ECOMECTIN CATTLE POUR-ON- ivermectin solution Huvepharma, Inc

ECOMECTIN
Cattle Pour-On
(ivermectin topical solution)

ECOMECTIN
CATTLE POUR-ON
(ivermectin topical solution)
Parasiticide for cattle
Contains 5 mg/mL ivermectin

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

INTRODUCTION

Ecomectin Cattle Pour-On (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application. Ecomectin Cattle Pour-On (ivermectin topical solution) contains ivermectin, a unique chemical entity.

MODE OF ACTION

Ivermectin is a member of the macrocylic 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

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

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

Ecomectin Cattle 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

Ecomectin Cattle Pour-On (ivermectin topical solution) controls horn flies (*Haematobia irritans*) for up to 28 days after dosing. For best results Ecomectin Cattle 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

Collapsible packs (1L, 4L, 10L and 20L)

Connect the applicator 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. (Because of the solvents used in Ecomectin Pour-On for Cattle (ivermectin topical solution), use dosing equipment compatible with Ecomectin 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.
- 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.

- 4. Follow the manufacturer's directions for adjusting the dose.
- 5. 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.
- 6. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

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

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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS),

contact Huvepharma, Inc. at 1-877-994-4883 or www.huvepharma.us. For additional information about adverse

drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

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 Ecomectin Cattle Pour-On (ivermectin topical solution) 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, Ecomectin Cattle 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

Ecomectin Cattle 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 Ecomectin Cattle Pour-On (ivermectin topical solution) at the end of the fly season may be re-treated with

Ecomectin Cattle Pour-On (ivermectin topical solution) 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 the 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 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.

HOW SUPPLIED

Ecomectin Cattle Pour-On is supplied in 1L, 4L, 10L, and 20L collapsible pack, including a self-venting draw-off assembly designed for use with automatic dosing equipment. Each 1L solution pack contains enough solution to treat $40 \times 250 \text{ kg}$ of body weight. Each 4L solution pack contains enough solution to treat $160 \times 250 \text{ kg}$ of body weight. Each 10L solution pack contains enough solution to treat $400 \times 250 \text{ kg}$ of body weight. Each 20L solution pack contains enough solution to treat $800 \times 250 \text{ kg}$ of body weight.

Approved by FDA under ANADA # 200-348

Manufactured for Huvepharma, Inc. Peachtree City, Georgia 30269 Made in Canada **ECO**

ECOMECTIN CATTLE POUR-ON (ivermectin topical solution)

Contains 5 mg ivermectin/mL

Parasiticide for cattle

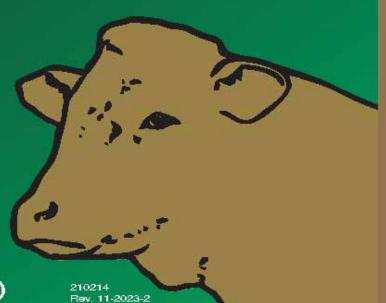
Kills:

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

Approved by FDA under A NADA #200-848

Net Contents:

1 Liters (0.26 Gallons)



ECOMECTIN CATTLE POUR-ON (ivermectin topical enlution)

Contains: 5mg ivermectin/mL

Parasiticide for cattle

This topically applied formulation of Ecomectin Cattle Pour-On (hermectin) topical solution) delivers internal and external parasite control in one convenient low-volume application.

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, hom flies, sucking and biting lice and sarcoptic mange mites in caftle.

See package insert for complete indications and use directions.

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:

Collapsible packs (11, 4L, 10L and 201)

- Connect the applicator 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.

 Because of the solvents used in Ecomectin Pour-On for Cattle inverment in topical solution), use dosing equipment compatible with ECOMECTIN 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.
- Replace the shipping cap with the self-venting draw-off cap which has the stem and tighten this cap.
- Invertithe pack and gently prime the dosing gun, check 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.

Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following

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.
To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Huvepharma, Inc. at 1-877-994-4983 or www.huvepharma us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

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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

Lot No .:

Exp. Date:

Rev. 11-2023-2

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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.

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).

Adecrease 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.

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

Cloudiness in the formulation may occur when Ecomectin Cattle Pour-On. (nermectin topical solution) 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.

Intermectin has been associated with adverse reactions in sensitive dogs; therefore Ecomectin Cattle Pour-On (intermectin topical solution) is not recommended for use in species other than cattle

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.

