

Date of Approval: DEC 6 2004

FREEDOM OF INFORMATION SUMMARY
ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-377

LINCOMED Soluble Powder
(Lincomycin hydrochloride)

For use in swine and broiler chickens

LINCOMED is indicated for control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin in broiler chickens and the treatment of swine dysentery (bloody scours).

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-377
- b. Sponsor: Cross Vetpharm Group Ltd.
Broomhill Rd, Tallaght
Dublin 24, Ireland
- Drug Labeler Code: 061623
- c. Established Name: Lincomycin hydrochloride
- d. Proprietary Name: LINCOMED Soluble Powder
- e. Dosage Form: Soluble powder
- f. How Supplied: 1.41 oz (40 gm) packet
25 x 40 gm packaging
2.82 oz (80 gm) packet
25 x 80 gm packaging
2 lb. (907.2 gm) pail
6 x 2 lb (907.2 gm) packaging
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 1.41 oz (40 gm) packet contains as active ingredient Lincomycin hydrochloride equivalent to lincomycin 16.0 g.
2.82 oz (80 gm) packet contains as active ingredient Lincomycin hydrochloride equivalent to lincomycin 32.0 g.
2 lb. (907.2 gm) pail contains as active ingredient Lincomycin hydrochloride equivalent to lincomycin 400 mg.
- i. Route of Administration: Oral
- j. Species/Class: Swine and broiler chickens
- k. Recommended Dosage: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water.
- l. Pharmacological Category: Antibacterial

- **Withdrawal Times**

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, August 11, 2002, the withdrawal times are those previously assigned to the pioneer product.

For this reason, no withdrawal period is required before slaughter of swine or broiler 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 file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that LINCAMED (lincomycin hydrochloride) Soluble Powder, when used under its proposed conditions for use, is safe and effective for its labeled indications.

Facsimile generic labeling and currently approved pioneer labeling are attached as follows

Generic Labeling for ANADA 200-377:

LINCAMED Soluble Powder;

- 1.41 oz (40 gm) packet (front panel)
- 1.41 oz (40 gm) packet (back panel)
- 25 x 40 gm packaging
- 2.82 oz (80 gm) packet (front panel)
- 2.82 oz (80 gm) packet (back panel)
- 25 x 80 gm packaging
- 2 lb. (907.2 gm) pail
- 6 x 2 lb (907.2 gm) packaging

Pioneer Labeling for NADA 111-636:

LINCOMIX Soluble Powder;

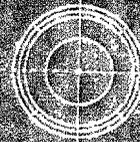
- 1.41 oz (40 gm) packet
- 48 x 40 gm packaging
- 2.82 oz (80 gm) packet
- 24 x 80 gm packaging
- 5.64 oz (160 gm) label
- 16.92 oz (480 gm) label

LincoMed™

(Brand of Lincomycin hydrochloride soluble powder)

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

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

Restricted Drug - Use Only as Directed (California)

Net Wt. 1.41 oz (40 gm)

ANADA 200 377, Approved by FDA

Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058

Bimeda, Inc. is a division of
Cross Veilphar II Group, Ltd.



Bimeda

1 41000 00000 0

SWINE: Directions for use

Indications: LincoMed 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 3.6 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 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 3.6 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 dispensers, prepare the stock solution by dissolving two packets in one gallon of water, then adjust the proportion 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

Indications: LincoMed 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 8 days of medication, discontinue treatment and re-determine 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. The safety of lincomycin has not been demonstrated for pregnant swine intended for breeding.
5. Do not allow rabbits, hamsters, guinea pigs, horses or ruminants access to water containing lincomycin treatment. Ingestion by these species may result in severe gastrointestinal effects.
6. Do not use the water treatment and the feed treatments simultaneously.
7. Not for use in layer and brooder chickens.

WARNINGS

No drug withdrawal period is required before slaughter of swine receiving LincoMed Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LincoMed Soluble Powder at the approved level of 64 mg per gallon of drinking water.

Store at controlled room temperature 20° to 25°C (68° to 77°F).

LincoMed is a Trademark of Bimeda, Inc.

TAKE TIME



OBSERVE LABEL
DIRECTIONS

Product No: 1LIN004
8LIN005-904

UPC CODE
8 99855 30015 7

LincoMed™

(Brand of Lincomycin hydrochloride soluble powder)
Soluble Powder

For oral use in swine and broiler chickens only

Each packet contains as active ingredient

Lincomycin hydrochloride

Equivalent to lincomycin

16.0 g

Product No. 1LIN004
8LIN002-804

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

Restricted Drug - Use Only as Directed (California)

Store at controlled room temperature 20° to 25°C (68° to 77°F)

LincoMed is a trademark of Bimeda, Inc.

Net Wt. 25 X 40 gm

ANADA 200-377, Approved by FDA

Manufactured by
Bimeda, Inc.
Le Sueur, MN 56058

Bimeda, Inc. is a division of
Cross Veterinary Group, Ltd.



