

**FREEDOM OF INFORMATION SUMMARY**

**ORIGINAL NEW ANIMAL DRUG APPLICATION**

**ANADA 200-241**

Lincomycin Hydrochloride Soluble Powder

SWINE: Lincosol Soluble Powder is indicated for the treatment of swine dysentery (bloody scours)

BROILER CHICKENS: Lincosol Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin

Sponsored by:

Med-Pharmex, Inc.  
2727 Thompson Creek Rd  
Pomona, CA 91767-1861

**FREEDOM OF INFORMATION SUMMARY:**

**I. General Information:**

ANADA Number: **200-241**

Sponsor Name and Address:  
Med-Pharmex, Inc.  
2727 Thompson Creek Rd  
Pomona, CA 91767-1861

Established Name:  
Lincomycin soluble powder

Trade Name:  
Lincosol Soluble Powder

Marketing Status: OTC

Dosage Form:  
The product is available in the form of a soluble powder for oral administration

Pioneer Product:  
Pharmacia & Upjohn's Lincomix<sup>®</sup> Soluble Powder, NADA 111-636

**II. Indications for Use:**

SWINE: Lincosol Soluble Powder is indicated for the treatment of swine dysentery (bloody scours)

BROILER CHICKENS: Lincosol Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**III. Route of Administration and Recommended Dosages:**

**Labeled Dosage  
and Administration**

**Swine:**

Dosage: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate

provided an average of 3.8 mg of lincomycin per pound of body weight per day.

**Treatment period:** The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days.

**Administration:** One packet (40 g) or one scoop (40 g) will medicate 64 gallons of drinking water providing 250 mg/gallon. One 80-g packet or two scoops will medicate 128 gallons of drinking water providing 250 mg/gallon.

**Indications for Use:** Lincomycin Soluble is indicated in swine for the treatment of dysentery (bloody scours).

**Labeled Dosage and Administration**

**Broiler chickens:**

**Dosage:** Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

**Treatment Period:** The drug should be administered for 7 consecutive days.

**Administration:** One packet (40 g) or one scoop (40 g) will medicate 250 gallons of drinking water providing 64 mg/gallon. One 80-g packet or two scoops will medicate 500 gallons of drinking water providing 64 mg/gallon.

**Indications for Use:** Lincosol Soluble Powder is indicated in broiler chickens for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**IV. TARGET ANIMAL SAFETY AND EFFECTIVENESS:**

Under the provisions of the Federal Food, Drug and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, 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 and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA. Ordinarily the

ANADA sponsor shows the generic product is bioequivalent to the pioneer, and the ANADA relies on the target animal safety, effectiveness, and human food safety data in the new animal drug application (NADA) for the pioneer. If bioequivalence is demonstrated through a clinical endpoint 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 the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, 1996).

Based on the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product LINCOSOL SOLUBLE POWDER (lincomycin hydrochloride soluble powder). The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product is Lincomix® Soluble Powder (lincomycin hydrochloride soluble powder), the subject of the Upjohn Company's (now Pharmacia & Upjohn Company) NADA 111-636, approved on January 2, 1983.

## V. HUMAN FOOD SAFETY

### Tolerances

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.1 part per million is already established for negligible residues in the edible tissues of swine under 21 CFR 556.360(a). A tolerance for tissue residues in chickens is not required (21 CFR 556.360(b)).

### Withdrawal Times

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 times for lincomycin HCl soluble powder are established under 21 CFR 520.1263c: Six days for swine and zero days for broiler chickens. Lincomycin HCl is not approved for use in layer and breeder chickens.

### Regulatory Method for Residues

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Sarcina lutea* (ATCC 9341). The method is on display in FDA's Freedom of Information Public Room, 5600 Fishers Lane, Rockville, MD 20857.

**VI. 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 Lincomycin Hydrochloride Soluble Powder when used under the proposed conditions of use, is safe and effective for its labeled indications.

**Attachments:**

generic product labeling

A 200 241

**(3) LABELING (CONT.):**

**FRONT PANEL- 40 G. PACKET**

**Lincosol Soluble Powder**  
(Brand of lincomycin hydrochloride Soluble Powder)

LINCOSOL SOLUBLE POWDER  
(Brand of Lincomycin hydrochloride soluble powder)

Antibacterial

FOR ORAL USE IN SWINE AND BROILER CHICKENS ONLY

This packet contains as active ingredient:

Lincomycin hydrochloride  
Equivalent to Lincomycin.....16.0 g.

