

INNER LABEL

DIN 02330369

Veterinary Use Only

IVERMECTIN
Pour-On for Cattle

5 LITRES

Active Ingredient: Each mL contains 5 mg of Ivermectin

Alberta Veterinary Laboratories Ltd
Calgary Alberta
411 – 19th Street. SE
Calgary, Alberta T2E 6J7
Ph: 1-866-620-6034

Warnings:

1. Treated cattle must not be slaughtered for use in food for at least forty-nine (49) days after the latest treatment with this drug.
2. Because a withholding time for milk has not been established, non-lactating-dairy cows must not be treated within two months before the calving date.
3. Do not use in calves to be processed for veal as a withdrawal period has not been established for this product in pre-ruminating calves.
4. This product may be irritating to human skin and eyes. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and contact a physician.
5. Use only in well ventilated areas or outdoors. Close container tightly when not in use.
6. Keep out of reach of children.

Indications:

For the treatment of parasitic infections and infestations due to gastrointestinal roundworms, eyeworms, lungworms, grubs, sucking lice, biting lice, mites, and horn flies in cattle. See package insert for complete list of parasites. In addition, due to its persistent effect, this product also controls certain parasitic infections and infestations as outlined in the enclosed package insert.

Dosage and Administration:

One mL of Ivermectin Pour-On for Cattle per 10kg of body weight applied along the topline from the withers to the tail head. See package insert for complete use directions.

Cautions:

1. For topical application only. Do not administer orally or parenterally.
2. This product is not for use in species other than cattle.
3. Cattle should not be treated when hair or hide is wet since reduced efficacy will be experienced. Rain falling on cattle in less than 2 hours after dosing may result in reduced efficacy.
4. The 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.
5. To prevent potential secondary reactions when treating infections with cattle grubs consult your veterinarian on the correct timing of treatment.

Storage:

Store below 25°C, store away from heat.

Ivermectin Pour-On for Cattle stored at temperatures below 0°C may become cloudy.

Warming at room temperature will restore the normal appearance without affecting efficacy. Store away from light.

Flammable: Keep away from heat, sparks, open flames, other sources of ignition.

Lot No.: XXXXX

Exp.: XXX-XXXX

Version 3 – April 5, 2013
Supersedes Version 2 – March 11, 2013

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Lot No.: XXXXXX

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OUTER LABEL
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Veterinary Use Only
IVERMECTIN
Pour-On for Cattle

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Version 3 – April 5, 2013
Supersedes Version 2 – March 11, 2013

FOR VETERINARY USE ONLY

Net Contents: 5L and 10L

IVERMECTIN Pour-On for Cattle

INTRODUCTION

IVERMECTIN Pour-On for Cattle contains ivermectin, a unique chemical entity. Its convenience, broad-spectrum efficacy and wide safety margin make it an excellent antiparasitic product for cattle. One dose effectively controls a wide range of internal and external parasites that can impair the health and productivity of cattle.

PRODUCT DESCRIPTION

IVERMECTIN Pour-On for Cattle is a clear, blue coloured liquid containing 5 mg of ivermectin per mL (0.5% w/v). IVERMECTIN Pour-On for Cattle is formulated to deliver the recommended dose level of 500 µg of ivermectin per kg of body weight in cattle when applied along the top line from the withers to the tail head at the rate of 1 mL per 10 kg.

ACTIVE INGREDIENT

Ivermectin is an antiparasitic agent derived from the avermectin family of compounds. The avermectins are highly active, broad-spectrum antiparasitic agents isolated from fermentation of the soil organism *Streptomyces avermitilis*.

INDICATIONS

IVERMECTIN Pour-On for Cattle applied at the recommended dose level of 500 µg of ivermectin per kg of body weight is indicated for the treatment of parasitic infections and infestations due to gastrointestinal roundworms, eyeworms, lungworms, grubs, sucking lice, biting lice, mites and hornflies in cattle. In addition, due to its persistent effect, this product also controls certain parasitic infections and infestations as outlined below.

Following is a complete list of parasites against which efficacy has been demonstrated:

Gastrointestinal roundworms

Ostertagia ostertagi, adults and fourth stage larvae including inhibited *O. ostertagi*; *Haemonchus placei*, adults and fourth stage larvae; *Trichostrongylus axei*, adults and fourth stage larvae; *Trichostrongylus colubriformis*, adults fourth stage larvae; *Cooperia sumabada* (syn. *mcmasteri*), adults, *Cooperia oncophora*, adults, *Cooperia punctata*, adults; *Nematodirus helvetianus*, fourth stage larvae; *Oesophagostomum radiatum*, adults and fourth stage larvae; *Oesophagostomum venulosum*, adults; *Trichuris ovis*, adults; *Strongyloides papillosus*, adults.

