

IVERMECTIN POUR-ON FOR CATTLE - ivermectin solution

Durvet

Durvet

IVERMECTIN

(ivermectin) POUR-ON for Cattle

Contains 5 mg ivermectin per mL

ANADA 200-272, Approved by FDA

Parasiticide

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

Introduction

Ivermectin (ivermectin) Pour-On delivers internal and external parasite control in one convenient low-volume application.

Indications

Ivermectin Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (adults and L₄)

(including inhibited stage)

Haemonchus placei (adults and L₄)

Trichostrongylus axei (adults and L₄)

T. colubriformis (adults and L₄)

Cooperia oncophora (adults and L₄)

Cooperia punctata (adults and L₄)

Cooperia surnabada (adults and L₄)

Strongyloides papillosus (adults)

Oesophagostomum radiatum (adults and L₄)

Trichuris 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

Ivermectin Pour-On 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

Ivermectin Pour-On controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Ivermectin Pour-On 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.

Administration

Collapsible Pack (33.8 fl oz/1 liter pack with dispensing cap)

The dispensing cap is graduated in 5 mL increments. Each 5 mL will treat 110 lbs body weight. When body weight is between markings, use the next higher increment. Attach the dispensing cap to the bottle. Select the correct dose rate by rotating the adjuster top in either direction to position the dose indicator to the appropriate level. Hold the bottle upright and gently 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. Tilt the bottle to deliver the dose. The "closed-off-shut" position will close the system between dosing. If the animal being treated weighs more than 550 lbs (250 kg), refill the dispensing cap to the additional amount required to provide the total dose for that animal and apply as directed.

Collapsible Pack (84.5 fl oz/2.5 liter pack; 169 fl oz/5 liter pack with dosing gun/applicator)

Because of the solvents used in Ivermectin Pour-On, the applicator gun from Simcro Tech, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Remove the shipping cap from the backpack container and replace with the vent cap provided. Attach the hose from the automatic dosing equipment to the outlet from the vent cap. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

Container (676 fl oz/20 liter container with draw-off device and dosing gun/applicator)

Because of the solvents used in Ivermectin Pour-On, the draw-off device and applicator gun from SimcroTech, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Screw Feedlot pack cap and dip tube onto the 20 liter drum ensuring a tight fit. Connect the long 3m feed tube at one end to the spigot on the Feedlot pack cap and the other end to the applicator gun. Then follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

When the interval between use of the applicator gun is expected to exceed 12 hours, disconnect the gun, draw off tubing and dip tub and cap from the product container, empty the product from the gun and

tubing back into the container and replace the shipping cap.

| Weight | Dose |
|------------------|-------------|
| 220 lb (100 kg) | 10 mL |
| 330 lb (150 kg) | 15 mL |
| 440 lb (200 kg) | 20 mL |
| 550 lb (250 kg) | 25 mL |
| 660 lb (300 kg) | 30 mL |
| 770 lb (350 kg) | 35 mL |
| 880 lb (400 kg) | 40 mL |
| 990 lb (450 kg) | 45 mL |
| 1100 lb (500 kg) | 50 mL |

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.

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.

RESIDUE INFORMATION: 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.

WARNING! NOT FOR USE IN HUMANS

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.

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

WARNING! FLAMMABLE!

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

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS, or for assistance call Durvet on 816-229-9101.

PRECAUTIONS

Store away from excessive heat (104°F/40°C) and protect from light.

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 Ivermectin (ivermectin) Pour-On is stored at temperatures below 32° F. Allowing it 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, Ivermectin Pour-On is not recommended for use in species other than cattle.

When to Treat Cattle with Grubs

Ivermectin Pour-On 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.* bows 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 Ivermectin Pour-On at the end of the fly season may be re-treated with Ivermectin 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 ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish or 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 the 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.

Package Information

Ivermectin Pour-On is available in a 33.8 fl oz/1 L collapsible pack for use with the dispensing cap provided, or in an 84.5 fl oz/2.5 L collapsible pack, in a 169 fl oz/5 L collapsible pack and a 676 fl oz/20 L container intended for use with appropriate automatic dosing equipment.

Manufactured for:
Durvet, Inc.

