

VETRIMEC PLUS- ivermectin and clorsulon injection

VetOne

Approved by FDA under ANADA #200-450 Restricted Drug (California)-Use Only as Directed

Vetrimec™ Plus

(ivermectin and clorsulon)

Injection for Cattle

For the effective treatment and control of internal parasites, including adult liver flukes, and external parasites.

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

INTRODUCTION: The ability of ivermectin to deliver internal and external parasite control has been proven in cattle markets around the world. Now, Vetrimec™ Plus combines ivermectin, the active ingredient of Vetrimec™ 1%, with clorsulon, an effective adult flukicide. A single injection of Vetrimec™ Plus (ivermectin and clorsulon) offers all the benefits of Vetrimec™ 1% plus control of adult *Fasciola hepatica*.

The dosage level of clorsulon supplied by Vetrimec™ Plus is effective only against adult liver flukes (*Fasciola hepatica*).

PRODUCT DESCRIPTION: Vetrimec™ Plus is a ready-to-use sterile solution containing 1% w/v ivermectin, 10% w/v clorsulon, 40% glycerol formal, and propylene glycol, q.s. ad 100%. It is formulated to deliver the recommended dose level of 200 mcg ivermectin/kg and 2 mg clorsulon/kg given subcutaneously behind the shoulder at the rate of 1 mL per 110 lb (50 kg) body weight.

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. Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as well as plasma are ingested by *Fasciola hepatica*. Adult *Fasciola hepatica* are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

INDICATIONS: Vetrimec™ Plus is indicated for the effective treatment and control of the following parasites in cattle:

Gastrointestinal Roundworms (adults and fourth-stage larvae):

Ostertagia ostertagi (including inhibited *O. ostertagi*)

O. lyrata

Haemonchus placei

Trichostrongylus axei

T. colubriformis

Cooperia oncophora

C. punctata

C. pectinata

Bunostomum phlebotomum

Nematodirus helvetianus (adults only)

N. spathiger (adults only)

Oesophagostomum radiatum

Lungworms (adults and fourth-stage larvae):

Dictyocaulus viviparus

Liver Flukes:

Fasciola hepatica (adults only)

Cattle Grubs (parasitic stages):

Hypoderma bovis

H. lineatum

Sucking Lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

Mange Mites (Cattle Scab*):

Psoroptes ovis (syn. *P. communis* var. *bovis*)

Sarcoptes scabiei var. *bovis*

Persistent Activity: Vetrimec™ Plus has been proved to effectively control infections and to protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Ostertagia ostertagi*, *Trichostrongylus axei* and *Cooperia punctata* for 21 days after treatment; *Haemonchus placei* and *Cooperia oncophora* for 14 days after treatment.

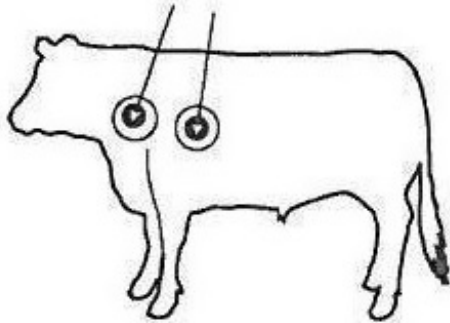
*Ivermectin has been approved as a scabicide by USDA/APHIS. Federal regulations require that cattle infested with or exposed to scabies (i.e., infestations with *Psoroptes ovis*) be treated. Ivermectin when used according to label instructions meets this requirement. Treated cattle may be shipped interstate, but they must not be mixed with other cattle for 14 days following treatment. The federal regulations make no restriction on the movement of cattle not affected with or exposed to scabies. However, individual states have additional regulations to govern the interstate shipment of cattle and the regulatory veterinarian in the state of destination should be consulted for applicable regulations on the use of ivermectin in the control of scabies.

