

FRONT

INSERT

BACK

NADA 141-079, Approved by the FDA



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

EPRINEX Pour-On delivers effective internal and external parasite control in one application. Discovered and developed by scientists from Merck Research Laboratories, EPRINEX 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

EPRINEX (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, EPRINEX Pour-On is indicated for the effective treatment and control of the following parasites.

Gastrointestinal Roundworms	
<i>Haemonchus placei</i>	(adults and L4)
<i>Ostertagia ostertagi</i> (including inhibited L4)	(adults and L4)
<i>Trichostrongylus axei</i>	(adults and L4)
<i>Trichostrongylus colubriformis</i>	(adults and L4)
<i>Trichostrongylus colospicularis</i>	(adults only)
<i>Cooperia oncophora</i>	(adults and L4)
<i>Cooperia punctata</i>	(adults and L4)
<i>Cooperia surrabada</i>	(adults and L4)
<i>Nematodirus helvetianus</i>	(adults and L4)
<i>Oesophagostomum radiatum</i>	(adults and L4)
<i>Bunostomum phlebotomum</i>	(adults and L4)
<i>Strongyloides papillosus</i>	(adults only)
<i>Trichuris</i> spp.	(adults only)

Lungworms
Dictyoacaulus viviparus (adults and L4)

Cattle Grubs (all parasitic stages)
Hypoderma lineatum
Hypoderma bovis

Lice
Damalinea bovis
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Mange Mites
Chorioptes bovis
Sarcoptes scabiei

Horn Flies
Haematobia irritans

Persistent Activity
EPRINEX (eprinomectin) Pour-On for Beef and Dairy Cattle has been proved to effectively control infections and to protect cattle from re-infection with *Dictyoacaulus 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 EPRINEX Pour-On.

Management Considerations for Treatment of External Parasites

For best results EPRINEX 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 EPRINEX 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 EPRINEX 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.

ADMINISTRATION

Squeeze-Measure-Pour System (250 mL/8.5 fl oz Bottle with 25 mL Metering Cup)

Attach the metering cup to the bottle. Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines. By releasing the pressure, the dose automatically adjusts to the correct level. The off (STOP) position will close the system between dosing. Tilt the bottle to deliver the dose.

Squeeze-Measure-Pour System (1 L/33.8 fl oz Bottle with 50 mL Metering Cup)

Attach the metering cup to the bottle. Set the dose by turning the top section of the cup to align the correct body weight with the pointer on the knurled cap. When body weight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

275mm deep

Square Corners

155mm wide

By releasing the pressure, the dose automatically adjusts to the correct level. When a 220 lb (10 mL) or 330 lb (15 mL) dose is required, turn the pointer to "STOP" before delivering the dose. The off (STOP) position will close the system between dosing. Tilt the bottle to deliver the dose.

Collapsible Pack (2.5 L/84.5 fl oz and 5 L/169 fl oz Packs)

Connect the dosing applicator and draw-off tubing to the collapsible pack 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.

20 Liter Pack (20 L/676 fl oz Pack)

Connect the dosing applicator and draw-off tubing to the container 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. 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 EPRINEX (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 material safety data sheet (MSDS) contains more detailed occupational safety information.

To report adverse effects, obtain an MSDS or for assistance, contact Merial at 1-888-637-4251.

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.

EPRINEX 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

EPRINEX 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 EPRINEX Pour-On at the end of the fly season may be re-treated with EPRINEX 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.

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 ivermectin/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.

HOW SUPPLIED

EPRINEX (eprinomectin) Pour-On for Beef and Dairy Cattle is available in a 250 mL/8.5 fl oz (67641) or 1 L/33.8 fl oz (67643) bottle with a squeeze-measure-pour system, or in a 2.5 L/84.5 fl oz (67645) or 5 L/169 fl oz (67647) collapsible pack or 20 L/676 fl oz (67648) container intended for use with appropriate automatic dosing equipment.

Marketed by: Merial Limited
Duluth, GA 30096 USA
Made in New Zealand
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1050-2355-06
Rev. 02-2013



275mm deep

Argenta Number 15x2mm (Placement can be adjusted to fit layout.)

155mm wide

MERIAL GRAPHIC ARTWORK APPROVAL

Code: 1050-2355-06	VERSION	COLORS	NOTES
PRODUCT: EPRINEX POUR ON INSERT SPEC#: DW275x155 COUNTRY: DOMESTIC (US) Dimensions: mm = 275 x 155 inches =	INITIALS: Duluth (CW) VERSION - DATE: A - 05/APR/2013 (CW) OLD CODE: 1050-2355-05	<div style="background-color: black; color: white; padding: 5px; text-align: center;">K</div> <p>! Please use the official PANTONE® (P) matching system for an accurate color representation.</p>	SITE/SUPPLIER: ARGENTA SOFTWARE: ADOBE Illustrator CSS BAR CODE(S): N/A

Marketing approval:	Regulatory approval:	PRINTER NOTES!
COMPLETE NAME + DATE + SIGNATURE:	COMPLETE NAME + DATE + SIGNATURE:	