Ivermectin Injection 1% Sterile Solution

Description:
Ivermectin Injection 1% Sterile Solution is a parasiticide for the treatment and control of internal and external parasites of cattle and swine.

Approved For Use On:
Cattle and Swine

Indications:
Cattle: Ivermectin Injection is indicated for the effective treatment and control of harmful species of gastrointestinal roundworms, lungworms, grubs, sucking lice, and mange mites in cattle.

Swine: Ivermectin Injection is indicated for the effective treatment and control of harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites in swine.

Benefits:
- Broad Spectrum: effective against a wide range of external and internal parasites in beef cattle and swine
- Convenient: single, small volume dose required
- Effective: causes paralysis and death of parasites and helps prevent reinfection
- Package safety: rigid plastic vials provide for a firm grip and prevent breakage, individual vial cartons protect vial contents from sunlight
- Economical: inexpensive on a cost per dose basis
- Safe: approved by FDA

Packaging:
- 50 mL vials, 12 vials per case, UPC# 7-45801-11015-1
- 250 mL vials, 12 vials per case, UPC# 7-45801-11017-5
- 500 mL vials, 12 vials per case, UPC# 7-45801-11018-2

See insert for Indications, Administration and Dosage.
Ivermectin Injection 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

Ivermectin (ivermectin) is an injectable parasiticide for cattles 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.

Ivermectin Injection is a clear, ready-to-use, sterile solution containing 1% ivermectin, 40% glycerol formal, and propylene glycol, q.s. at 100%. Ivermectin 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/10 lb (50 kg). In Swine, Ivermectin Injection is formulated to deliver the recommended dose level of 500 mcg ivermectin/kilogram body weight when given subcutaneously in the neck at the rate of 1 mL per 75 lb (33 kg).

MODE OF ACTION

Ivermectin is a member of the macrocyclic lactone class of antiparasitic agents that work by interfering with the activity of voltage-gated chloride channels in the nervous system of nematode parasites. This interference causes the nerve cells to depolarize, leading to paralysis and death of the parasite.

INDICATIONS

Cattle: Ivermectin 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 (adults and fourth-stage larvae):
  - Ostertagia ostertagi
  - O. triangularis
  - Haemonchus placei
  - Trichostrongylus axei
  - T. colubriformis
  - Cooperia oncophora
  - C. punctata
  - C. plotocærica
  - Oesophagostomum radiatum
  - Bunostomum phlebotomum
  - Nematodirus helvetianus (adults only)
  - N. spathiger (adults only)
  - Lungworms (adults and fourth-stage larvae):
    - Dictyocaulus viviparous
  - Cattle Grubs (parasitic stages):
    - Hypoderma bovis
    - H. lineatum
  - Sucking Lice:
    - Linognathus setosus
    - Haematopinus eurysternus
    - Solenopotes capillatus
  - Mites (scabies):
    - Psoroptes ovis (sheep, P. communis var. bovis)
    - Sarcoptes scabiei var. bovis

Swine: Ivermectin 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, Hysterothylacium rudivis (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)
- Haematopinus suis

Mange Mites:
- Sarcoptes scabiei var. suis

DOSAGE

Cattle: Ivermectin Injection should be given only by subcutaneous injection in the neck of cattle weighing 1100 lb (500 kg) or less. A 1 mL dose is sufficient to treat 100 head of 550 lb (250 kg) cattle or 1000 head of 38 lb (17.3 kg) swine. The 500 mL plastic bottle suitable for use with automatic syringe equipment. Each bottle contains sufficient product to treat 100 head of 550 lb (250 kg) cattle or 1000 head of 38 lb (17.3 kg) swine.

- Body Weight (lb) Dose Volume (mL)
  - 220
  - 320
  - 440
  - 550
  - 660
  - 770
  - 880
  - 990
  - 1100

- Body Weight (lb) Dose Volume (mL)
  - 300
  - 400
  - 500
  - 600

Swine: Ivermectin Injection should be given only by subcutaneous injection in the neck of swine at the recommended dose level of 300 mcg of ivermectin per kilogram (2.2 lb) of body weight. Each mL of Ivermectin Injection contains 10 mg of ivermectin, sufficient to treat 75 lb (34 kg) of body weight.

- Body Weight (lb) Dose Volume (mL)
  - 110
  - 175

ADMINISTRATION

Cattle: Ivermectin Injection is to be given only subcutaneously to cattle weighing 1100 lb (500 kg) or less. Ivermectin Injection is administered to cattle as follows:

1. Cattle should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, ½ to ¾” needle is suggested. Inject under the loose skin, immediately behind the ear (see illustration).

