

HTV-305

Date of Approval Letter: OCT 25 2002

FREEDOM OF INFORMATION SUMMARY

ANADA 200-313

Levamisole Hydrochloride Soluble Pig Wormer

Indication for use: A broad spectrum anthelmintic
Effective against nematode infections in swine.

Sponsored by:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503

ANADA 200-313

FOIS-1

FREEDOM OF INFORMATION SUMMARY

1 GENERAL INFORMATION

ANADA 200-313

ANADA/GENERIC SPONSOR:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503

- a. **Established Name:** Levamisole Hydrochloride
- b. **Trade Name/Proprietary Name:** Levamisole Hydrochloride Soluble Pig Wormer
- c. **Dosage Form:** Soluble Powder
- d. **How Supplied:** Levamisole Hydrochloride Soluble Pig Wormer (18.15 grams of levamisole hydrochloride activity) is supplied with 20.17 g levamisole hydrochloride (0.712 oz) in a 500 mL graduated HDPE bottle.
- e. **How Dispensed:** OTC
- f. **Amount of Active Ingredients:** Each bottle contains the equivalent of 18.15 grams of levamisole hydrochloride activity
- g. **Species:** Swine
- h. **Labeled Dosage and Indications:** (Refer to attached labeling for additional details on mixing instructions)

SWINE- INDICATIONS

A broad-spectrum anthelmintic effective against the following nematode infections: Large roundworms (*ascaris suum*), nodular worms (*Oesophagostomum spp.*), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*)

Do not administer within 72 hours of slaughter for food.

DOSAGE

Dissolve contents of bottle in 500 mL, add 10 mL this solution per gallon of drinking water.

- i. Pioneer Product "Listed" Product: Tramisol® Soluble Pig Wormer (levamisole hydrochloride).
NADA # 112-049

2. 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. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. A tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter, Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study on Levamisole Hydrochloride Soluble Pig Wormer by a letter dated May 19, 1999. The generic and pioneer products are water-soluble powders with the same active ingredients and no differences in the inactive ingredients which would affect absorption of the active ingredients.

3 HUMAN FOOD SAFETY:

Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for residues of levamisole hydrochloride in uncooked edible tissues of swine at 0.1 part per million (negligible residues).

[21 CFR 556.350]

Withdrawal Time:

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for Levamisole Hydrochloride Soluble Pig Wormer is established under:

21 CFR 520.1242a (3) (iii)

Swine – 72 hours before slaughter

Regulatory Method for Residues:

No new method required for this approval

Human Safety Relative to Possession, Handling and Administration:

Labeling Contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

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

Attachments: The following **generic** labeling and currently approved **pioneer** labeling are attached.

- | | |
|------------------|--|
| Generic Labeling | 1. Facsimile package labeling for generic product, as AM Tech®. Levamisole Hydrochloride Pig Wormer. |
| Pioneer Labeling | 2. Pioneer package labeling for Tramisol® Soluble Pig Wormer |

NDC 59130-728-50

**LEVAMISOLE
HYDROCHLORIDE
SOLUBLE PIG WORMER
ANTHELMINTIC
FOR USE IN DRINKING WATER**

This bottle contains 18.15 grams of levamisole hydrochloride activity which will treat the following

- 200 - 25 lb pigs, or
- 100 - 50 lb pigs, or
- 50 - 100 lb pigs, or
- 25 - 200 lb pigs

RECOMMENDATIONS:

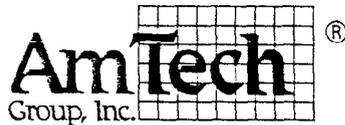
Levamisole Hydrochloride is a broad-spectrum anthelmintic and is effective against the following nematode infections in swine

- LARGE ROUNDWORMS:** (*Ascaris suum*)
- NODULAR WORMS:** (*Desophagostomum* spp)
- LUNGWORMS:** (*Metastrongylus* spp)
- INTESTINAL THREADWORMS:** (*Strongyloides ransomi*)

WARNING: Keep out of reach of children

ANADA 200-313, Approved by FDA

NET WT. 20.17 g (0.712 oz)



DIRECTIONS FOR PREPARING SOLUBLE PIG WORMER SOLUTION
When you are ready to worm your pigs, add water to the powder in this bottle up to 500 mL mark. Agitate to mix thoroughly before using. If any solution is left over, it may be stored for up to 3 months in this tightly capped bottle, agitate well before using.

DATE WATER WAS ADDED TO THIS BOTTLE Month Day Year

DIRECTIONS FOR USE Withholding water from pigs prior to treatment is not necessary for optimum anthelmintic efficacy and is not recommended during hot weather. Add 10 mL (2 teaspoonfuls) of the solution from this bottle to 1 gallon of water; mix thoroughly. Allow one gallon of medicated water for each 100 pounds body weight of pigs to be treated. No other source of water should be offered. As soon as pigs have consumed all the medicated water, resume use of regular water.

NOTE Careful estimates of pig weights are essential for proper performance of this product.

