

HFA 305
SEP 7 2000

F R E E D O M O F I N F O R M A T I O N
S U M M A R Y

Levamisole Phosphate Injectable Solution

ANADA 200-271

Agri Laboratories, Ltd.

P.O. Box 3103

St. Joseph, MO 64503

A N A D A 200-271

F O I S 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

ANADA Number: 200-271

Sponsor: Agri Laboratories, Ltd.
P. O. Box 3103
St. Joseph, MO 64503-0103

Generic Name: Levamisole Phosphate Injectable Solution, 13.65%

Trade Name: N/A

Marketing Status: OTC

Pioneer Product: Levasole Injectable Solution
NADA 126-742, Schering Plough, Inc.

2. INDICATIONS FOR USE

Levamisole Phosphate is a sterile solution recommended for the treatment of cattle infected with the following parasites. Each mL of solution contains levamisole phosphate equivalent to 136.5 mg of levamisole hydrochloride.

STOMACH WORMS: (*Haemonchus, Ostertagia, Trichostrongylus*)

INTESTINAL WORMS: (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia*)

LUNGWORMS: (*Dictyocaulus*)

3. DOSE INFORMATION

A. DOSAGE FORM: Injection

B. ROUTE OF ADMINISTRATION:

Levamisole Phosphate Injectable Solution, 13.65% is for subcutaneous injection in cattle.

C. ESTABLISHED DOSAGE:

Inject subcutaneously in the mid-neck region at the rate of 2 mL per 100 lb body weight. It is recommended that no more than 10 mL be injected at one site.

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

The maturation of some helminth species may be arrested at a pre-adult stage when adult worm populations are heavy.

Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

NOTE: Careful weight estimates are essential for proper performance of this product.

4. **TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will be required to include bioequivalence and residue studies. A tissue residue study will generally be required to accompany a clinical end-point, pharmacologic end-point, and blood level bioequivalence studies that can not quantify the concentration of the drug in the blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalency study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalency Guideline, April 1990).

Based upon the formulation characteristics of the generic product, AgriLabs, Ltd. was granted a waiver from conducting an *in vivo* bioequivalency study for Levamisole Phosphate Injectable Solution, 13.65%. The generic product is administered as a subcutaneous injection.

It contains the same active ingredient and drug concentration as the pioneer product. It is the same dosage form as the pioneer and contains no inactive ingredients that may significantly affect absorption of the active ingredient.

In lieu of *in vivo* bioequivalency testing, chemical equivalence of the generic product to the pioneer product was demonstrated. Testing was conducted by CIA Labs of St. Joseph, Missouri. Product identity and potency testing was conducted using a validated High Pressure Liquid Chromatography (HPLC) method. The results of the testing procedures adequately demonstrate chemical equivalence to the pioneer product.

5. **HUMAN FOOD SAFETY:**

Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.1 ppm is established for Levamisole residues in the uncooked edible tissues of cattle under 21 CFR 556.350.

Withdrawal Time

Under the CVM Bioequivalence Guidelines, when a generic product is granted a waiver of in vivo bioequivalence testing, the withdrawal period established for the pioneer product is also assigned to the generic product.

For Levamisole Phosphate Injectable Solution, 13.65%, a withdrawal period of 7 days has been established for cattle (21 CFR 522.1244).

Regulatory Method for Residues

The analytical method for the determination of Levamisole in the tissues uses a chemical procedure.

6. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that levamisole phosphate injectable solution when used under the proposed conditions of use, is safe and effective for its labeled indications.

Attachments: Labeling

Generic Labeling

Pioneer Labeling

500mL VIAL LABEL

RECOMMENDATIONS:

Levamisole Phosphate is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle:

STOMACH WORMS:

(*Haemonchus*, *Ostertagia*,
Trichostrongylus)

INTESTINAL WORMS:

(*Trichostrongylus*, *Cooperia*, *Nematodius*,
Bunostomum, *Oesophagostomum*,
Chabertia)

LUNGWORMS:

(*Dictyocaulus*)

DOSAGE: Inject 2 mL per 100 lb body weight. See accompanying literature for full directions.

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

Lot No. Exp. Date



LEVAMISOLE PHOSPHATE

Injectable Solution, 13.65%

Sterile Anthelmintic

For Subcutaneous Injection
in Cattle.

