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FREEDOM OF INFORMATION  
SUMMARY

Prohibit™ (levamisole HCL) Soluble Drench  
Antiparasitic for Cattle and Sheep

ANADA 200-225

Agri Laboratories, LTD

P.O. Box 3103

St. Joseph, MO 64503

ANADA 200-225

FOIS 1

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION

ANADA Number: 200-225

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

Generic Name: Levamisole HCl

Trade Name: PROHIBIT™ Soluble Drench Powder

Marketing Status: OTC

Pioneer Product: Levasole Soluble Drench Powder  
NADA 112-051, Schering-Plough, Inc.

### 2. INDICATIONS FOR USE

PROHIBIT™ Soluble Drench Powder is indicated as an anthelmintic effective against Stomach Worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), Intestinal Worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*) (*Chabertia*, sheep only), Lung worms (*Dictyocaulus*) in cattle and sheep.

### 3. DOSE INFORMATION

A. DOSAGE FORM: Soluble Drench Powder

B. ROUTE OF ADMINISTRATION:

PROHIBIT™ Soluble Drench Powder is recommended as an oral drench in cattle and sheep.

## C. ESTABLISHED DOSAGE:

Add water to contents of container (544.5 g of Levamisole HCl) to the 3 Liter mark and dissolve. This provides approximately 180 mg/mL of Levamisole HCl activity. Administer as a single drench as follows:

## CATTLE - 2 mL per 100 lb. body weight

Weight	Drench Dosage	Bottle will Treat
100 lb.	2 mL	1,500 head
300 lb.	6 mL	500 head
500 lb.	10 mL	300 head
700 lb.	14 mL	214 head
1,000 lb.	20 mL	150 head

## SHEEP - 1 mL per 50 lb. body weight

Weight	Drench Dosage	Bottle will Treat
50 lb.	1 mL	3,000 head
100 lb.	2 mL	1,500 head
150 lb.	3 mL	1,000 head
200 lb.	4 mL	750 head

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

Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

## 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. Approval of an ANADA requires that the sponsor show that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then 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 (Fifth GADPTRA Policy Letter, 55 FR 24645, June 18, 1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Agri Laboratories Ltd was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product PROHIBIT™ (levamisole HCL) Soluble Drench Powder. The generic product is administered as an oral solution and contains the same active and inactive ingredients in the same concentration as 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 and sheep 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 PROHIBIT™ Soluble Drench Powder, a withdrawal period of 2 days has been established for cattle and 3 days for sheep (21 CFR 520.1242a).

Regulatory Method for Residues

The analytical method for the determination of Levamisole HCl 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 PROHIBIT™ (levamisole HCL) Soluble Drench Powder when used under its proposed conditions of use, is safe and effective for the labeled indications.

Attachment: Generic and pioneer labeling

Front

## **PROHIBIT™**

(levamisole hydrochloride)

**Soluble Drench Powder**

**Anthelmintic**

Each packet contains 46.8 grams of levamisole hydrochloride activity.

### **FOR ORAL USE IN CATTLE AND SHEEP**

Administer as a standard drench with standard drench syringe or administer as a concentrated drench solution with an automatic drenching syringe.

### **RECOMMENDATIONS:**

Prohibit (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

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

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

[*Chabertia* - sheep only]

**LUNGWORMS:** (*Dictyocaulus*)

**WARNING:** Keep out of reach of children.  
For Animal Use Only.

ANADA 200-225, Approved by FDA

Net Wt. 1.8 oz. (52 g)

Manufactured for:  
**Agri Laboratories, Ltd.**

P. O. Box 3103

St. Joseph, MO 64503

Back**DOSAGE AND ADMINISTRATION****CATTLE--STANDARD DRENCH**

**SOLUTION**--Place the contents of this packet in a 1 quart (32 fl. oz.) container, fill with water, swirl until dissolved. Administer as a single drench dose according to the following table:

Weight	Drench Dosage	Packet Will Treat
200 lb.	1/2 fl. oz.	64 head
400 lb.	1 fl. oz.	32 head
600 lb.	1 1/2 fl. oz.	21 head
800 lb.	2 fl. oz.	16 head

**CONCENTRATED DRENCH**

**SOLUTION**--For use with automatic syringe. Place the contents of this packet in a standard household measuring container and add water to the 8 3/4 fl. oz. level; or use the measuring container available from your supplier and add water to the mark. Swirl until dissolved. Give 2 ml (milliliter) per 100 lb. body weight. Refer to the table above for the number of cattle this packet will treat.