ANADA #: 200- , Approved by FDA Lot No./Exp. Date

Net wt: 1.41 oz (40 grams)

Med - Pharmex Inc.  
Pomona, CA 91767

**REAR PANEL OF THE PACKET (40 g. PACKET)**

2  
Generis

Restricted Drug – Use only as Directed (California)

**SWINE: Direction for Use**

**INDICATIONS:** Lincomycin Soluble Powder is indicated for the treatment of swine dysentery (bloody scours)

**DOSAGE:** Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

**TREATMENT PERIOD:** The drug should be administered for a minimum of 5 consecutive days beyond disappearance of symptoms (bloody stools) up to maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

**ADMINISTRATION:** This packet will medicate 64 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs. of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving two packets in one gallon of water: then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

**NOTE:** After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

**BROILER CHICKENS: Direction for Use**

**INDICATIONS:** Lincosol Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**DOSAGE:** Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

**TREATMENT PERIOD:** Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

**ADMINISTRATION:** This packet will medicate 250 gallons of drinking water providing 64 mg/gallon.

**NOTE:** After water medication is discontinued, a recommended control program for necrotic enteritis consists of feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

**CAUTIONS**

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily.
2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis.
3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and /or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment.
4. Not for used in swine weighing more than 250 pounds.
5. Do not allow rabbits, hamsters, guinea pigs, horses or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.
6. Do not use the water treatment and the feed treatment simultaneously.
7. Not for use in layer and breeder chickens.

**WARNINGS**

1. Do not slaughter swine for human consumption for 6 days following last treatment.
2. No drug withdrawal period is required before slaughter of birds receiving Lincosol Soluble powder at the approved level of 64 mg per gallon of drinking water.
3. Not for human use.

Store at controlled room temperature 15° to 30°C (59° to 86°F)

Med-Pharmex Inc. Pomona, CA 91767, USA

A 200241  
generic

(3) LABELING (CONT.):

**FRONT PANEL OF THE 80 g PACKET**

**Lincosol Soluble Powder**

(Brand of Lincomycin Hydrochloride Antibacterial Soluble Powder)

LINCOSOL SOLUBLE POWDER

(Brand of Lincomycin hydrochloride soluble powder)

Antibacterial

FOR ORAL USE IN SWINE AND BROILER CHICKENS ONLY

This packet contains as active ingredient:

Lincomycin hydrochloride

Equivalent to Lincomycin.....32.0 g.

ANADA # , Approved by FDA Lot No./Exp. Date

Net wt: 2.82 oz (80 grams)

Med-Pharmex Inc.  
Pomona, CA 91767

Generis

**BACK PANEL OF THE PACKET (80 g. PACKET)**

Restricted Drug – Use only as Directed (California)

**SWINE: Direction for Use**

**INDICATIONS:** Lincomycin Soluble Powder is indicated for the treatment of swine dysentery (bloody scours)

**DOSAGE:** Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

**TREATMENT PERIOD:** The drug should be administered for a minimum of 5 consecutive days beyond disappearance of symptoms (bloody stools) up to maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

**ADMINISTRATION:** This packet will medicate 128 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs. of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving one packet in one gallon of water: then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

**NOTE:** After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

**BROILER CHICKENS: Direction for Use**

**INDICATIONS:** Lincosol Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**DOSAGE:** Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

**TREATMENT PERIOD:** Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

**ADMINISTRATION:** This packet will medicate 500 gallons of drinking water providing 64 mg/gallon.

**NOTE:** After water medication is discontinued, a recommended control program for necrotic enteritis consists of feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

**CAUTIONS**

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily.
2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis.
3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and /or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment.
4. Not for used in swine weighing more than 250 pounds.
5. Do not allow rabbits, hamsters, guinea pigs, horses or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.
6. Do not use the water treatment and the feed treatment simultaneously.
7. Not for use in layer and breeder chickens.

**WARNINGS**

1. Do not slaughter swine for human consumption for 6 days following last treatment.
2. No drug withdrawal period is required before slaughter of birds receiving Lincosol Soluble powder at the approved level of 64 mg per gallon of drinking water.
3. Not for human use.

Store at controlled room temperature 15° to 30°C (59° to 86°F)

Med-Pharmex Inc. Pomona, CA 91767, USA

A 200 241  
generic

(3) LABELING (CONT.):

**LEFT PANEL OF THE LABEL – 2 LB. CONTAINER**

**Lincosol Soluble Powder**

(Brand of Lincomycin Hydrochloride Antibacterial Soluble Powder)

LINCOSOL SOLUBLE POWDER  
(Brand of Lincomycin hydrochloride soluble powder)

Antibacterial

FOR ORAL USE IN SWINE AND BROILER CHICKENS ONLY

Each gram of powder contains:  
Lincomycin hydrochloride  
Equivalent to Lincomycin.....400 mg.