2. Transitory discomfort has been observed in some cattle following subcutaneous administration. A low-grade fever may also be observed.

3. Observe cattle for injection site reactions. Reactions may be due to clostridial infection and should be treated accordingly.

4. Discontinue use if reaction is severe or persists. Reactions may also be due to a sensitivity to ivermectin. In the event of an anaphylactic reaction, treat accordingly.

5. Do not treat cattle within 35 days of slaughter. Because ivermectin can be transferred to milk, do not use in female dairy cattle within 21 days of expected calving.

6. Because of the mode of action of ivermectin, treatment is not expected to be effective against internal parasites that have not reached the mature stage in the host at the time of treatment. These parasites include certain lungworms (e.g., Dictyocaulus viviparous), Eimeria species and Haemonchus placei (parasitic stages) in cattle. Control of these parasites requires additional treatments.

7. When using the 50 mL, 250 mL or 500 mL package size, use only automatic syringe equipment. Use sterile equipment and sanitize the injection site by applying a suitable disinfectant.

Environmental Safety

Studies indicate that when ivermectin comes in contact with soil, it readily and tightly binds to the soil and contaminates the contents. Mild and transient pain reactions may be seen in some swine following subcutaneous administration.

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Ivermectin Injection
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Clean, properly disinfected needles should be used to reduce the potential for injection site infections. No special handling or protective clothing is necessary.

Storing: Ivermectin (ivermectin) 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 swine 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 50 mL, 250 mL or 500 mL package 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 ivermectin injection regularly as follows:

**BRIDGING ANIMALS**
Scheduled treatment pre-breeding and post-weaning is recommended. Infestations may persist for long periods and require treatment at least 3 to 4 times per year.

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

**Gilts:**
- Treat 7-14 days prior to breeding.
- Treat 7-14 days prior to farrowing.

Boars:
- Frequency and need for treatments 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 quarters.
- Pigs exposed to contaminated soil or pasture may need retreatment if reinfection occurs.

**NOTE:**
(1) Ivermectin 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 reinfection from exposure to untreated animals or contaminated facilities. Generally, pigs should not be moved to clean quarters or exposed to unprotected 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) Loose eggs are unaffected by ivermectin injection and may require up to three weeks to hatch. Loose 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 (Oedemagamara 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 6 weeks (96 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 an MSDS or for assistance, contact Durvet, Inc. at 1-800-821-5570.

**RESIDUE WARNING:** Do not treat cattle within 25 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.

**Do not treat swine within 16 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 infection site infections. Observe cattle for injection site reactions. Reactions may be due to oral ingestion and should be aggressively treated with appropriate antibiotics. If injection site infections are suspected, consult your veterinarian.

This product is not for intravenous or intramuscular use. Protect product from light.

Ivermectin 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.

Restricted Drug (California) - Use Only as Directed.

**WHEN TO TREAT CATTLE WITH GRUBS**
Ivermectin Injection 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 bovis (cattle grub), at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing Hypoderma bovis when it is in the tissue surrounding the esophagus (gullet) may cause salivation and boating of the rumen. The soiling of the ventral canal may cause staggering or paralysis. These reactions are not specific to treatment with Ivermectin Injection, but can occur with any successful treatment of grubs. Cattle should be treated either before or after these stages of grub development. Consult your veterinarian concerning the proper time for treatment.

Cattle treated with Ivermectin Injection after the end of the heel fly season may be retreated with Ivermectin Injection 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 soil, it readily and tightly binds to the soil and becomes inactive over time. Free Ivermectin may adversely affect fish and certain aquatic 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. Disposes 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**
Ivermectin Injection for Cattle and Swine is available in three ready-to-use sizes:
- The 50 mL plastic bottle suitable for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 10 head of 550 lb (250 kg) cattle or 100 head of 38 lb (17.3 kg) swine.
- The 250 mL plastic bottle suitable for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 50 head of 550 lb (250 kg) cattle or 500 head of 38 lb (17.3 kg) swine.
- The 500 mL plastic bottle suitable for use with automatic syringe equipment. Each bottle contains sufficient solution to treat 100 head of 550 lb (250 kg) cattle or 100 head of 38 lb (17.3 kg) swine.

**STORAGE**
Store at 20º C to 25º C (68º F to 77º F). Protect from light.

Manufactured by:
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Manufactured for:
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