IVOMEC PLUS- ivermectin and clorsulon injection
Boehringer Ingelheim Animal Health USA Inc.

Ivomec® Plus
(ivermectin and clorsulon)
Injection for Cattle

Approved by FDA under NADA # 140-833

160022, 160023, 160024, 160025

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 IVOMEC® (ivermectin) to deliver internal and external parasite control has been proven in cattle markets around the world. Now, Boehringer Ingelheim Animal Health combines ivermectin, the active ingredient of IVOMEC, with clorsulon, an effective adult flukicide. A single injection of IVOMEC Plus (ivermectin and clorsulon) offers all the benefits of IVOMEC plus control of adult *Fasciola hepatica*.

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

PRODUCT DESCRIPTION

IVOMEC Plus is a ready-to-use sterile solution containing 1% w/v ivermectin, 10% 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

IVOMEC Plus Injection is indicated for the effective treatment and control of the following parasites of 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[1]):
Psoroptes ovis (syn. *P. communis* var. *bovis*)
Sarcoptes scabiei var. *bovis*

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1 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.

Persistent Activity

IVOMEC Plus Injection 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.

DOSAGE

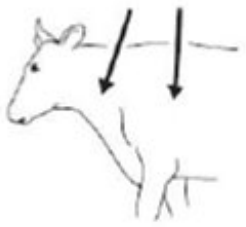
IVOMEC Plus should be given only by subcutaneous injection at a dose volume of 1 mL per 110 lb (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon. For example:

Body Weight (lb)	Dose (mL)
220	2
330	3
440	4
550	5
660	6
770	7
880	8
990	9
1100	10

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

IVOMEC Plus (ivermectin and clorsulon) Injection is to be given subcutaneously only. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, 1/2" to 3/4" sterile needle is recommended. Inject the solution subcutaneously (under the skin) behind the shoulder (see illustration).



Any single-dose syringe or standard automatic syringe equipment may be used with the 50 mL bottle. Use the 50 mL bottle within 6 months of first puncture and puncture a maximum of 12 times. If more than 12 punctures are anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16-gauge, discard any product remaining in the bottle immediately

after use.

When using the 200 mL, 500 mL or 1000 mL pack size, use only automatic syringe equipment. Discard any product remaining in the pack immediately after use.

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 IVOMEC® Plus at temperatures of 5°C (41°F) or below may be difficult. Users can make dosing easier by warming both the product and injection equipment to about 15°C (59°F).

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 the reach of children.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report suspected adverse drug events, for technical assistance, or to obtain a copy of the SDS, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251.

RESIDUE WARNING

Do not treat cattle within 21 days of slaughter. 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

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.

IVOMEC Plus Injection 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

IVOMEC 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 fly (warble fly) 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 IVOMEC 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 IVOMEC Plus after the end of the heel fly 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.

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 soil it readily and tightly binds to the soil and becomes inactive overtime. 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.

STORAGE CONDITIONS

Store at or below 25°C (77°F) with excursions permitted up to 30°C (86°F). Protect product from light.

HOW SUPPLIED

IVOMEC Plus Injection is available in four ready-to-use pack sizes:

The 50 mL pack is a multiple-dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 10 head of 550 lb (250 kg) cattle.

The 200 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 40 head of 550 lb (250 kg) cattle.

The 500 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 100 head of 550 lb (250 kg) cattle.

The 1000 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 200 head of 550 lb (250 kg) cattle.