ANADA # 200- , Approved by FDA

Restricted Drug – Use only as Directed (California)

Lot No./Exp. Date

Net wt: 2 lbs

Med-Pharmex Inc.  
Pomona, CA 91767

generic

**(3) LABELING (CONT.):**

## RIGHT PANEL OF THE LABEL – 2 LB. CONTAINER.

Restricted Drug – Use only as Directed (California)

## SWINE: Directions for Use

INDICATIONS: LINCOSOL Soluble Powder is indicated for the treatment of swine dysentery (bloody scours)

DOSAGE: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

TREATMENT PERIOD: The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

ADMINISTRATION: One scoop (provided) of this powder will medicate 64 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs. of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption.

For use in automatic water proportioners, prepare the stock solution by dissolving two scoops in *one* gallon of water: then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

## BROILER CHICKENS: Directions for Use

INDICATION: LINCOSOL Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

DOSAGE: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

TREATMENT PERIOD: Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

ADMINISTRATION: One scoop (provided) of this powder will medicate 250 gallons of drinking water providing 64 mg/gallon.

NOTE: After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

## CAUTIONS

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily.
2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis.
3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and /or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment.
4. Not for use in swine weighing more than 250 pounds.
5. Do not allow rabbits, hamsters, guinea pigs, horses or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.
6. Do not use the water treatment and the feed treatment simultaneously.
7. Not for use in layer and breeder chickens.

## WARNINGS

1. Do not slaughter swine for human consumption for 6 days following last treatment.
2. No drug withdrawal period is required before slaughter of birds receiving LINCOSOL Soluble Powder at the approved level of 64 mg per gallon of drinking water.
3. Not for human use.

Store at Controlled Room Temperature 15° to 30°C (59° to 86°F)  
 Med-Pharmex Inc. Pomona, CA 91767, USA

*Pioneer*

(3) LABELING (CONT.):

PIONEER LABEL 1.41 oz (40 G) FRONT PANEL

NDC 0009-0962-13

**LINCOMIX®**

Soluble Powder

**lincomycin hydrochloride**

Antibacterial

LOT 51AKW

EXP 1/01



FOR ORAL USE IN SWINE AND BROILER CHICKENS ONLY

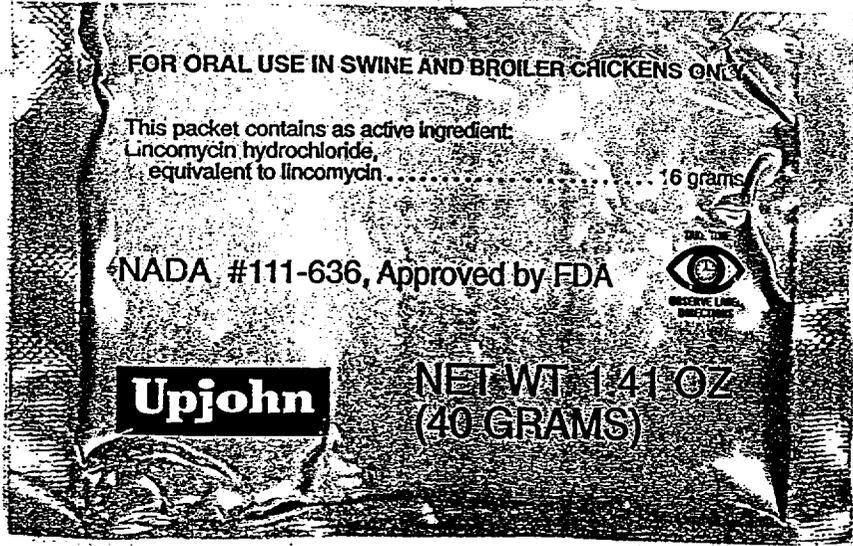
This packet contains as active ingredient:  
Lincomycin hydrochloride  
equivalent to lincomycin ..... 16 grams

NADA #111-636, Approved by FDA



**Upjohn**

NET WT 1.41 OZ  
(40 GRAMS)



pioneer

## (3) LABELING (CONT.):

## PIONEER LABEL 1.41 OZ. ( 40 G) REAR PANEL

**Restricted Drug—Use Only as Directed (California)****SWINE: Directions for Use**

**INDICATION:** LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

**DOSAGE:** Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

**TREATMENT PERIOD:** The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

**ADMINISTRATION:** This packet will medicate 64 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption.

For use in automatic water proportioners, prepare the stock solution by dissolving two packets in one gallon of water; then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

**NOTE:** After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

**BROILER CHICKENS: Directions for Use**

**INDICATION:** LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**DOSAGE:** Administer at a dose rate of 54 mg of lincomycin per gallon of drinking water.