**SHEEP--STANDARD DRENCH**

**SOLUTION**--Place the contents of this packet in a 1 gallon (128 fl. oz.) container, fill with water, swirl until dissolved. Administer as a single drench dose according to the following table:

Weight	Drench Dosage	Packet Will Treat
50 lb.	1/2 fl. oz.	256 head
100 lb.	1 fl. oz.	128 head
150 lb.	1 1/2 fl. oz.	84 head
200 lb.	2 fl. oz.	64 head

**CONCENTRATED DRENCH**

**SOLUTION**--For use with automatic syringe. Place the contents of this packet in a standard household measuring container and add water to the 17 1/2 fl. oz. level. Swirl until dissolved. Give 2 ml per 50 lb. body weight. Refer to the table above for the number of sheep this packet will treat.

**NOTE:** Careful weight estimates are essential for proper performance of this product. Prepare solutions as needed. However, excess solutions may be stored in clean closed containers up to 90 days without loss of anthelmintic activity.

Cattle and Sheep maintained under conditions of constant helminth exposure may require re-treatment within two to four weeks after the first treatment.

**WARNING:** Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

**CAUTION:** Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

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

Store between 15-30°C (59-86°F).

**RECOMMENDATIONS:**

PROHIBIT (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

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

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

[*Chabertia*--sheep only]

LUNGWORMS: (*Dictyocaulus*)

**WARNING:** Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

Issue Date 0997

Manufactured for  
Agri Laboratories, Ltd.  
P. O. Box 3103  
St. Joseph, MO 64503

**PROHIBIT™**

(levamisole hydrochloride)  
Soluble Drench Powder  
Anthelmintic

**FOR ORAL USE IN CATTLE  
AND SHEEP**

Each packet contains 46.8 grams of  
levamisole hydrochloride activity.

For Animal Use Only  
Keep Out of Reach of Children

ANADA 200-225, Approved by FDA

NET CONTENTS: 30 X 52 Gram  
Pouches

**DOSAGE AND ADMINISTRATION**

Refer to packet for complete dosage and administration instructions.

**NOTE:** Careful weight estimates are essential for proper performance of this product. Prepare solutions as needed. However, excess solutions may be stored in clean closed containers up to 90 days without loss of anthelmintic activity. Cattle and Sheep maintained under conditions of constant helminth exposure may require re-treatment within two to four weeks after the first treatment.

**CAUTION:** Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

Store between 15-30°C (59-86°F).

**INDICATIONS:** PROHIBIT (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

**STOMACH WORMS:** (*Haemonchus*, *Trichostrongylus*, *Ostertagia*)  
**INTESTINAL WORMS:** (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*)  
[*Chabertia*-Sheep only]  
**LUNGWORMS:** (*Dictyocaulus*)

**WARNING:** Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

**CAUTION:** Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

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

Store between 15-30°C (59-86°F).

Issue Date 0997  
Manufactured for:  
Agri Laboratories, Ltd.  
P. O. Box 3103  
St. Joseph, MO 64503

**PROHIBIT™**  
(levamisole hydrochloride)  
**Soluble Drench Powder**  
Anthelmintic

For Oral Use in Cattle and Sheep

This bottle contains 544.5 grams of levamisole hydrochloride activity.

For Animal Use Only

Keep Out of Reach of Children

ANADA 200-225, Approved by FDA

Net Wt.: 21.34 oz (1.3 lb.)  
(605 g)

**DOSAGE AND ADMINISTRATION:** When you are ready to deworm your cattle or sheep, add water to the powder in this bottle up to the 3 liter mark. Swirl 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, shake well before using.