TAKE TIME



PRESERVE LABEL
DIRECTIONS

UPC CODE
8 99855 39015 8

LOT:
EXP:

LincoMed™

(Brand of Lincomycin hydrochloride soluble powder)

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

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

Restricted Drug - Use Only as Directed (California)

Net Wt. 2.82 oz (80 gm)

ANADA 200-377, Approved by FDA

Manufactured by:

Bimeda, Inc.

Le Sueur, MN 56058

Bimeda, Inc. is a division of
Cross Veterinary Group, Ltd.



Bimeda

SWINE: Directions for use

Indications: LincoMed 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 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

Indications: LincoMed 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 anile. 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. The safety of lincomycin has not been demonstrated for pregnant swine intended for breeding.
5. Do not allow rabbits, hamsters, guinea pigs, horses or ruminants access to water containing lincomycin treatment. Ingestion by these species may result in severe gastrointestinal effects.
6. Do not use the water treatment and the feed treatments simultaneously.
7. Not for use in layer and breeder chickens.

WARNINGS

No drug withdrawal period is required before slaughter of swine receiving LincoMed Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LincoMed Soluble Powder at the approved level of 64 mg per gallon of drinking water.

Store at controlled room temperature 20° to 25°C (68° to 77°F)

LincoMed is a Trademark of Bimeda, Inc.

TAKE TIME  OBSERVE LABEL DIRECTIONS

Product No: 1LINO05
8LINO03-904

UPC CODE
8 99855 30016 4

LincoMedTM

(Brand of Lincomycin hydrochloride soluble powder)

Soluble Powder

Antibacterial



For oral use in swine and broiler chickens only

Each packet contains as active ingredient

Lincomycin hydrochloride

Equivalent to lincomycin

32.0 g

Product No. 11LIN005
BL 89006-904

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

Restricted Drug - Use Only as Directed (California)

Store at controlled room temperature 20° to 25°C (68° to 77°F)

LincoMed is a Trademark of Bimeda, Inc.

Net Wt. 25 X 80 gm

ANADA 200-377 Approved by FDA

Manufactured by

Bimeda, Inc.

Le Sueur, MN 56058

Bimeda, Inc. is a Division of
Cress V. Elpharm Group, Ltd.



Bimeda

TAKE TIME



OBSERVE LABEL
DIRECTIONS

UPC CODE
8 99855 39016 5

LOT:
EXP:

SWINE: Directions for Use

Indication: LincoMed Soluble Powder is indicated for the treatment of swine dysentery (colic) caused by:

Dosage: Administer a dose rate of 250 mg of lincomycin per gallon of drinking water. A diluted dose rate of 100 mg is provided in dosage of 4.3 mg of lincomycin per gallon 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 a maximum of 10 consecutive days. If water treatment is discontinued prior to the 10th day, lincomycin per gallon of body weight should be continued for 10 days. Administeration: One scoop (200 mg) of 10's powder will measure 64 gallons of drinking water providing 250 mg/gal. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by measuring 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 stress of production, the concentration of lincomycin may not be maintained well and may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity and other stressors which affect water intake.

For use in automatic water supply units, prepare the stock solution by dissolving one scoop in one gallon of water. This stock solution is proportional to 25 mg of stock solution per gallon of drinking water.

Note: After a treatment program is discontinued, a control program for swine dysentery may be started by adding lincomycin powder at 40 grams lincomycin per gallon of water as feed as the pig returns.

BROILER CHICKENS: Directions for Use

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

Dosage: Administer the dosage rate of 84 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 representative veterinarian or veterinary diagnostic laboratory to determine if other drugs should be administered for *Clostridium perfringens*. The drug should be administered for 7 consecutive days.

Administration: One scoop (200 mg) of this powder will treat one 200 gallons of drinking water providing 84 mg/gal.

Note: One scoop (200 mg) of powder will treat one 200 gallons of drinking water. This may be received by feed as follows: 2 grams lincomycin per 100 lbs of body weight.

LincoMed™

(Brand of Lincomycin hydrochloride soluble powder)
Soluble Powder

Antibacterial



For oral use in swine and broiler chickens only
Each gram of powder contains
Lincomycin hydrochloride
Equivalent to lincomycin

400 mg

FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

Refrigerated Drug - Use Only as Directed (Call for info)

Net Wt. 2 lb. (907.2 gm)

ANADA 200-377. Approved by FDA

Manufactured by
Bimeda, Inc.
140 South Main Street
Bimeda, Inc. is a Division of
Ciba-Geigy North America, Inc.



CATIONS

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily.
2. If clinical signs of a body weight loss, reduced or bloody stools, have not improved during the last 5 days of medication, discontinue treatment and administer the drug for 5 days.
3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or bleeding of the anus. The rare cases are usually mild and self-limiting. In all the other cases, the behavior of these conditions have been self-limiting within 10 to 15 days without special drug treatment.
4. The safety of lincomycin has not been demonstrated for pregnant sows intended for breeding.
5. Do not allow rabbits, hamsters, guinea pigs, ferrets or farm birds 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 broiler chickens.

WARNINGS

No drug withdrawal period is required before slaughter of swine receiving LincoMed Soluble Powder at the approved level of 250 mg per gallon of drinking water. No drug withdrawal of birds receiving LincoMed Soluble Powder at the approved level of 84 mg per gallon of drinking water.