**TREATMENT PERIOD:** Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

**ADMINISTRATION:** This packet will medicate 250 gallons of drinking water providing 64 mg/gallon.

**NOTE:** After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

**CAUTIONS**

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. Not for use in swine weighing more than 250 pounds. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer and breeder chickens.

**WARNINGS**

1. Do not slaughter swine for human consumption for 6 days following last treatment.
2. No drug withdrawal period is required before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
3. Not for human use.

Store at Controlled Room Temperature 15° to 30° C (59° to 86° F).  
The Upjohn Company - Kalamazoo, MI 49001, USA

814 518 003

690446

*pioneer*

(3) LABELING (CONT.):

PIONEER LABEL 2.82 OZ. (80 G) FRONT PANEL

NDC 0009-0962-18

# LINCOMIX®

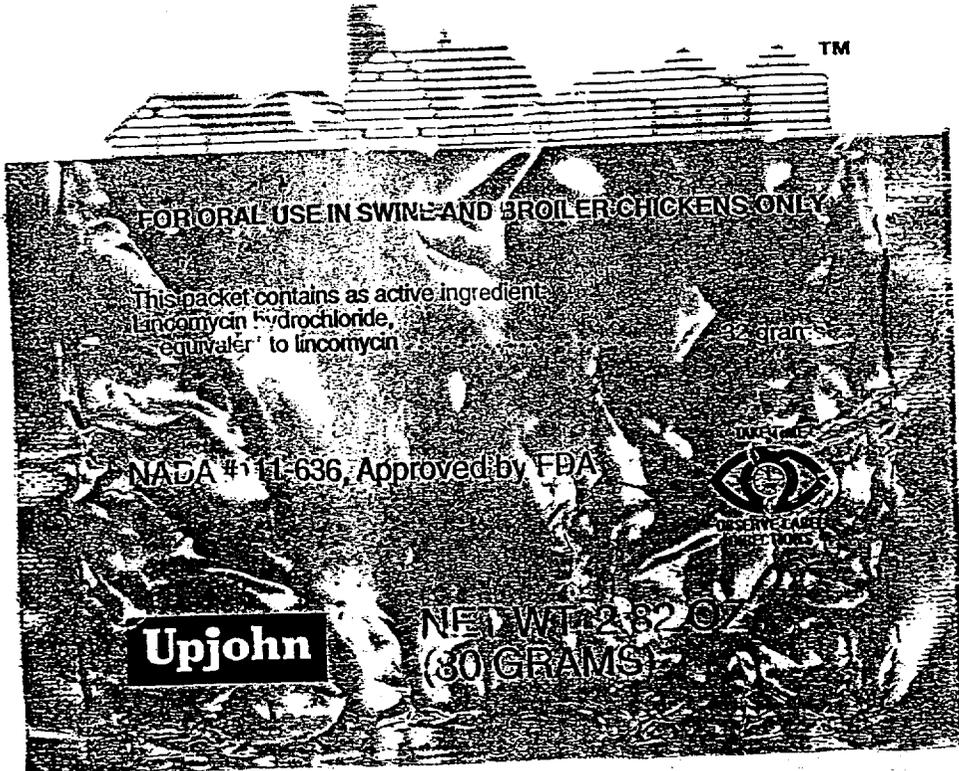
Soluble Powder

**lincomycin hydrochloride soluble powder**

**Antibacterial**

LOT 87AAX

EXP 6/00



Pioneer

## (3) LABELING (CONT.):

## PIONEER LABEL 2.82 OZ. (80 G) REAR PANEL

**Restricted Drug—Use Only as Directed (California)****SWINE: Directions for Use**

**INDICATION:** LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

**DOSAGE:** Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

**TREATMENT PERIOD:** The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

**ADMINISTRATION:** This packet will medicate 128 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving one packet in one gallon of water; then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

**NOTE:** After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

**BROILER CHICKENS: Directions for Use**

**INDICATION:** LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

**DOSAGE:** Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.

**TREATMENT PERIOD:** Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

**ADMINISTRATION:** This packet will medicate 500 gallons of drinking water providing 64 mg/gallon.

**NOTE:** After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

**CAUTIONS**

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. Not for use in swine weighing more than 250 pounds. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer and breeder chickens.

**WARNINGS**

1. Do not slaughter swine for human consumption for 6 days following last treatment.
2. No drug withdrawal period is required before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
3. Not for human use.

Store at Controlled Room Temperature 15° to 30° C (59° to 86° F)  
The Upjohn Company • Kalamazoo, MI 49001, USA

815 934 000

690445