Manufactured for Huvepharma, Inc. Peachtree City, Georgia 30269 Made In Canada







ECOMECTIN CATTLE POUR-ON

(ivermectin topical solution)

Contains 5 mg ivermectin/mL

Parasiticide for cattle

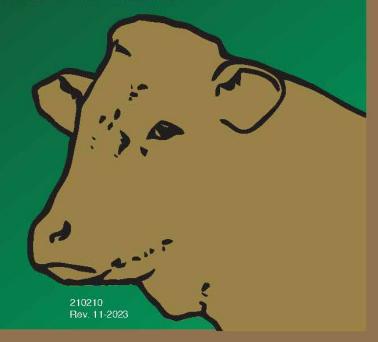
Kills:

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

Approved by FDA under ANADA # 200-348

Net Contents:

4 Liters (1.06 Gallons)



ECOMECTIN CATTLE POUR-ON (ivermectin topical solution) Contains: 5 mg ivermectin/mL Parasiticide for cattle

This topically applied formulation of Ecomectin Cattle Pour-On (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application.

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.

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

ADMINISTRATION:

Collapsible packs (1L, 4L, 10L and 20L)

Connect the applicator gun to the collapsible pack as follows:

- 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. (Because of the solvents used in Ecomectin Pour-On for Cattle (ivermectin topical solution), use dosing equipment compatible with ECOMECTIN 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.
- Replace the shipping cap with the self-venting draw-off cap which has the stem and tighten this cap.
- Invert the pack and gently prime the dosing gun, check 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.
- Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

ANIMAL SAFETY:

Lot No.:

Rev 11-2023

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

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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

Exp. Date:

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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 yeal

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 para site 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

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

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Manufacture d for Huvepharma, Inc. Peachtree City, Georgia 30269 Made in Canada

TAKE TIME **OBSERVE LABEL** DIRECTIONS





ECOMECTIN CATTLE POUR-ON

(ivermectin topical solution)

Contains 5 mg ivermectin/mL

Parasiticide for cattle

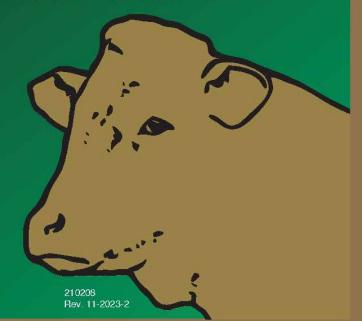
Kills:

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

Approved by FDA under ANADA # 200-348

Net Contents:

10 Liters (2.64 Gallons)



ECOMECTIN CATTLE POUR-ON (ivermectin topical solution) Contains: 5mg ivermectin/mL

Parasiticide for cattle

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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, hom flies, sucking and biting lice and sarcoptic mange mites in cattle.

See package insert for complete indications and use directions.

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:

Collapsible packs (1L, 4L, 10L and 20L)

Connect the applicator gun to the collapsible pack as follows:

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 to the self-venting cap with the stem. (Because of the solvents used in Ecomectin
 Pour-On for Cattle (ivermectin topical solution), use dosing equipment compatible with
 ECOMECTIN 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.
- 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.
- 4. Follow the manufacturer's directions for adjusting the dose.
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ANIMAL SAFETY:

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

Lot No.: Exp. Date:

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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 yeal.

OTHER WARNINGS:

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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.

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.

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Ivermectin has been associated with adverse reactions in sensitive dogs; therefore Ecomectin Cattle Pour-On (ivermectin topical solution) is not recommended for use in species other than cattle.

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.

TAKE TIME

Manufactured for Huvepharma, Inc. Peachtree City, Georgia 30269 Made in Canada OBSERVE LABEL DIRECTIONS



ECO

ECOMECTIN CATTLE POUR-ON (ivermectin topical solution)

Contains 5 mg ivermectin/mL

Parasiticide for cattle

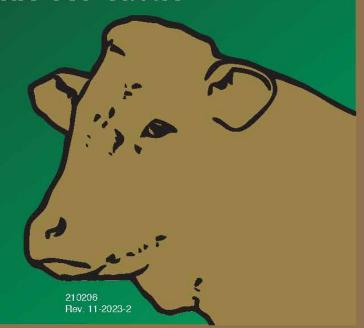
Kills:

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

Approved by FDA under ANADA # 200-348

Net Contents:

20 Liters (5.28 Gallons)



ECOMECTIN CATTLE POUR-ON (ivermectin topical solution) Contains: 5mg ivermectin/mL Parasiticide for cattle

This topically applied formulation of Ecomectin Cattle Pour-On (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application.

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

See package insert for complete indications and use directions.