Pigs maintained under conditions of constant worm exposure may require retreatment within 4-5 weeks after the first treatment due to reinfection.

CAUTION Consult veterinarian before administering Levamisole Hydrochloride solution to sick swine. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication.

If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after medicated water is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours. Follow recommended dosage carefully to assure removal of worms and avoid overdose of Levamisole Hydrochloride solution.

WARNING Do not administer within 72 hours of slaughter for food.

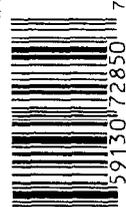
800510

Manufactured by
Phoenix Scientific, Inc
St Joseph, MO 64503

Iss 5-01

Lot No

Exp Date



SBS-30-01
 04 5-30-01
 CA 5-30-01
 10/1 5-31-01
 26 5/31/01
 6206-1-01

CUSTOMER PROOF • CHECK CAREFULLY!

Customer: Phoenix Scientific P.O. #: Lisa
 CYREL #: 26655 (sh) Date Sent: 6/10/99 6/11/99 6/22/99 7/1/99 5/21/01

LABEL: Levamisole Hydrochloride UNWIND #: 4
 SIZE: 4.5" x 6"
 VARNISH: YES PATTERN FLOOD
 NO
 COLORS: 179 red black

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: _____ Date approved: _____

TRAMISOL[®]

(levamisole hydrochloride)

SOLUBLE PIG WORMER



TRAMISOL[®] is a registered trademark of American Cyanamid Company,
used under license. Product of Janssen Research.

Copyright © 1997, Schering-Plough
Animal Health Corp., Union, NJ 07083
20718803 Rev 9/97

0010

✓
9/97
FWS

NDC 0061-5067-01



TRAMISOL®

(levamisole hydrochloride)
SOLUBLE PIG WORMER
ANTHELMINTIC

FOR USE IN DRINKING WATER

This bottle contains 18.15 grams of levamisole hydrochloride, activity which will treat the following:

- 200 - 25 lb. pigs, or
- 100 - 50 lb. pigs, or
- 50-100 lb. pigs, or
- 25-200 lb. pigs

RECOMMENDATIONS:

TRAMISOL® (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in swine:

LARGE ROUNDWORMS: (*Ascaris suum*)

NODULAR WORMS: (*Oesophagostomum* spp.)

LUNGWORMS: (*Metastrongylus* spp.)

INTESTINAL THREADWORMS: (*Strongyloides ransomi*)

WARNING: Keep out of reach of children.

Net Wt. 0.712 oz. (20.17 g)



Schering-Plough Animal Health

Schering-Plough Animal Health Corp.
Union, NJ 07083
Made in Ireland
NADA #112-049, Approved by FDA.

20468904 Rev. 8/97

DIRECTIONS FOR PREPARING SOLUBLE PIG WORMER SOLUTION

When you are ready to worm your pigs, add water to the powder in this bottle up to the 500 mL mark. Agitate to mix thoroughly before using. If any solution is left over, it may be stored for up to 3 months in this tightly capped bottle, agitate well before using.

DATE WATER

WAS ADDED

TO THIS BOTTLE Month Day Year

DIRECTIONS FOR USE: Withholding water from pigs prior to treatment is not necessary for optimum anthelmintic efficacy and is not recommended during hot weather. Add 10 mL (2 teaspoonfuls) of the solution from this bottle to 1 gallon of water, mix thoroughly. Allow one gallon of medicated water for each 100 pounds body weight of pigs to be treated. No other source of water should be offered. As soon as pigs have consumed all the medicated water, resume use of regular water.

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

Pigs maintained under conditions of constant worm exposure may require retreatment within 4-5 weeks after the first treatment due to reinfection.

CAUTION: Consult veterinarian before administering TRAMISOL® (levamisole hydrochloride) solution to sick swine. **Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.**

Salivation or muzzle foam may be observed. This reaction is occasionally seen and will disappear in a short time after medication.

If pigs are infected with mature lungworms, coughing and vomiting may be observed soon after medicated water is consumed. This reaction is due to the expulsion of worms from the lungs and will be over in several hours. Follow recommended dosage carefully to assure removal of worms and avoid an overdose of TRAMISOL® solution.

WARNING: Do not administer within 72 hours of slaughter for food.

TRAMISOL® is a registered trademark of American Cyanamid Company, used under license. Product of Janssen Research. Copyright © 1997, Schering-Plough Animal Health. All rights reserved.



Rev 8/97

TRAMISOL®
(levamisole hydrochloride)
SOLUBLE PIG WORMER

0061-5067-01

WARNING
KEEP OUT OF REACH OF CHILDREN
24-0.712 oz (20.17g)

20375302

TRAMISOL® is a registered trademark of American Cyanamid Company, used under license. Product of Janssen Research.



Schering-Plough Animal Health
Schering-Plough Animal Health Corp.
Union, NJ 07083
Made in Ireland
NADA #112-049, Approved by FDA.

20469200 Rev. 8/97



0009