IVERMECTIN Pour-On for Cattle administered at the recommended dose controls infections with *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia sumabada* acquired up to 14 days after treatment, *Oesophagostomum radiatum* acquired up to 28 days after treatment, and *Trichostrongylus axei* and *Cooperia punctata* acquired up to 21 days after treatment.

Eye worms – *Thelazia gulosa*, adults; *Thelazia skrjabini*, adults

Mites – *Chorioptes bovis*, *Sarcoptes scabiei* var. *bovis*

If psoroptic mange is to be treated, ivermectin injectable for cattle, sheep and swine is recommended.

Lungworms - *Dictyocaulus viviparus*, adults and fourth stage larvae
IVERMECTIN Pour-On for Cattle administered at the recommended dose controls infections with *Dictyocaulus viviparus*, acquired up to 28 days after treatment.

Lice - *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinea bovis*

IVERMECTIN Pour-On for Cattle administered at the recommended dose controls infestations of *Damalinea (Bovicola) bovis* and *Linognathus vituli* acquired up to 49 days after treatment.

Cattle Grubs (migrating stages) - *Hypoderma bovis*, *H. lineatum*

Horn Flies - *Haematobia irritans*

IVERMECTIN Pour-On for Cattle administered at the recommended dosage controls infections with *Haematobia irritans* acquired up to 35 days after treatment.

Note to User – For best results, IVERMECTIN Pour-On for Cattle should be part of a total parasite control program including internal and external parasites based on the epidemiology of these parasites. Consult your local veterinarian or an entomologist for the most effective timing of applications.

ADMINISTRATION

IVERMECTIN Pour-On for Cattle is formulated for external use only in cattle; it should not be used in other species. The formulation should be applied along the top-line in a narrow strip extending from the withers to the tail head at a dose range of 1 mL per 10 kg of body weight.

Collapsible packs (5L & 10L) Use dosing equipment compatible with IVERMECTIN Pour-On for Cattle. Follow manufacturers directions for use and care of the equipment. Other dosing equipment may be incompatible resulting in locking, incorrect dosage and leakage. Connect the dosing gun to the collapsible pack as follows:

1. Attach the open end of the draw-off tubing to the dosing gun and attach draw off tubing to the self-venting cap with the stem.
2. Replace the shipping cap with the self-venting draw-off cap which has the stem and tighten this cap.
3. Invert the pack and gently prime the dosing gun, check for leaks.

MODE OF ACTION

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of this 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.

NOTE TO USER

The colour of IVERMECTIN Pour-On for Cattle fades when exposed to light, and depending on the light intensity, fading may occur in less than 30 minutes. This rapid loss of colour does not reflect loss of potency of ivermectin. However, prolonged exposure (i.e. weeks) to light can also result in a gradual decline of ivermectin potency in the formulation.

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 water runoff from feedlots to enter lakes, streams or ponds. Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers and any residual contents in an approved landfill or by incineration.

SAFETY

Studies have demonstrated a wide safety margin. 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 has demonstrated an adequate safety margin in breeding animals.

WARNING

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5. Use only in well ventilated areas or outdoors. Close container tightly when not in use.
6. Keep this and all drugs out of reach of children.

CAUTION

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2. This product is not for use in species other than cattle.
3. Cattle should not be treated when hair or hide is wet since reduced efficacy will be experienced. Rain falling on cattle in less than 2 hours after dosing may result in reduced efficacy.
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STORAGE

Store below 25°C, store away from heat. IVERMECTIN Pour-On for Cattle stored at temperatures below 0°C may become cloudy. Warming at room temperature will restore the normal appearance without affecting efficacy. Protect from light.

Flammable: keep away from heat, sparks, open flame, or other sources of ignition.

PACKAGE INFORMATION

IVERMECTIN Pour-On for Cattle is supplied in 5L and 10 L collapsible pack including a self-venting draw-off assembly designed for use with automatic dosing equipment. Each 5L pack contains

enough solution to treat 200 x 250 kg of body weight. Each 10L pack contains enough solution to treat 400 x 250 kg of body weight.

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April 30, 2013