

OUTER (Box) and INNER (Bottle) LABELS/FRONT PANEL/ENGLISH

Net Contents: 250 mL	DIN 00761842
Net Contents: 1 L	DIN 00761842
Net Contents: 2.5 L	DIN 00761842
Net Contents: 5 L	DIN 00761842
Net Contents: 20 L	DIN 00761842

VETERINARY USE ONLY

**IVOMEC®
(ivermectin)**

Pour-On for Cattle

Active ingredient: Each mL contains 5 mg of ivermectin

WARNINGS

1. Treated animals 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 withdrawal time for milk has not been established, non-lactating dairy cows must not be treated within two months of calving.
3. 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.
4. Use only in well-ventilated areas or outdoors. Close container when not in use.
5. Keep out of reach of children.

Merial Canada Inc.
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OUTER (box) and INNER (Bottle) LABEL/RIGHT SIDE PANEL/ENGLISH

INDICATIONS

For the **treatment** of parasitic infections and infestations due to gastrointestinal roundworms, eyeworms, lungworms, grubs, biting and sucking lice, mites and hornflies in cattle. See enclosed 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 under PERSISTENT EFFECT.

DOSAGE AND ADMINISTRATION

One mL of IVOMEK Pour-On for Cattle per 10 kg 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 two 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 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

IVOMEK 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 bottle in carton to protect from light.

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

Lot:

Exp:

PACKAGE INSERT/ENGLISH
VETERINARY USE ONLY

IVOMEC® (ivermectin)
Pour-On for Cattle

PRODUCT DESCRIPTION

IVOMEC Pour-On for Cattle is a clear, blue colored liquid containing 5 mg of ivermectin per mL (0.5% w/v). IVOMEC 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

For the **treatment** of parasitic infections and infestations due to gastrointestinal roundworms, eyeworms, lungworms, grubs, biting and sucking lice, mites and hornflies in cattle. In addition, due to its persistent effect, this product also **controls** certain parasitic infections and infestations as outlined in this document under PERSISTENT EFFECT.

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)*
T. colubriformis (adults and fourth stage larvae)
Cooperia surnabada (syn. *mcmasteri*) (adults)*
C. oncophora (adults)*
C. punctata (adults)*
Nematodirus helvetianus (fourth stage larvae)
Oesophagostomum radiatum (adults and fourth stage larvae)*
O. venulosum (adults)
Strongyloides papillosus (adults)
Trichuris ovis (adults)

EYEWORMS

Thelazia gulosa (adults)

T. skrjabini (adults)

LUNGWORMS

Dictyocaulus viviparus (adults and fourth stage larvae)*

CATTLE GRUBS (MIGRATING STAGES)

Hypoderma bovis

H. lineatum

LICE

Linognathus vituli

Haematopinus eurysternus

Damalinia bovis

MITES

Chorioptes bovis

Sarcoptes scabiei var *bovis*

If psoroptic mange is to be treated, IVOMEC Injection for Cattle, Sheep and Swine is recommended.

HORNFLIES

Haematobia irritans

(*) See **PERSISTENT EFFECT**

PERSISTENT EFFECT

Endoparasites

IVOMEC Pour-On for Cattle given at the recommended dosage of 500 µg of ivermectin per kg of body weight effectively controls infections of *Dictyocaulus viviparus* and *Oesophagostomum radiatum* acquired up to 28 days after treatment; *Trichostrongylus axei* and *Cooperia punctata* acquired up to 21 days after treatment; and *Haemonchus placei*, *Ostertagia ostertagi*, *Cooperia oncophora* and *Cooperia surnabada* (syn. *mcmasteri*) acquired up to 14 days after treatment.

Ectoparasites

IVOMEC Pour-On for Cattle given at recommended dosage of 500 µg of ivermectin per kg of body weight effectively controls infestations of *Haematobia irritans* acquired up to 35 days

after treatment; and *Damalinia (Bovicola) bovis* and *Linognathus vituli* acquired up to 49 days after treatment.

For best results, IVOMEC 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 entomologist for the most effective timing of applications.

ADMINISTRATION

IVOMEC 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 rate of 1 mL per 10 kg of body weight.

Squeeze-Measure-Pour System (250 mL)

Attach the metering cup to the bottle. Set the dose by turning the top section of the cup aligning the correct body weight with the pointer on the knurled cap. When body weight is between the 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. Tilt the bottle to dispense the dose. An off (stop) position is provided to close the system between dosing. Bottles should remain upright during storage.

Squeeze-Measure-Pour System (1 L oval bottle with 50 mL metering cup)

Attach the metering cup to the bottle. Set the dose by turning the top section of the cup, aligning the correct body weight with the pointer on the knurled cap. When body weight is between the 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. Tilt the bottle to dispense the dose. When 100 kg (10 mL) or 150 kg (15 mL) dose is required, turn the pointer to "stop" before dispensing the dose. The off (stop) position will close the system. Bottles should remain upright during storage.

Collapsible Packs (2.5 L and 5L)

Use dosing equipment compatible with IVOMEC Pour-On for Cattle. Follow manufacturer's 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, checking for leaks.

20 Liter Pack

Use dosing equipment compatible with IVOMEC Pour-On for Cattle. Follow manufacturer's 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 drum 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)** Gently prime the dosing gun, checking 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 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 channels and they do not readily cross the blood-brain barrier.

NOTE TO USER

The color of IVOMEK 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 color 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.

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.

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. Drug containers and any residual contents should be disposed of safely (e.g. by burying or incinerating) as free ivermectin may adversely affect fish or certain water-borne organisms.

WARNINGS

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10. Keep out of reach of children.

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PACKAGING

IVOMEK Pour-On for Cattle is available in four ready to use sizes: 250 mL, 1 L, 2.5 L and 5 L.

The 250 mL size is supplied in a multiple-dose bottle with metering cup. Each bottle contains enough solution to treat 10 x 250 kg of body weight (one mL per 10 kg).

The 1 L size is supplied in a multiple-dose bottle with metering cup. Each pack contains enough solution to treat 40 x 250 kg of body weight.

The 2.5 L size is supplied in a soft, collapsible pack including a self-venting draw-off assembly designed for use with automatic dosing equipment. Each pack contains enough solution to treat 100 x 250 kg of body weight.

The 5 L size is supplied in a soft, collapsible pack including a self-venting draw-off assembly designed for use with automatic dosing equipment. Each pack contains enough solution to treat 200 x 250 kg of body weight.

The 20 L size is supplied in a drum and includes a self-venting draw-off assembly designed for use with automatic dosing equipment. Each pack contains enough solution to treat 800 x 250 kg of body weight.

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