

HFA - 305

DATE OF APPROVAL LETTER: FEB 28 2002

**FREEDOM OF INFORMATION SUMMARY**

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 97-505

Lincomycin Feed Medications (LINCOMIX<sup>®</sup> 20, LINCOMIX<sup>®</sup> 50)

“...for the control of porcine proliferative enteropathies  
(ileitis) caused by *Lawsonia intracellularis*”

SPONSORED BY:

Pharmacia & Upjohn Company

97-505

FOIS 1

## I. GENERAL INFORMATION

NADA number: 97-505

Sponsor: Pharmacia & Upjohn Company  
7000 Portage Rd.  
Kalamazoo, MI 49001

Established Name: Lincomycin hydrochloride

Proprietary Name: LINCOMIX<sup>®</sup> 20  
LINCOMIX<sup>®</sup> 50

Marketing Status: Over-The-Counter (OTC).

Effect of Supplement: To add the label claim for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.

## II. INDICATIONS FOR USE

SWINE: For the treatment and control of swine dysentery.

For the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.

For reduction in the severity of swine mycoplasmal pneumonia.

For increase in rate of weight gain in growing-finishing swine.

## III. DOSAGE

Dosage Form: LINCOMIX<sup>®</sup> 20 and LINCOMIX<sup>®</sup> 50 are Type A medicated articles.

Route of Administration: Oral, in feed

Recommended Dosage: For the treatment of swine dysentery, and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*: Feed 100 grams of lincomycin per ton of complete feed as the sole ration for three weeks, or until signs of disease (watery, mucoid or bloody stools) disappear.

For the treatment and control of swine dysentery, and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*: Feed 100 grams of lincomycin per

ton of complete feed as the sole ration for three weeks, or until signs of disease (watery, mucoid or bloody stools) disappear, followed by 40 grams of lincomycin per ton.

For the control of swine dysentery and porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*: Feed 40 grams of lincomycin per ton of complete feed as the sole ration. For use in animals or on premises with a history of swine dysentery, but where symptoms have not yet occurred.

#### IV. EFFECTIVENESS

##### DOSE JUSTIFICATION

Dose Selection Study – Swine: Pharmacia & Upjohn Study Reports 768-9690-97-002 and 768-9690-98-003.

1. Type of Study: An induced challenge model study.
2. Investigators:

Cornell CP, Kratzer DD, Evans RA. Pharmacia & Upjohn, Kalamazoo, MI 49001  
NL Winkelman. Swine Services Unlimited Inc., Morris, MN 56267.

3. Study Design:

The study was designed to evaluate the effectiveness of 20 grams, 40 grams, and 100 grams of lincomycin per ton of complete feed for the prevention and control of porcine proliferative enteropathies (ileitis) in an induced-challenge model. One hundred weaned commercial crossbred pigs (Landrace/York), 4 to 5 weeks old, were used in the study. The source herd was serologically negative for *Lawsonia intracellularis*, TGE virus, and PRRS virus. Pigs were randomly assigned to treatment groups by weight. A randomized complete block design was used; pigs in each weight group were assigned to one of four pens within a location in the building. Treatment (0 grams, 20 grams, 40 grams, or 100 grams of lincomycin per ton of feed) was randomly assigned to pens of pigs in each location. There were five pigs per pen and five replicates of each treatment, including non-medicated controls. All clinical personnel involved in making and recording observations were blinded to treatments.

All pigs received the assigned test diet *ad libitum* for 21 days, beginning on Day -4. A total dose of  $1.2 \times 10^8$  *Lawsonia intracellularis* organisms was administered as an oral intestinal mucosal homogenate to each pig on the two challenge days (Days 0 and 1). Each pig also received an IM injection of prednisolone (10 mg/kg body weight) on both challenge days to facilitate pathogenesis. After the 21-day treatment period, all pigs were fed an unmedicated diet *ad libitum* and observed for an additional 14 days.