Blue Springs, MO 64014
USA

Restricted Drug - California. Use Only as Directed.

Made in the UK

Rev: 5/09

009215I03

Principal Display Panel

Principal Display Panel – 5 L Container Label

NDC 30798-240-19

durvet

IVERMECTIN

(ivermectin) POUR-ON for Cattle

Contains 5 mg ivermectin per mL

ANADA 200-272, Approved by FDA

Parasiticide

Kills: Roundworms, (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

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

WARNING!

NOT FOR USE IN HUMANS.

NET CONTENTS: 5 L (169 fl oz)

010215L01

Lot No. & Exp. Date

Manufactured for:

Durvet, Inc.

Blue Springs, MO 64014

www.durvet.com

Manufactured by:

Norbrook Laboratories Ltd.


Newry, Co. Down, BT35 6PU,

Northern Ireland

NDC 30798-240-19

durvet

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POUR-ON
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Manufactured by: Norbrook Laboratories Ltd, Newry, Co. Down, BT35 6PU, Northern Ireland

Manufactured for: Durvet, Inc., Blue Springs, MO 64014, www.durvet.com

Lot No. & Exp. Date ▼

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Iss: 9/04

NET CONTENTS: 5 L (169 fl oz) 010215L01

NDC 30798-240-19

durvet

IVERMECTIN
 (ivermectin)
POUR-ON
 for Cattle

 Contains 5 mg ivermectin per mL

ANADA 200-272, Approved by FDA

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

INDICATIONS:
 For the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites in cattle. See package insert for complete indications and use directions.

RECOMMENDED DOSE:
 1 mL per 22 lb of body weight.

Administration
 Because of the solvents used in Ivermectin Pour-On, the applicator gun from Simcro Tech, or equivalent, is recommended. Other applicators may exhibit compatibility problems resulting in locking, incorrect dosage or leakage. Remove the shipping cap from the backpack container and replace with the vent cap provided. Attach the hose from the automatic dosing equipment to the outlet from the vent cap. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

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WARNING
NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS, or for assistance call Durvet on 816-229-9101.

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PRECAUTIONS:
Store away from excessive heat (104°F/40°C) and protect from light.

Use only in well-ventilated areas or outdoors. Close container tightly when not in use.

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Ivermectin has been associated with adverse reactions in sensitive dogs; therefore, Ivermectin Pour-On is not recommended for use in species other than cattle.

Disposal:
 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.

Restricted Drug - California. Use Only as Directed.
 Made in the UK.