DOSAGE: Vetrimec Plus should be given only by subcutaneous injection at a dose volume of 1 mL per 110 lb. (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon. For example:

Body Weight (lb)	Dose Volume (mL)
220	2
330	3
440	4

550	5
660	6
770	7
880	8
990	9
1100	10

ADMINISTRATION: Vetrimec™ Plus (ivermectin and clorsulon) is to be given subcutaneously only. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, ½” to ¾” sterile needle is recommended. Inject the solution subcutaneously (under the skin) behind the shoulder (see illustration).



When using the 500 mL or 1000 mL package size, use only automatic syringe equipment.

Use sterile equipment and sanitize the injection site by applying a suitable disinfectant. Clean, properly disinfected needles should be used to reduce the potential for injection site infections.

No special handling or protective clothing is necessary.

The viscosity of the product increases in cool temperatures. Administering Vetrimec™ Plus at temperatures of 5°C (41°F) or below may be difficult. Users can make dosing easier by warming both the product and the injection equipment to about 15°C (59°F).

Use within 28 days of first puncture and puncture a maximum of 14 times with a dosage delivery device.

ANIMAL SAFETY: In breeding animals (bulls and cows), ivermectin and clorsulon used at the recommended level had no effect on breeding performance.

WARNING: NOT FOR USE IN HUMANS.

Keep this and all drugs out of reach of children.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse effects, obtain an SDS or for assistance, contact Bimeda, Inc. at 1-888-524-6332.

RESIDUE WARNING: Do not treat cattle within 21 days of slaughter. Because a withdrawal period 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: Transitory discomfort has been observed in some cattle following subcutaneous administration. Soft tissue swelling at the injection site has also been observed. These reactions have disappeared without treatment. Divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction. Different injection sites should be used for other parenteral products.

Vetrimec™ Plus has been developed specifically for use in cattle only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

For subcutaneous injection in cattle only.

This product is not for intravenous or intramuscular use.

Restricted Drug (California) - Use Only as Directed.

When to Treat Cattle with Grubs: Vetrimec™ Plus effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fy (warble fy) season.

Destruction of *Hypoderma larvae* (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *Hypoderma lineatum* when it is in the tissue surrounding the esophagus (gullet) may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with Vetrimec™ Plus, but can occur with any successful treatment of grubs. Cattle should be treated either before or after stages of grub development. Consult your veterinarian concerning the proper time for treatment.

Cattle treated with Vetrimec™ Plus after the end of the heel fy season may be retreated with ivermectin during the winter for internal parasites, mange mites, or sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

Protect product from light.

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 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: Vetrimec™ Plus is available in two ready-to-use sizes:

The 500 mL plastic bottle is suitable for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 100 head of 550 lb (250 kg) cattle.

The 1000 mL plastic bottle is suitable for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 200 head of 550 lb (250 kg) cattle.

Store at 20°C to 25°C (68°F to 77°F). Protect from light.

1000mL

WARNING: NOT FOR USE IN HUMANS.
Keep this and all drugs out of the reach of children.

RESIDUE WARNING: Do not treat cattle within 21 days of slaughter. Because a withdrawal period 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: Use automatic syringe equipment only. For subcutaneous injection in cattle only. Protect product from light. Restricted Drug (California) - Use Only as Directed.

TAKE TIME  OBSERVE LABEL DIRECTIONS

NDC 13985-550-10


Vetrimec[™] PLUS
(ivermectin and clorisulon)

Injection for Cattle



1000 mL

Approved by FDA under
ANADA # 200-450

V1 505035

For the treatment and control of internal parasites, including adult liver flukes, and external parasites.

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

Do not contaminate water. Dispose of containers in an approved landfill or by incineration. See package insert for complete indications, precautions, warnings, residue information, and use directions.

Store at 20°C to 25°C (68°F to 77°F).

Use within 28 days of first puncture and puncture a maximum of 14 times with a dosage delivery device.