Variables measured were mortality, abnormal clinical impression score days, abnormal diarrhea score days, ileal/jejunal lesion length and lesion incidence, average daily gain (ADG), average daily feed intake (ADFI), and feed conversion efficiency (ADFI/ADG).

4. Results: Feed assay results for lincomycin content of the 20 g/ton diet were unacceptably low ( $\approx$  4 g/ton), therefore the data from this group were not evaluated. The challenge was very severe and resulted in high mortality (52%) for the control group pigs. The 40 g/ton and 100 g/ton medicated groups demonstrated improvement over the controls in clinical scores and gain variables.

There were no reports of drug-related adverse effects in this study.

5. Conclusions:

Lincomycin doses of 40 g/ton and 100 g/ton of feed were effective in preventing the clinical signs of PPE in an induced challenge model study when compared to non-medicated control animals.

#### DOSE CONFIRMATION

##### B. Dose Confirmation Study: Pharmacia & Upjohn Study Report a0075523.

1. Type of Study: This study was a clinical trial using an induced model infection of *Lawsonia intracellularis*.
2. Investigators:  
  
Crane JP, Kratzer DD, Evans RA, Dame KJ, Buckham SL. Pharmacia & Upjohn, Kalamazoo, MI 49001  
NL Winkelman. Swine Services Unlimited Inc., Morris, MN 56267.
3. Study Design:
  - a. Purpose: This induced-challenge model study was conducted to evaluate the clinical effectiveness of lincomycin at 40 g/ton and 100 g/ton of complete feed, for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.
  - b. Experimental Animals: One hundred and eighty weaned commercial crossbred pigs (Large White/Landrace), approximately 5 weeks old, were used in the study. The source herd was serologically negative for *Lawsonia intracellularis* and PRRS virus.

- c. Randomization: A randomized complete block design was used. There were a total of 6 pigs per pen with 10 replicates of each treatment group (non-medicated control, 40 grams lincomycin per ton of feed, and 100 grams lincomycin per ton of feed). Pigs were housed in two adjacent barns. All clinical personnel involved in making and recording observations were blinded to treatments.
- d. Dosage Form, Route, and Duration of Administration: LINCOMIX<sup>®</sup> 20 Feed Medication was mixed with swine feed to produce medicated test diets containing 40 grams and 100 grams of lincomycin per ton of feed. A swine feed of the same dietary composition as the medicated test diets but without lincomycin was used as a negative control diet in one group of pigs. All pigs were fed a non-medicated feed *ad libitum* from Day 0 to Day 7.
- e. Entrance Criteria: Treatment was initiated once at least 10% of pigs in each barn manifested either Grade 3 diarrhea scores or Grade 2 clinical impression scores.
- 1) Diarrhea was scored as follows: 1 = no diarrhea; 2 = semi-solid, no blood; 3 = watery stool, runs through the floor slats, no blood; 4 = blood tinged feces, loose or formed; 5 = profuse diarrhea with blood or very dark tarry feces.
  - 2) Clinical impression scores were obtained from the sum of the pig demeanor score (PDS) and the abdominal appearance score (AAS) divided by two. PDS were scored as follows: 1 = normal; 2 = slightly to moderately depressed, listless, will stand; 3 = severely depressed, recumbent, will not stand. AAS were scored as follows: 1 = normal; 2 = moderately gaunt; 3 = severely gaunt.
- f. Challenge: A total dose of  $1.8 \times 10^9$  *Lawsonia intracellularis* organisms was administered as an oral intestinal mucosal homogenate to each pig over the two challenge days (Days 0 and 1). Each pig also received an IM injection of prednisolone (10 mg/kg body weight) on both challenge days to facilitate pathogenesis.
- g. Study Duration: Treatment was initiated on Day 7. The test diets were then provided *ad libitum* for 21 consecutive days. The study duration was 28 days.
- h. Variables Measured: The primary variables for determining effectiveness were a comparison of mortality, abnormal clinical impression days, and abnormal diarrhea days between the treated and control groups. Clinical impression score was considered abnormal if either pig demeanor scores were  $\geq 2$  or abdominal appearance scores were  $\geq 2$ . Diarrhea score was considered abnormal if  $\geq 2$ . Other variables measured were lesion incidence, lesion length, average daily gain (ADG), average daily feed intake (ADFI), and feed conversion efficiency (ADFI/ADG).

