INDICATIONS

For the treatment and control of gastrointestinal roundworms, lungworms, lice, and mange mites. See package insert for complete indications, precautions, warnings, residue warning, and use directions.

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

RECOMMENDED DOSE

Cattle: 1 mL per 110 lb body weight. Swine: 1 mL per 75 lb body weight.



EXP. DATE:

NDC 57561-468-06

AGRI-MECTIN®

(ivermectin)

Injection for Cattle and Swine 1% Sterile Solution

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

ANADA 200-429, Approved by FDA

NET CONTENTS: 500 mL



WARNING Not for use in humans. Keep this and all drugs out of the reach of children.

RESIDUE WARNING: Do not treat cattle within 35 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

Do not treat swine within 18 days of slaughter.

PRECAUTIONS: For subcutaneous injection in cattle and swine only. Use automatic syringe equipment only. Protect product from light.

Restricted Drug (California) - use only as directed. Store at 20-25°C.



® Registered Trademark of Agri Laboratories, Ltd.

I-3468-06 Iss. 04-10



treated either before or after these stages of grub development. Consult your veterinarian concerning the proper time for treatment.

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

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 water-borne organisms on which they feed. Do not permit water runoff from feedlots or production sites to enter lakes, streams, or ponds. 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: 50 mL, 200 mL, 500 mL

Store at 20-25°C.

Restricted Drug (California) - use only as directed.

Manufactured for Agri Laboratories, Ltd. St. Joseph, MO 64503, USA

ANADA #200-429. Approved by F.D.A.

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Do not treat swine within 18 days of slaughter.

PRECAUTIONS: For subcutaneous injection in cattle and swine only. Use automatic syringe equipment only. Protect product from light.

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I-3468-06 Iss. 04-10 ANADA 200-429, Approved by FDA

AGRI-MECTIN®

(ivermectin) Injection for Cattle and Swine

1% Sterile Solution

A Parasiticide for the Treatment and Control of Internal and External Parasites of Cattle and Swine

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

Introduction

AGRI-MECTIN® is an injectable parasiticide for cattle and swine. One low-volume dose effectively treats and controls the following internal and external parasites that may impair the health of cattle and swine: gastrointestinal roundworms (including inhibited Ostertagia ostertagi in cattle), lungworms, grubs, sucking lice, and mange mites of cattle; and gastrointestinal roundworms, lungworms, lice, and mange mites of swine.

Product Description

Ivermectin is derived from the avermectins, a family of potent, broad-spectrum antiparasitic agents isolated from fermentation of

Streptomyces avermitilis. Streptomyces avermiums.

AGRI-MECTIN® Injection is a clear, ready-to-use, sterile solution containing 1% ivermectin, 40% glycerol formal, and propylene glycol, q.s. ad 100%. AGRI-MECTIN® Injection is formulated to deliver the recommended dose level of 200 mcg ivermectin/kilogram of body weight in cattle when given subcutaneously at the rate of 1 mL/110 lb (50 kg). In Swine, AGRI-MECTIN® Injection is formulated to deliver the recommended dose level of 300 mcg ivermectin/kilogram body weight when given subcutaneously in the neck at the rate of 1 mL/75 lb (33 kg).

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 namma-aminobutyric acid (GABA).

Mode of Action

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

Cattle: AGRI-MECTIN® Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, grubs, sucking lice and mange mites in cattle:

Gastrointestinal Roundworms Lungworms (adults and fourth-stage larvae):

Ostertagia ostertagi (including inhibited O. ostertagi)

O. Ivrata Haemonchus placei Trichostrongylus axei T. colubriformis Cooperia oncophora . punctata . pectinata Oesophagostomum radiatum Bunostomum phlebotomum Nematodirus helvetianus (adults only)

N. spathiger (adults only)

(adults and fourth-stage larvae): Dictyocaulus viviparus Cattle Grubs (parasitic stages): Hypoderma bovis

H lineatum Sucking Lice: Linognathus vituli Haematopinus eurysternus Solenopotes capillatus Mites (scables):

Psoroptes ovis

(syn. P. communis yar, boyis) Sarcoptes scabiei var. bovis

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Persistent Activity

AGRI-MECTIN® 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,

Swine: AGRI-MECTIN® Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice and mange mites in swine:

Gastrointestinal Roundworms

Large roundworm, Ascaris suum (adults and fourth-stage larvae) Red stomach worm. Hvostronavlus rubidus (adults and fourth-stage larvae) Nodular worm. Oesophagostomum spp. (adults and fourth-stage larvae) Threadworm, Strongyloides ransomi (adults)

Somatic Roundworm Larvae:

Threadworm, Strongyloides ransomi (somatic larvae) Sows must be treated at least seven days before farrowing to prevent infection in piglets.