Store at controlled room temperature (20° to 25° C (68° to 77° F)).
LincoMed is a Trademark of Bimeda, Inc.

TIME TIME



OBSERVE LABEL DIRECTIONS

UPC CODE
8 99855 30017 1

Product No. 161007
801007-303

Lot:
Exp:

2 Lb
Label

LincoMed™

(Brand of Lincomycin hydrochloride soluble powder)
Soluble Powder

Antibacterial



For oral use in swine and broiler chickens only

Each gram of powder contains as active ingredient:

Lincomycin hydrochloride

Equivalent to lincomycin

400 mg

Product No. 1LIN007

BLIN008-907

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

Restricted Drug - Use Only as Directed (California)

Store at controlled room temperature 20° to 25°C (68° to 77°F)

LincoMed is a trademark of Bimeda, Inc.

Net Wt. 6 X 2 lb. (907.2 gm)

TAKE TIME



OBSERVE LABEL
DIRECTIONS

UPC CODE
8 99855 39017 2

ANADA 200 377. Approved by FDA

Manufactured by

Bimeda, Inc.

Le Sueur, MN 56058

Bimeda, Inc. is a division of
Crosse-Vedehm Group, Ltd.



Bimeda

LOT:

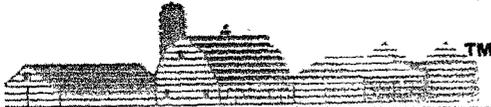
EXP:

NDC 0009-0962-13

LINCOMIX[®]

Soluble Powder

lincomycin hydrochloride
(agricultural grade)
soluble powder
Antibacterial



FOR ORAL USE IN SWINE AND
BROILER CHICKENS ONLY

Each packet contains as active ingredient:
lincomycin hydrochloride
equivalent to lincomycin 16 grams

ADA #111-636, Approved by FDA

Pharmacia
Upjohn

NET CONTENTS
48-40 g (1.4 Oz) PACKETS

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: Each 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 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: Each 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.

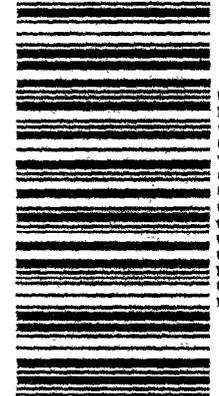
WARNINGS

1. No drug withdrawal period is required before slaughter of swine receiving LINCOMIX Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
2. Not for human use.

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F) [see USP].

Pharmacia & Upjohn Company • Kalamazoo, MI 49001, USA

814 632 207



NDC 0009-0962-18

LINCOMIX[®]

Soluble Powder

lincomycin hydrochloride (agricultural grade) soluble powder Antibacterial



TAKE TIME
OBSERVE LABEL
DIRECTIONS



FOR USE IN SWINE AND
BROILER CHICKENS ONLY

Each packet contains 20 grams of the ingredient.

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: Each 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: Each 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. The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding. 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 or breeder chickens.

WARNINGS

1. No drug withdrawal period is required before slaughter of swine receiving LINCOMIX Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
2. Not for human use.

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F) [see USP].
Pharmacia & Upjohn Company • Kalamazoo, MI 49001, USA

815 935 104E



50300090962185

NDC 0009-0962-35

LINCOMIX[®]

Soluble Powder

**lincomycin hydrochloride
(agricultural grade) soluble powder**
Antibacterial

**FOR ORAL USE IN SWINE AND
BROILER CHICKENS ONLY**

This bottle contains as active ingredient:

Lincomycin hydrochloride
equivalent to lincomycin 64 grams

NADA #111-636,
Approved by FDA

Pharmacia
& Upjohn

PEEL HERE FOR
SPANISH LANGUAGE

NET WT. 5.64 OZ
(160 GRAMS)



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 bottle will medicate 256 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 bottle in two gallons 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.



N 3 0009-0962-35 7 EXP.

818882001

LOT

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 bottle will medicate 1000 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. The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding.
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. No drug withdrawal period is required before slaughter of swine receiving LINCOMIX Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water. 2. Not for human use.

Store at Controlled Room Temperature
20° to 25° C (68° to 77° F) [see USP].

Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA

NDC 0009-0962-36

LINCOMIX®

Soluble Powder

lincomycin hydrochloride
(agricultural grade) soluble powder

Antibacterial

**FOR ORAL USE IN SWINE AND
BROILER CHICKENS ONLY**

This bottle contains as active ingredient:

lincomycin hydrochloride,
equivalent to lincomycin 192 grams

NADA #111-636, Approved by FDA

Pharmacia
& Upjohn

NET WT. 16.92 OZ
(480 GRAMS)

PEEL HERE FOR
SPANISH LANGUAGE



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 bottle will medicate 768 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 bottle in six gallons 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



N
3 0009-0962-36 4

818884001

LOT

EXP

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 bottle will medicate 3000 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. The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding.
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. No drug withdrawal period is required before slaughter of swine receiving LINCOMIX Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
2. Not for human use.

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F) [see USP].

Pharmacia & Upjohn Company • Kalamazoo, MI 49001, USA