Distributed by:
Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096

Made in Brazil

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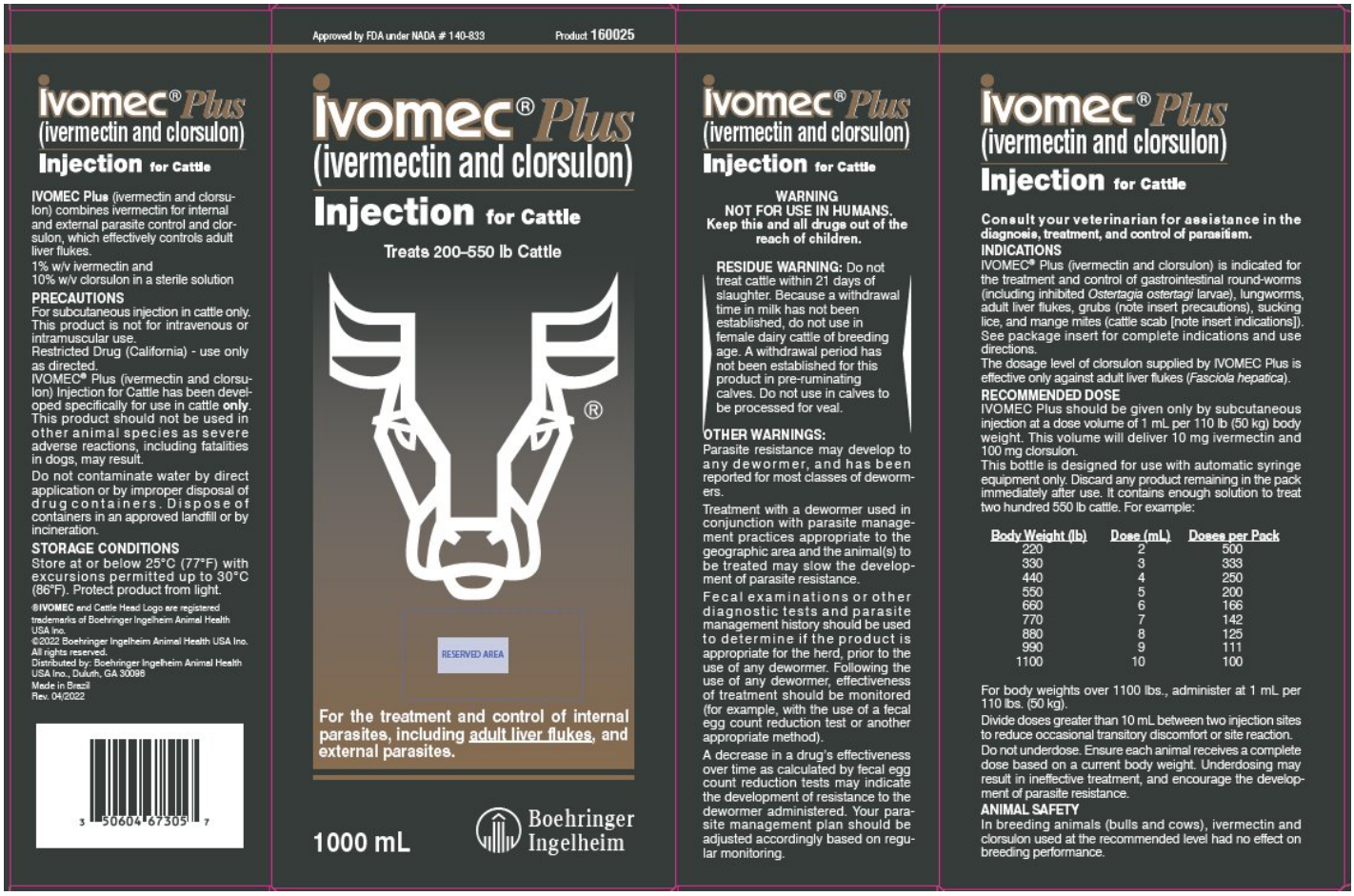
156264-004

PRINCIPAL DISPLAY PANEL - 1000 mL Display Carton

1000 mL



IVOMEC PLUS

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Product Information

Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:0010-4747
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

Inactive Ingredients

Ingredient Name	Strength
glycerol formal (UNII: 3L7GR2604E)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:0010-4747-01	1 in 1 CARTON		
1		50 mL in 1 BOTTLE		
2	NDC:0010-4747-02	1 in 1 CARTON		
2		200 mL in 1 BOTTLE		
3	NDC:0010-4747-03	1 in 1 CARTON		
3		500 mL in 1 BOTTLE		
4	NDC:0010-4747-04	1 in 1 CARTON		
4		1000 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140833	01/24/2022	

Labeler - Boehringer Ingelheim Animal Health USA Inc. (007134091)

Establishment

Name	Address	ID/FEI	Business Operations
Alivira Animal Health Limited		650916617	API MANUFACTURE

Revised: 6/2024 Boehringer Ingelheim Animal Health USA Inc.