ANADA 200-271, Approved by FDA

NET CONTENTS: 500 mL



Each mL of solution contains levamisole phosphate equivalent to 136.5 mg of levamisole hydrochloride.

OPEN
HERE

Do not administer to cattle within 7 days of slaughter for food to avoid tissue residues. To prevent residues in milk, do not administer to dairy animals of breeding age.

WARNING: KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

STORAGE CONDITIONS: To assure maximum potency and efficacy, STORE AT OR BELOW 70°F REFRIGERATION ADVISABLE AVOID FREEZING.

TAKE TIME



OBSERVE LABEL DIRECTIONS

600096

Iss. 5-00

Mfd. For: Agri Laboratories, Ltd.
St. Joseph, MO 64503

should be consulted. Follow recommended dosage carefully.

Experience under field conditions indicates that stressful procedures such as vaccination, castration, dehorning, concurrent exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals, may increase the risk associated with the use of this product. Such concurrent stress should be avoided when using this product.

Consult veterinarian before using in severely debilitated animals.

Available in 500 mL vials

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Each mL of solution contains levamisole phosphate equivalent to 136.5 mg of levamisole hydrochloride.

Do not administer to cattle within 7 days of slaughter for food to avoid tissue residues. To prevent residues in milk, do not administer to dairy animals of breeding age.

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STORAGE CONDITIONS: To assure maximum potency and efficacy, STORE AT OR BELOW 70°F REFRIGERATION ADVISABLE AVOID FREEZING.

TAKE TIME



OBSERVE LABEL DIRECTIONS

600096

Mfd. For: Agri Laboratories, Ltd.
St. Joseph, MO 64503

Iss. 5-00

LEVAMISOLE PHOSPHATE

**Injectable Solution, 13.65%
STERILE Anthelmintic**

Levamisole Phosphate is a sterile solution recommended for the treatment of cattle infected with the following parasites. Each mL of solution contains levamisole phosphate equivalent to 136.5 mg of levamisole hydrochloride.



1

STOMACH WORMS:
(*Haemonchus*, *Ostertagia*, *Trichostrongylus*)

INTESTINAL WORMS:
(*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*)

LUNGWORMS:
(*Dictyocaulus*)

DOSAGE: Inject subcutaneously in the mid-neck region at the rate of 2 mL per 100 lb body weight. It is recommended that no more than 10 mL be injected at one site.

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

The maturation of some helminth

2

species may be arrested at pre-adult stage when adult worm populations are heavy.

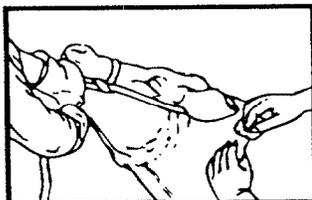
Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

ADMINISTRATION: Thoroughly clean and disinfect syringes and needles by boiling in water for twenty minutes. Use 14 or 16 gauge 1/2 to 1 inch needles.

Do not remove rubber stopper from the bottle, but clean and disinfect it with 70% alcohol. With syringe attached to needle, insert needle through the rubber stopper and withdraw the required dose.

3

The proper method of injection site preparation by swabbing with 70% alcohol or other suitable disinfectant, and the proper method of administration under a fold of skin in the mid-neck region are demonstrated below. A clean, sterile needle should be used for each animal to avoid spreading infection.



4



CAUTION: Careful cattle weight estimates are essential for proper performance of this product. It is recommended that Levamisole Phosphate be injected only in cattle in stocker or feeder condition. Cattle nearing slaughter weight and condition may show objectionable reactions at the site of injection. An occasional animal in stocker or feeder flesh may show swelling at the injection site. The swelling will

5

subside in 7 to 14 days and is no more severe than that observed from commonly used vaccines and bacterins.

The mid-neck region is the preferred injection site. Always use sterile needles and syringes. Non-sterile equipment may cause abscesses at the site of injection. Contents should be used as soon as possible after the seal has been broken. It is recommended that the cap be wiped with alcohol prior to withdrawing solution. Also, skin at injection site should be swabbed with alcohol to avoid infection.