Manufactured by
Lundbeck, 7710 Animal Health Dr.
Cincinnati, OH 45240-1162 USA
Product No. 1V51035 2001/01/01 KVM 10/116



Injection for Cattle


Vetrimec[™] PLUS
(ivermectin and clorisulon)

NDC 13985-550-10


Vetrimec[™] PLUS
(ivermectin and clorisulon)

Injection for Cattle

Treats 200-550 lb Cattle

For the treatment and control of internal parasites, including adult liver flukes, and external parasites.



Vetrimec Plus (ivermectin and clorisulon) combines ivermectin for internal and external parasite control and clorisulon, which effectively controls adult liver flukes.

1% w/v ivermectin and 10% w/v clorisulon in a sterile solution

WARNING: NOT FOR USE IN HUMANS.

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

RESIDUE WARNING: Do not treat cattle within 21 days of slaughter. Because a withdrawal period 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: Use automatic syringe equipment only. For subcutaneous injection in cattle only. This product is not for intravenous or intramuscular use.

Protect product from light.

Restricted Drug (California) - Use Only as Directed

Vetrimec Plus (ivermectin and clorisulon) injection for Cattle has been developed specifically for use in cattle only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

contaminants or an appropriate volume of by incubation.

ANIMAL SAFETY: In breeding animals (bulls and cows), ivermectin and closulon used at the recommended level had no effect on breeding performance.

Store at 20°C to 25°C (68°F to 77°F).

Use within 28 days of first puncture and puncture a maximum of 14 times with a dosage delivery device.

Manufactured by: VMI
Box 2, 285705
www.vermex.net

Manufactured by:
Winoda-MTC Animal Health Inc.
Cambridge, ON Canada N3C 2V1

Product No. VCT025
64CT035
Rev. 12/15



3 13985 55010 2



Approved by FDA under
ANADA # 200-450

V1 505035

1000 ml

NDC 13695-550-10

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

INDICATIONS: Vetrimec™ Plus (ivermectin and clorsulon) is indicated for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* larvae), lungworms, adult liver flukes, grubs (note insert precautions), sucking lice, and mange mites (cattle scab) (note insert indications). See package insert for complete indications and use directions.

The dosage level of clorsulon supplied by Vetrimec Plus is effective only against adult liver flukes (*Fasciola hepatica*).

RECOMMENDED DOSE: Vetrimec Plus should be given only by subcutaneous injection at a dose volume of 1 mL per 110 lb (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon.

This bottle is designed for use with automatic syringe equipment only. It contains enough solution to treat five hundred 500 lb cattle. For example:

Body Weight (lb)	Dose (mL)	Doses per Pack
220	2	500
330	3	333
440	4	250
550	5	200
660	6	166
770	7	142
880	8	125
990	9	111
1100	10	100

For body weights over 1100 lbs., administer at 1 mL per 110 lbs. (50 kg).

Divide doses greater than 10 mL between two injection sites to reduce occasional transitory discomfort or site reaction.


Vetrimec™ PLUS
(ivermectin and clorsulon)

Injection for Cattle

Treats 200-550 lb Cattle

For the treatment and control of internal parasites, including adult liver flukes, and external parasites.



Approved by FDA under
ANADA # 200-450

V1 505035

1000 mL

500mL

WARNING: NOT FOR USE IN HUMANS.
Keep this and all drugs out of the reach of children.

RESIDUE WARNING: Do not treat cattle within 21 days of slaughter. Because a withdrawal period 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: Use automatic syringe equipment only. For subcutaneous injection in cattle only. Protect product from light.

Restricted Drug (California) - Use Only as Directed.

TAKE TIME  OBSERVE LABEL DIRECTIONS

MDC 13585-550-50


Vetrimec PLUS
(ivermectin and clorsulon)

Injection for Cattle



Approved by FDA under
ANADA # 200-450

V1 5J4035

500 mL

For the treatment and control of internal parasites, including adult liver flukes, and external parasites.

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. Do not contaminate water. Dispose of containers in an approved landfill or by incineration.

See package insert for complete indications, precautions, warnings, residue information, and use directions.

Store at 20°C to 25°C (68°F to 77°F).

