

IVOMEK POUR-ON- ivermectin solution
Boehringer Ingelheim Animal Health USA Inc.

Ivomec® Pour-On
(ivermectin topical solution)

Approved by FDA under NADA # 140-841

Parasiticide for cattle

Contains 5 mg ivermectin/mL

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

INTRODUCTION

IVOMEK® Pour-On (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application. Discovered and developed by scientists from Merck Research Laboratories, IVOMEK Pour-On (ivermectin topical solution) contains ivermectin, a unique chemical entity.

MODE OF ACTION

Ivermectin 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

IVOMEK Pour-On (ivermectin topical solution) applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (including inhibited stage) (adults and L4)

Haemonchus placei (adults and L4)

<i>Trichostrongylus axei</i>	(adults and L4)
<i>T. colubriformis</i>	(adults and L4)
<i>Cooperia oncophora</i>	(adults and L4)
<i>Cooperia punctata</i>	(adults and L4)
<i>Cooperia surnabada</i>	(adults and L4)
<i>Strongyloides papillosus</i>	(adults)
<i>Oesophagostomum radiatum</i>	(adults and L4)
<i>Trichuris</i> spp.	(adults)

Lungworms

Dictyocaulus viviparus (adults and L4)

Cattle Grubs

(parasitic stages)

Hypoderma bovis

H. lineatum

Mites

Sarcoptes scabiei var. *bovis*

Lice

Linognathus vituli

Haematopinus eurysternus

Damalinia bovis

Solenopotes capillatus

Horn Flies

Haematobia irritans

PERSISTENT ACTIVITY

IVOMEC Pour-On (ivermectin topical solution) has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

TREATMENT OF CATTLE FOR HORN FLIES

IVOMEC Pour-On (ivermectin topical solution) controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results IVOMEC Pour-On (ivermectin topical solution) should be part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult your veterinarian or an entomologist for the most effective timing of applications.

DOSAGE

The dose rate is 1 mL for each 22 lb of body weight. The formulation should be applied along the topline 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 Container with 25 mL Metering Cup and 1 Liter Container with 60 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.

Collapsible Pack (2.5 L Pack and 5 L Pack)

Connect the applicator gun to the collapsible pack as follows:

- Attach the open end of the draw-off tubing to the dosing equipment. (Because of the solvents used in the formulation, only the Protector Drench Gun from Instrument Supplies Limited, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage.)
- Replace the shipping cap with the draw-off cap and tighten down. Attach draw-off tubing to the draw-off cap.
- Gently prime the applicator gun, checking for leaks.
- Follow the manufacturer's directions for adjusting the dose.
- When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun and draw-off tubing from the product container and empty the product from the gun and tubing back into the product container. To prevent removal of special lubricants from the Protector Drench Gun, the gun and tubing must not be washed.

20 Liter Pack

Use dosing equipment (applicator, draw-off tubing, cap with stem) compatible with IVOMEC Pour-On (ivermectin topical solution). Other dosing equipment may be incompatible, resulting in locking, incorrect dosage and leakage. Follow the dosing equipment manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing equipment. Connect the dosing applicator and the 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.
- When the interval between uses of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw-off tubing and cap with stem from the product container, empty the product from the gun and tubing back into the product container and replace the shipping cap.

ANIMAL SAFETY

Studies conducted in the U.S.A. have demonstrated the safety margin for ivermectin. Based on plasma levels, the topically applied formulation is expected to be at least as well tolerated by breeding animals as is the subcutaneous formulation which had no effect on breeding performance.

WARNING

NOT FOR USE IN HUMANS.

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

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 Safety Data Sheet (SDS), contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251.

WARNING! FLAMMABLE!

KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME, AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

RESIDUE WARNING

Cattle must not be treated within 48 days of slaughter for human consumption. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS

- **Store at or below 25°C (77°F) and protect from light. Excursions permitted to 104°F (40°C).**
- Use only in well-ventilated areas or outdoors.
- Close container tightly when not in use.

- Cattle should not be treated when hair or hide is wet since reduced efficacy may be experienced.
- Do not use when rain is expected to wet cattle within six hours after treatment.
- This product is for application to skin surface only. Do not give orally or parenterally.
- Cloudiness in the formulation may occur when IVOME[®] Pour-On is stored at temperatures below 32°F. Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.
- Antiparasitic activity of ivermectin will be impaired if the formulation is applied to areas of the skin with mange scabs or lesions, or with dermatoses or adherent materials, e.g., caked mud or manure.
- Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, IVOME[®] Pour-On (ivermectin topical solution) is not recommended for use in species other than cattle.
- Restricted Drug (California) - Use only as directed.

When to Treat Cattle with Grubs

IVOME[®] Pour-On (ivermectin topical solution) effectively controls 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 ivermectin, 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 IVOME[®] Pour-On (ivermectin topical solution) at the end of the fly season may be re-treated with IVOME[®] 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, 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 ivermectin comes in contact with soil it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least six hours after treatment. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, ivermectin 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.

How Supplied

IVOMEK Pour-On (ivermectin topical solution) is available in an 250 mL bottle or 1 L bottle with a measure-squeeze-pour system, or in an 2.5 L or 5 L collapsible pack, or 20 L container intended for use with appropriate automatic dosing equipment.

Marketed by:

Boehringer Ingelheim Animal Health USA Inc.

Duluth, GA 30096

Origin China

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PRINCIPAL DISPLAY PANEL - 250 mL Display Carton

ivomec[®] Pour-On (ivermectin topical solution)

Contains: 5 mg ivermectin/mL

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250 mL



Boehringer
Ingelheim

IVOMEK POUR-ON

ivermectin solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:0010-4734
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ivermectin (UNII: 8883YP2R6D) (ivermectin - UNII:8883YP2R6D)	ivermectin	5 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4734-01	1 in 1 CARTON		
1		250 mL in 1 BOTTLE, PLASTIC		
2	NDC:0010-4734-02	1 in 1 CARTON		
2		1000 mL in 1 BOTTLE, PLASTIC		
3	NDC:0010-4734-03	1 in 1 CARTON		
3		2500 mL in 1 BOTTLE, PLASTIC		
4	NDC:0010-4734-04	1 in 1 CARTON		
4		5000 mL in 1 BOTTLE, PLASTIC		
5	NDC:0010-4734-05	1 in 1 CARTON		
5		20000 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140841	08/18/2020	

Labeler - Boehringer Ingelheim Animal Health USA Inc. (007134091)

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Boehringer Ingelheim Animal Health USA Inc.