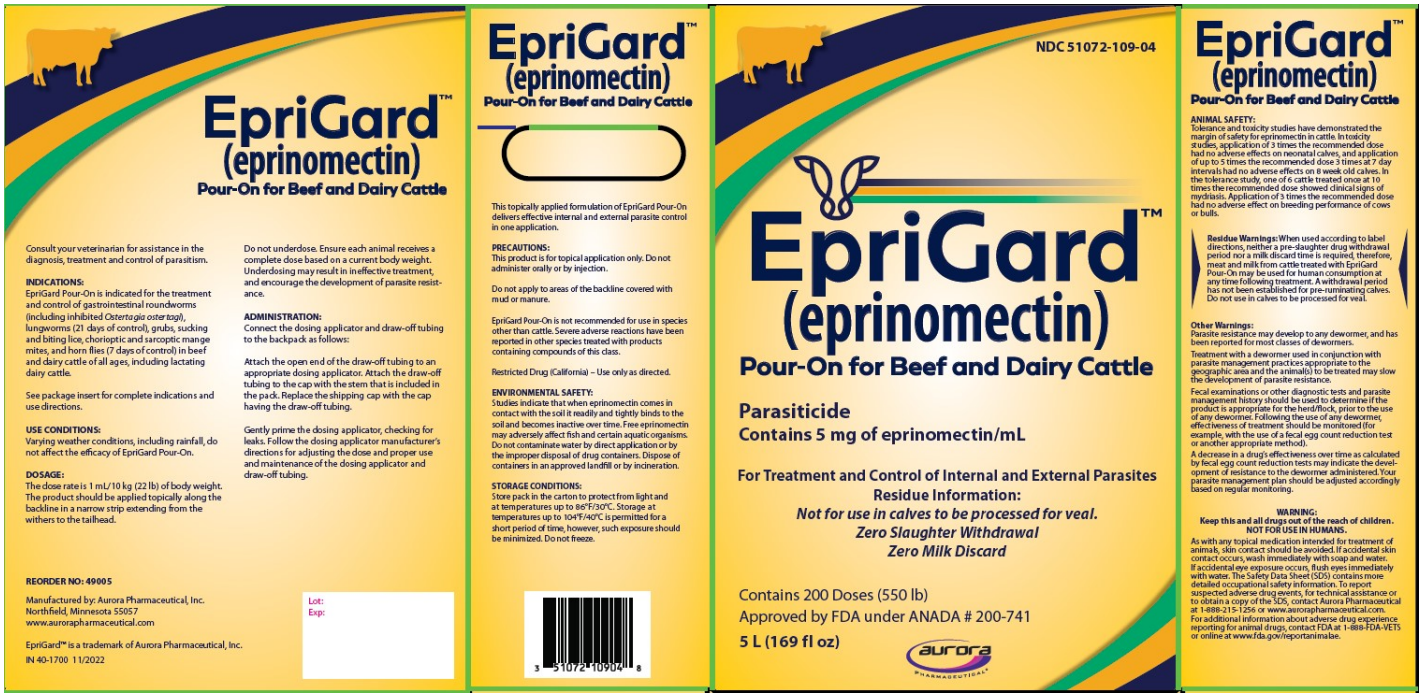
5000 mL (169 fl oz)

EpriGard™ is a trademark of Aurora Pharmaceutical, Inc.