Use within 28 days of first puncture and puncture a maximum of 14 times with a dosage delivery device.

Manufactured for: MVI
Boke, ID 83705
www.VetOne.net

Manufactured by:
Elmida-MTC Animal Health Inc.
Cambridge, ON Canada N3C 2W4
Product No. 1VETC24 8VET033 Rev. 12/13



NDC 13985-550-50

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

INDICATIONS: Vetrimec™ Plus (ivermectin and clorsulon) is indicated for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi* larvae), lungworms, adult liver flukes, grubs (note insert precautions), sucking lice, and mange mites (cattle scab (note insert indications)). See package insert for complete indications and use directions.

The dosage level of clorsulon supplied by Vetrimec Plus is effective only against adult liver flukes (*Fasciola hepatica*).

RECOMMENDED DOSE: Vetrimec Plus should be given only by subcutaneous injection at a dose volume of 1 mL per 110 lb (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon.

This bottle is designed for use with automatic syringe equipment only. It contains enough solution to treat one hundred 550 lb cattle. For example:

Body Weight (lb)	Dose (mL)	Doses per Pack
220	2	250
330	3	166
440	4	125
550	5	100
660	6	83
770	7	71
880	8	62
990	9	56
1100	10	50

For body weights over 1100 lbs., administer at 1 mL per 110 lbs. (50 kg).

Divide doses greater than 10 mL between two injection sites to reduce occasional transitory discomfort or site reaction.


Vetrimec™ PLUS
(ivermectin and clorsulon)

Injection for Cattle

Treats 100-550 lb Cattle

For the treatment and control of internal parasites, including adult liver flukes, and external parasites.



Approved by FDA under
ANADA # 200-450

V1 504035

500 mL

Injection for Cattle



NDC 13985-550-50

Vetrimec Plus (ivermectin and clorsulon) combines ivermectin for internal and external parasite control and clorsulon, which effectively controls adult liver flukes.

1% w/v ivermectin and 10% w/v clorsulon in a sterile solution

WARNING: NOT FOR USE IN HUMANS.

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

RESIDUE WARNING: Do not treat cattle within 21 days of slaughter. Because a withdrawal period 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: Use automatic syringe equipment only. For subcutaneous injection in cattle only. This product is not for intravenous or intramuscular use.

Protect product from light.

Restricted Drug (California) - Use Only as Directed.

Vetrimec Plus (ivermectin and clorsulon) Injection for Cattle has been developed specifically for use in cattle **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

ANIMAL SAFETY: In breeding animals (bulls and cows), ivermectin and clorsulon used at the recommended level had no effect on breeding performance.

Store at 20°C to 25°C (68°F to 77°F).

Use within 28 days of first puncture and puncture a maximum of 14 times with a dosage delivery device.

Made in/produced for: KVM
Delta, D.E.3763
www.vetone.net

Manufactured by:
Bristol-Myers Squibb
Cambridge, ON Canada N3C 2W4

Product No. 1951054
2/97034
Rev. 12/19



Injection for Cattle

Treats 100-550 lb Cattle

For the treatment and control of internal parasites, including adult liver flukes, and external parasites.



Approved by FDA under
ANADA # 200-450

V1 504035

500 mL

VETRIMEC PLUS

ivermectin and clorsulon injection

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13985-550
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IVERMECTIN (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	IVERMECTIN	10 mg in 1 mL
CLORSULON (UNII: EG1ZDO6LRD) (CLORSULON - UNII:EG1ZDO6LRD)	CLORSULON	100 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-550-50	500 mL in 1 VIAL, MULTI-DOSE		
2	NDC:13985-550-10	1000 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200450	03/28/2019	

Labeler - VetOne (019926120)**Registrant** - Bimeda, Inc. (060492923)**Establishment**

Name	Address	ID/FEI	Business Operations
Bimeda- MTC		256232216	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Aino Co., Ltd. of North China Pharmaceutical Group		529804676	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Alivira Animal Health Limited		650916617	api manufacture