**DATE WATER  
WAS ADDED TO  
THIS BOTTLE**

Month Day Year  
Administer as a single drench dose as follows:

Weight	CATTLE--2 mL per 100 lb. body weight	
	Drench	Bottle
100 lb	2 mL	Will Treat 1,500 head
300 lb	6 mL	500 head
500 lb.	10 mL	300 head
700 lb.	14 mL	214 head
1,000 lb.	20 mL	150 head

Weight	SHEEP--1 mL per 50 lb. body weight	
	Drench	Bottle
50 lb.	1 mL	Will Treat 3,000 head
100 lb.	2 mL	1,500 head
150 lb.	3 mL	1,000 head
200 lb.	4 mL	750 head

**NOTE:** Careful weight estimates are essential for proper performance of this product. Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

**INDICATIONS: PROHIBIT** (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

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

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

[*Chabertia*-Sheep only]

**LUNGWORMS:** (*Dictyocaulus*)

**WARNING:** Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

**CAUTION:** Muzzle foam may be observed.

However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

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

Store between 15-30°C (59-86°F).

Issue Date 0997  
Manufactured for:  
Agri Laboratories, Ltd.  
P. O. Box 3103  
St. Joseph, MO 64503

**PROHIBIT™**  
(levamisole hydrochloride)  
**Soluble Drench Powder**  
Anthelmintic

For Oral Use in Cattle and Sheep

This bottle contains 544.5 grams of levamisole hydrochloride activity.

For Animal Use Only

Keep Out of Reach of Children

ANADA 200-225, Approved by FDA

Net Wt.: 21.34 oz (1.3 lb.)  
(605 g)

**DOSAGE AND ADMINISTRATION:** When you are ready to deworm your cattle or sheep, add water to the powder in this bottle up to the 3 liter mark. Swirl 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, shake well before using.

**DATE WATER  
WAS ADDED TO  
THIS BOTTLE**

Month Day Year  
Administer as a single drench dose as follows:  
**CATTLE--2 mL per 100 lb. body weight**

Weight	Drench Dosage	Bottle Will Treat
100 lb	2 mL	1,500 head
300 lb	6 mL	500 head
500 lb.	10 mL	300 head
700 lb.	14 mL	214 head
1,000 lb.	20 mL	150 head

**SHEEP--1 mL per 50 lb. body weight**

Weight	Drench Dosage	Bottle Will Treat
50 lb.	1 mL	3,000 head
100 lb.	2 mL	1,500 head
150 lb.	3 mL	1,000 head
200 lb.	4 mL	750 head

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

Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

50865

NDC 11716-5086-5

# Levasole

(levamisole hydrochloride)  
Soluble Drench Powder  
Anthelmintic

## Cattle and Sheep Dewormer For Oral Use

This bottle contains 544.5 grams of levamisole hydrochloride activity.

**INDICATIONS:** LEVASOLE (levamisole hydrochloride) is a broad-spectrum anthelmintic and is effective against the following nematode infections in cattle and sheep:

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

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

**LUNGWORMS:** (*Dictyocaulus*)



**WARNING:** Keep out of reach of children.

Net Wt. 21.34 oz. (605 g)



**PITMAN-MOORE**

Pitman-Moore, Inc.

Washington Crossing, NJ 08560, U.S.A.

**DOSAGE AND ADMINISTRATION:** When you are ready to deworm your cattle or sheep, add water to the powder in this bottle up to the 3 liter mark. Swirl 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; shake well before using.

### DATE WATER

WAS ADDED

TO THIS BOTTLE      Month      Day      Year

Administer as a single drench dose as follows:

**CATTLE**—2 mL per 100 lb. body weight

Weight	Drench Dosage	Bottle Will Treat
100 lb.	2 mL	1,500 head
300 lb.	6 mL	500 head
500 lb.	10 mL	300 head
700 lb.	14 mL	214 head
1,000 lb.	20 mL	150 head

**SHEEP**—1 mL per 50 lb. body weight

Weight	Drench Dosage	Bottle Will Treat
50 lb.	1 mL	3,000 head
100 lb.	2 mL	1,500 head
150 lb.	3 mL	1,000 head
200 lb.	4 mL	750 head

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

Cattle and Sheep maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

**WARNING:** Do not administer to cattle within 48 hours of slaughter for food. Do not administer to sheep within 72 hours of slaughter for food. To prevent residues in milk, do not administer to dairy animals of breeding age.

**CAUTION:** Muzzle foam may be observed. However, this reaction will disappear within a few hours. If this condition persists, a veterinarian should be consulted. Follow recommended dosage carefully. Consult veterinarian before using in severely debilitated animals.

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

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Exp. Date 12/90

List No. 757087