Muzzle foam may be observed; however, this reaction will disappear within a few hours. If this condition persists, a veterinarian

6

12 x 500mL SHIPPER LABEL

RECOMMENDATIONS:

Levamisole Phosphate is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle:

STOMACH WORMS:

(*Haemonchus*, *Ostertagia*, *Trichostrongylus*)

INTESTINAL WORMS:

(*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*)

LUNGWORMS:

(*Dictyocaulus*)

DOSAGE: Inject 2 mL per 100 lb body weight. See accompanying literature for full directions.

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

Lot No. Exp. Date



LEVAMISOLE PHOSPHATE

**Injectable Solution, 13.65%
Sterile Anthelmintic
For Subcutaneous Injection
in Cattle.**

ANADA 200-271, Approved by FDA

NET CONTENTS: 500 mL



Each mL of solution contains levamisole phosphate equivalent to 136.5 mg of levamisole hydrochloride.

OPEN HERE

Do not administer to cattle within 7 days of slaughter for food to avoid tissue residues. To prevent residues in milk, do not administer to dairy animals of breeding age.

WARNING: KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

STORAGE CONDITIONS: To assure maximum potency and efficacy, STORE AT OR BELOW 70°F REFRIGERATION ADVISABLE AVOID FREEZING.

TAKE TIME

OBSERVE LABEL DIRECTIONS

600096

Mfd. For: Agri Laboratories, Ltd.
St. Joseph, MO 64503

Iss. 5-00

RECOMMENDATIONS: LEVASOLE (levamisole phosphate) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle:

STOMACH WORMS: (*Haemonchus*, *Ostertagia*, *Trichostrongylus*)

INTESTINAL WORMS: (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*)

LUNGWORMS: (*Dictyocaulus*)

DOSAGE: Inject 2 mL per 100 lb body weight. Consult accompanying fold-out leaflet for complete dosing instructions.

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

**WARNING:
KEEP THIS AND ALL DRUGS OUT
OF REACH OF CHILDREN.**

Do not administer to cattle within 7 days of slaughter for food to avoid tissue residues. To prevent residues in milk, do not administer to dairy animals of breeding age.

**STORE AT OR BELOW 70°F
REFRIGERATION ADVISABLE
AVOID FREEZING**

20789808 Rev. 10/97

▲ OPEN ALONG PERFORATION ▲

NDC 0061-5042-01

Levasole®
(levamisole phosphate)
Injectable Solution, 13.65%

**STERILE
Anthelmintic**

For Subcutaneous Injection
in Cattle

Each mL of solution contains levamisole phosphate equivalent to 136.5 mg of levamisole hydrochloride.

500 mL

NADA #102-437, Approved by FDA

 Schering-Plough
Animal Health

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Union, NJ 07083. All rights reserved.
By Boehringer Ingelheim Animal Health, Inc.
St. Joseph, MO 64506

RECOMMENDATIONS: LEVASOLE (levamisole phosphate) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle:

STOMACH WORMS: (*Haemonchus*, *Ostertagia*, *Trichostrongylus*)

INTESTINAL WORMS: (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*)

LUNGWORMS: (*Dictyocaulus*)

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STORE AT OR BELOW 70°F
REFRIGERATION ADVISABLE
AVOID FREEZING

20789808 Rev. 10/97

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The maturation of some helminth species may be arrested at the adult stage when adult worm populations are heavy.

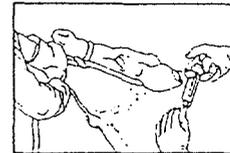
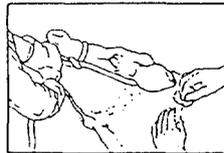
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Do not remove rubber stopper from the bottle, but clean and disinfect with 70% alcohol. With syringe attached to needle, insert needle through the rubber stopper and withdraw the required dose.

The proper method of injection site preparation, is swabbing with alcohol or other suitable disinfectant, and the proper method of administration is under a fold of skin in the mid-neck region as demonstrated. A clean sterile needle should be used for each animal to avoid spreading infection.



CAUTION:

Careful cattle weight estimates are essential for proper performance of this product. It is recommended that LEVASOLE Injectable Solution, 13.65% be injected only in cattle in stocker or feeder condition. Cattle nearing slaughter weight and condition may show objectionable reactions at the site of injection. An occasional animal in stocker or feeder flesh may show swelling at the injection site. The swelling will subside in 7 to 14 days and is no more severe than that observed from commonly used vaccines and bacterins.

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