VETRIMEC- ivermectin solution
MWI VetOne

Vetrimec™ Pour-On
(ivermectin topical solution)
FOR CATTLE
Approved by FDA under ANADA # 200-318
Contains 5 mg ivermectin/mL
Parasiticide

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

INTRODUCTION

Vetrimec™ Pour-On (ivermectin topical solution) delivers internal and external parasite control in one convenient low-volume application. Vetrimec™ 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 the 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

Vetrimec™ 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)
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.	(parasitic stages)

Lung Worms
Dictyocaulus viviparus (adults and L4)
Cattle Grubs
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 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

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

Measure-Squeeze-Pour System (33.8 fl oz 1/Liter Bottle with 25 mL Measuring Cap)

This pack contains 1 measuring cap and 1 dip tube.

1. Insert the dip tube into the base of the measuring cap. Leave the “slotted end” of the dip tube exposed in the bottom of the container.
2. Unscrew shipping cap from container top.
3. Screw measuring cap 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 measuring cap 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 measuring cap is empty.
7. **Storage**:The measuring cap should not remain attached to the container when not in use. Detach the measuring cap after each use and replace the shipping cap to close the container top.

BackPack (84.5 fl oz/2.5 Liter Pack and 169 fl oz/5 Liter Pack)

Connect the applicator gun to the backpack 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.

Free standing bottle (338 fl oz/10 Liter Bottle and 676 fl oz/20 Liter Bottle)

Use dosing equipment (applicator, draw-off tubing, cap with stem) compatible with Vetrimec™ 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 maintenance of the dosing equipment.

Connect the dosing applicator and the draw-off tubing to the bottle 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 applicator gun, 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 and empty the product from the gun and the 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 adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at 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 20°C-25°C (68°F-77°F) and protect from light. Excursions permitted between 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 Vetrimec™ 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, Vetrimec™ 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

Vetrimec™ 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 Vetrimec™ Pour-On (ivermectin topical solution) at the end of the fly season may be re-treated with Vetrimec™ 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/flock, 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 or certain aquatic organisms. Do not permit cattle to enter lakes, streams, or ponds for at least 6 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-dependant insects.

HOW SUPPLIED

Vetrimec™ Pour-On (ivermectin topical solution) is available in a 33.8 fl oz/1 Liter Bottle with a measure-squeeze-pour system, an 84.5 fl oz/2.5 Liter Pack, a 169 fl oz/5 Liter Pack, a 338 fl oz/10 Liter Bottle and a 676 fl oz/20 Liter Bottle intended for use with appropriate automatic dosing equipment.

NDC 13985-523-08

VET one®

Vetrimec™ Pour-On

(ivermectin topical solution)

for Cattle

Contains 5 mg ivermectin/mL

Parasiticide

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

Approved by FDA under ANADA # 200-318

Manufactured for: MWI
Boise, ID 83705
www.VetOne.net
by: Bimeda, Inc.
Le Sueur, MN 56058
1VET017 8VET021 Rev 07/20

V1 503001

Net Contents:
5L (169 fl oz)

VETone

Vetrimec™ Pour-On

(ivermectin topical solution)

for Cattle

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 the complete indications and use directions.

Recommended Dose: 1 mL per 22 lb of body weight.

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.

WARNING

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TAKE TIME OBSERVE LABEL DIRECTIONS

V1 503001 1VET017 8VET021B Rev. 07/20

Lot:

Exp:

3 13985 00924 2

VETRIMEC

ivermectin solution

Product Information			
Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:13985-523
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ivermectin (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	Ivermectin	5 mg in 0.001 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-523-08	5 L in 1 BOTTLE, WITH APPLICATOR		
2	NDC:13985-523-01	1 L in 1 BOTTLE, WITH APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200318	08/07/2009	

Labeler - MWI VetOne (019926120)

Registrant - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda, Inc.		060492923	manufacture

Revised: 5/2021 MWI VetOne