5 L (169 fl oz) Iss: 5/09 011215L02

Principal Display Panel

Principal Display Panel – 5 L Carton Label

NDC 30798-240-19

durvet

IVERMECTIN

(ivermectin) POUR-ON for Cattle

Contains 5 mg ivermectin per mL

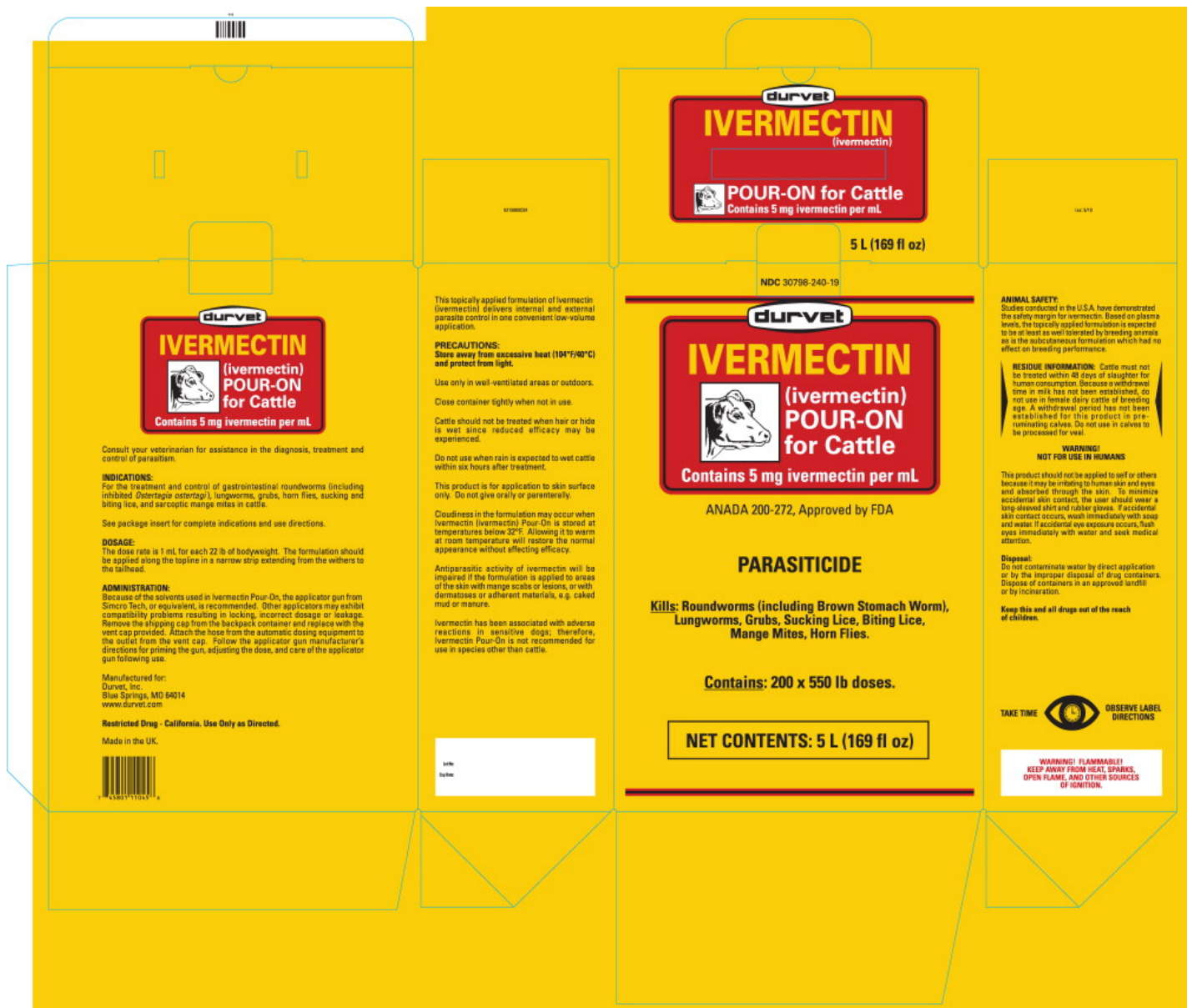
ANADA 200-272, Approved by FDA

Parasiticide

Kills: Roundworms, (including Brown Stomach Worm), Lungworms, Grubs, Sucking Lice, Biting Lice, Mange Mites, Horn Flies

Contains: 200 x 550 lb doses.

NET CONTENTS: 5 L (169 fl oz)



IVERMECTIN POUR-ON FOR CATTLE

ivermectin solution

Product Information

| | | | |
|--------------------------------|-----------------|---------------------------|---------------|
| Product Type | OTC ANIMAL DRUG | Item Code (Source) | NDC:30798-240 |
| 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 |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| isopropyl myristate (UNII: 0RE8K4LNJS) | |

| | |
|--------------------------------------|--|
| trolamine (UNII: 9O3K93S3TK) | |
| FD&C Blue No. 1 (UNII: H3R47K3TBD) | |
| isopropyl alcohol (UNII: ND2M416302) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------|----------------------|--------------------|
| 1 | NDC:30798-240-20 | 1 in 1 CARTON | | |
| 1 | | 1000 mL in 1 CONTAINER | | |
| 2 | NDC:30798-240-78 | 1 in 1 CARTON | | |
| 2 | | 2500 mL in 1 CONTAINER | | |
| 3 | NDC:30798-240-19 | 1 in 1 CARTON | | |
| 3 | | 5000 mL in 1 CONTAINER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200272 | 08/01/2005 | |

Labeler - Durvet (056387798)

Registrant - Norbrook Laboratories Limited (214580029)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|-----------------------|
| Armagh Road | | 232880554 | MANUFACTURE, ANALYSIS |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|---------------------|
| Carnbane Industrial Estate | | 211218325 | MANUFACTURE |