Lungworms:

Metastrongylus spp. (adults) Lice:

Haematopinus suis Mano Sarcoi

Catt Injecti only injecti skin

ge Mites:	(lb)	(n
optes scabiei var. suis	220	- 2
Dosage	330 440	
<u>lle:</u> AGRI-MECTIN®	550 660	5
tion should be given	770	- 1
by subcutaneous ion under the loose	880 990	8
in front of or behind	1100	1

the shoulder at the recommended dose level of 200 mcg ivermectin per kilogram of body weight. Each mL of AGRI-MECTIN® contains 10 mg of ivermectin, sufficient to treat 110 lb (50 kg) of body weight (maximum 10 mL per injection site).

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Swine:	AGRI-MECTIN®
Injection sho	uld be given only
by subcutan	eous injection in
	f swine at the
	ed dose level of
	rmectin per kilo-
gram (2.2 lb) of body weight.
	AGRI-MECTIN®
contains 1	0 mg of iver-
	fficient to treat
75 lb of boo	y weight.

should be given only		(lb)	(mL)
utaneous injection in k of swine at the	Growing Pigs	19 38	1/4 1/2
ended dose level of ivermectin per kilo-		_ 150 _	- 2
2 lb) of body weight. of AGRI-MECTIN®	Breeding Animals (Sows, Gilts, and Boars)	225 300 375	3 4 5
s 10 mg of iver- sufficient to treat	Dom'oy	450	5 6

Administration

Cattle: AGRI-MECTIN® Injection is to be given subcuta-neously only, to reduce risk of potentially fatal clostridial infection of the injection site. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, 1/2 to 3/4" needle is suggested. Inject under the loose skin in front of

or behind the shoulder (see illustration). When using the 200 mL, 500 mL 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.

Swine: AGRI-MECTIN® Injection is to be given subcutaneously in the neck, Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16- or 18-gauge needle is



suggested for sows and boars, while an 18- or 20-gauge needle may be appropriate for young animals. Inject under the skin, immediately behind the ear (see illustration). When using the 200 mL, 500 mL size, use only automatic syringe equipment. As with any injection, sterile equipment should be used. The injection site should be cleaned and disinfected with alcohol before injection. The rubber stopper should also be disinfected with alcohol to prevent contamination of the contents. Mild and transient pain reactions may be seen in some swine following subcutaneous administration.

Recommended Treatment Program SWINE: At the time of initiating any parasite control program, it is

important to treat all breeding animals in the herd. After the initial treatment, use AGRI-MECTIN® Injection regularly as follows: BREEDING ANIMALS:

Sows: Treat prior to farrowing, preferably 7-14 days before, to minimize infection of piglets.

Treat 7-14 days prior to breeding. Treat 7-14 days prior to farrowing.

Boars: Frequency and need for treatment are dependent upon

exposure. Treat at least two times a year.

FEEDER PIGS

(Weaners/Growers/Finishers)

All weaner/feeder pigs should be treated before placement in clean

Pigs exposed to contaminated soil or pasture may need retreatment if reinfection occurs. NOTE:

(1) AGRI-MECTIN® Injection has a persistent drug level sufficient to control mite infestations throughout the egg to adult life cycle. However, since the ivermectin effect is not immediate, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities. Generally, pigs should not be moved to clean quarters or exposed to uninfested pigs for approximately one week after treatment. Sows should be treated at least one week before farrowing to minimize transfer of mites to newborn baby pigs.

(2) Louse eggs are unaffected by AGRI-MECTIN® Injection and may require up to three weeks to hatch. Louse infestations developing from hatching eggs may require retreatment.

(3) Consult a veterinarian for aid in the diagnosis and control of internal and external parasites of swine.

Special Minor Use
Reindeer: For the treatment and control of warbles (Oedemagena tarandi) in reindeer, inject 200 micrograms ivermectin per kilogram of body weight, subcutaneously. Follow use directions for cattle as described under ADMINISTRATION.

American Bison: For the treatment and control of grubs (Hypoderma bovis) in American bison, inject 200 micrograms ivermectin per kilogram of body weight, subcutaneously, Follow use directions for cattle as described under ADMINISTRATION.

RESIDUE WARNING: Do not treat reindeer or American bison within 8 weeks (56 days) of slaughter.

WARNING

Not for use in humans.

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

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain a MSDS or for assistance, contact Auri Laboratories, Ltd. at 1-800-542-8916.

RESIDUE WARNING: Do not treat cattle within 35 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 yeal.

Do not treat swine within 18 days of slaughter.

Precautions

Transitory discomfort has been observed in some cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed. These reactions have disappeared without treatment. For cattle, divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction

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.

Observe cattle for injection site reactions. Reactions may be due to clostridial infection and should be aggressively treated with appropriate antibiotics. If injection site infections are suspected.

This product is not for intravenous or intramuscular use.

consult your veterinarian. Protect product from light.

AGRI-MECTIN® Injection for Cattle and Swine has been developed specifically for use in cattle, swine, reindeer and American bison only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

When to Treat Cattle with Grubs

AGRI-MECTIN® 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 salivation and bloat: killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with AGRI-MECTIN®, but can occur with any successful treatment of grubs. Cattle should be

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