Reorder# 49005

IN 40-1700

rev 11/2022



Principal Display Panel – 5000 mL Container Label

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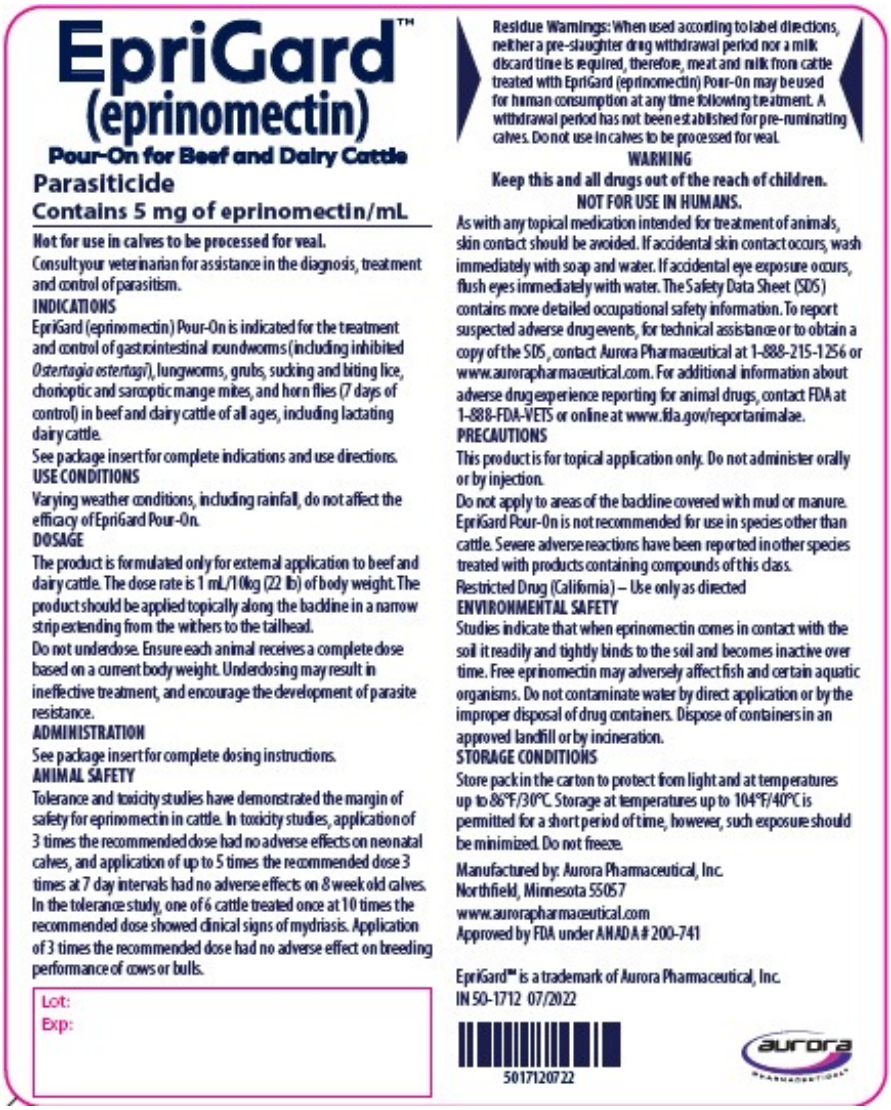
Reorder# 49005

IN 50-1694

rev 07/2022

IN 50-1712

rev 07/2022



EpriGard™ (eprinomectin)

Pour-On for Beef and Dairy Cattle

Parasiticide

Contains 5 mg of eprinomectin/mL

Not for use in calves to be processed for veal.

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

INDICATIONS

EpriGard (eprinomectin) Pour-On is indicated for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, sucking and biting lice, chorioptic and sarcoptic mange mites, and horn flies (7 days of control) in beef and dairy cattle of all ages, including lactating dairy cattle.

See package insert for complete indications and use directions.

USE CONDITIONS

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ADMINISTRATION

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Lot:
Exp:

Residue Warnings: When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk discard time is required, therefore, meat and milk from cattle treated with EpriGard (eprinomectin) Pour-On may be used for human consumption at any time following treatment. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

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STORAGE CONDITIONS

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Manufactured by: Aurora Pharmaceutical, Inc.
Northfield, Minnesota 55057
www.aurorapharmaceutical.com
Approved by FDA under ANADA # 200-741

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IN 50-1712 07/2022

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aurora PHARMACEUTICAL

EPRIGARD POUR-ON FOR BEEF AND DAIRY CATTLE

eprinomectin solution

Product Information

Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:51072-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
eprinomectin (UNII: 75KP30FD8O) (eprinomectin - UNII:75KP30FD8O)	eprinomectin	5 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51072-109-01	1 in 1 CARTON		
1		250 mL in 1 BOTTLE, PLASTIC		
2	NDC:51072-109-02	1 in 1 CARTON		

2		1000 mL in 1 BOTTLE, PLASTIC		
3	NDC:51072-109-03	1 in 1 CARTON		
3		2500 mL in 1 BOTTLE, PLASTIC		
4	NDC:51072-109-04	1 in 1 CARTON		
4		5000 mL in 1 BOTTLE, PLASTIC		
5	NDC:51072-109-05	1 in 1 CARTON		
5		10000 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200741	03/27/2023	

Labeler - Aurora Pharmaceutical, Inc. (832848639)

Establishment

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

Revised: 12/2023 Aurora Pharmaceutical, Inc.