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:

Collapsible packs (1L, 4L, 10L and 20L)

Connect the applicator 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 And the open and of the down of monitor the cosing gain and attact and a work to the self-venting cap with the stem. (Because of the solvents used in Ecomectin Pour-On for Cattle (ivermectin topical solution), use dosing equipment compatible with ECOMECTIN 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.
- Replace the shipping cap with the self-venting draw-off cap which has the stem and tighten this cap.
- Invert the pack and gently prime the dosing gun, check 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.
- 6. Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Huvepharma, Inc. at 1-877-994-4883 or www.huvepharma.us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

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.

Lot No.: Exp. Date:

Rev. 11-2023-2 210207 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. Awithdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal

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.

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 Ecomectin Cattle Pour-On (ivermectin topical solution) 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.

livermectin has been associated with adverse reactions in sensitive dogs: therefore Ecomectin Cattle Pour-On (ivermectin topical solution) is not recommended for use in species other than cattle

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.

Manufacture d for Huvepharma, Inc. Peachtree City, Georgia 30269 Made in Canada

TAKE TIME **OBSERVE LABEL** DIRECTIONS





ECOMECTIN

CATTLE POUR-ON

(ivermectin topical solution)

Parasiticide for cattle Contains 5 mg/mL ivermectin

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

INTRODUCTION

Ecomectin Cattle Pour-On (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application. Ecomectin Cattle Pour-On (ivermectin topical solution) contains ivermectin, a unique chemical entity.

MODE OF ACTION

Ivermectin is a member of the macrocylic 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

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

(adults and L4)

(parasitic stages)

Gastrointestinal Roundworms

Ostertagia ostertagi	(adults and L4)
(including inhibited stage)	N 98
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

Cattle Grubs

Hypoderma bovis

H. lineatum

Mites

Sarcoptes scabiei var. bovis

Lice

Linognathus vituli Haematopinus eurystemus Damalinia bovis Solenopotes capillatus

Hom Flies

Haematobia irritans

PERSISTENT ACTIVITY

Ecomectin Cattle Pour-On (ivermectin topical solution) has been proved to effectively control infections and to protect cattle from re-infection with: Oesophagostonum 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 sumabada for 14 days after treatment; Damalinia bovis for 56 days after treatment.

TREATMENT OF CATTLE FOR HORN FLIES

Ecomectin Cattle Pour-On (ivermectin topical solution) controls horn flies (*Haematobia initans*) for up to 28 days after dosing. For best results Ecomectin Cattle 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

Collapsible packs (1L, 4L, 10L and 20L)

Connect the applicator gun to the collapsible pack as follows:

- 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. (Because of the solvents used in Ecomectin Pour-On for Cattle (ivermectin topical solution), use dosing equipment compatible with Ecomectin 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.
- Replace the shipping cap with the self-venting draw-off cap which has the stem and tighten this cap.
- Invert the pack and gently prime the dosing gun, check for leaks.
- 4. 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.
- Follow the applicator gun manufacturer's directions for priming the gun, adjusting the dose, and care of the applicator gun following use.

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

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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Huvepharma, Inc. at 1-877-994-4883 or www.huvepharma.us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

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 yeal.

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 freated 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 Ecomectin Cattle Pour-On (ivermectin topical solution) 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, Ecomectin Cattle 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

Ecomectin Cattle 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 Ecomectin Cattle Pour-On (ivermectin topical solution) at the end of the fly season may be re-treated with Ecomectin Cattle Pour-On (ivermectin topical solution) 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 the 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 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.

HOW SUPPLIED

Ecomectin Cattle Pour-On is supplied in 1L, 4L, 10L, and 20L collapsible pack, including a self-venting draw-off assembly designed for use with automatic dosing equipment. Each 1L solution pack contains enough solution to treat 40 x 250 kg of body weight. Each 4L solution pack contains enough solution to treat 160 x 250 kg of body weight. Each 10L solution pack contains enough solution to treat 400 x 250 kg of body weight. Each 20L solution pack contains enough solution to treat 800 x 250 kg of body weight.

Approved by FDA under ANADA # 200-348

Manufactured for Huvephama, Inc. Peachtree City, Georgia 30269 Made in Canada

220011 Rev. 11-2023

ECOMECTIN CATTLE POUR-ON

ivermectin solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:23243-2102
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	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23243-2102-1	1000 mL in 1 BOTTLE		
2	NDC:23243-2102-2	4000 mL in 1 BOTTLE		
3	NDC:23243-2102-5	10000 mL in 1 BOTTLE		
4	NDC:23243-2102-9	20000 mL in 1 PACKAGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200348	06/12/2025	

Labeler - Huvepharma, Inc (619153559)

Revised: 6/2025 Huvepharma, Inc