4. Statistical methods used: Mixed model ANOVA procedures were used to analyze the data. Rates per pen for mortality, abnormal diarrhea scores, and abnormal clinical impression scores were computed for the entire 21-day treatment period. Freeman-Tukey arcsine transformations were applied if necessary. Analyses were conducted using a model with Treatment as a fixed effect and Weight block as a random effect. Pairwise comparisons were made between the lincomycin treatment groups and the nonmedicated control group. Two-sided tests were used for the pairwise comparisons.
5. Results: The results for the 21-day treatment period are summarized in Table 4.1.

**Table 4.1:** Summary of results for the 21-day treatment period

Study Group	Least Squares Mean Pen Rate (2-sided p-value vs. control)		
	Non-Medicated Controls	Lincomycin 40 g/ton	Lincomycin 100 g/ton
% mortality	2.5	3.3 (0.67)	0 (0.35)
% abnormal diarrhea score pig days	39.5	30.4 (0.04)	24.6 (<0.01)
% abnormal clinical impression score pig days	13.8	11.0 (0.42)	6.7 (0.02)

Mortality was numerically lower in the 100 grams lincomycin per ton of feed treatment group compared to the non-medicated group. There was a statistically significant decrease in abnormal diarrhea score pig days and abnormal clinical impression score pig days in the 100 grams lincomycin per ton of feed treatment group compared to the non-medicated group.

There were no reports of drug-related adverse effects in this study.

6. Conclusions: Lincomycin, fed at a level of 100 g/ton of feed for 21 consecutive days, was effective in the control of PPE in swine challenged with an oral *Lawsonia intracellularis* intestinal mucosal homogenate.
- C. Dose Confirmation Study: Pharmacia & Upjohn Study Report a0075522.
1. Type of Study: This study was a clinical trial using an induced infection of *Lawsonia intracellularis*.

2. Investigators:

Crane JP, Kratzer DD, Meeuwse DM, Dame KJ, Buckham SL. Pharmacia & Upjohn, Kalamazoo, MI 49001.  
NL Winkelman. Swine Services Unlimited Inc., Morris, MN 56267.

3. Study Design:

- a. Purpose: This study was conducted to evaluate the clinical effectiveness of lincomycin at 40 g/ton and 100 g/ton of feed, for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*, using an induced-challenge model.
- b. Experimental Animals: One hundred and thirty-two weaned commercial crossbred pigs (Large White/Landrace/Duroc), 4½ to 5 weeks old, were used in the study. The source herd was serologically negative for *Lawsonia intracellularis* and PRRS virus.
- c. Randomization: A randomized incomplete block design was used. There were a total of 12 pigs per pen with 4 replicates of both the non-medicated control and 40 grams of lincomycin per ton of feed treatment groups, and 3 replicates of the 100 grams lincomycin per ton of feed treatment group. All clinical personnel involved in making and recording observations were blinded to treatments.
- d. Dosage Form, Route, and Duration of Administration: LINCOMIX® 20 Feed Medication was mixed with swine feed to produce medicated test diets containing 40 grams and 100 grams of lincomycin per ton of feed. A swine feed of the same dietary composition as the medicated test diets but without lincomycin was used as a negative control diet in one group of pigs. All pigs were fed a non-medicated feed *ad libitum* from Day 0 to Day 7.
- e. Entrance Criteria: Treatment was initiated once at least 20% of pigs manifested either ≥ Grade 2 diarrhea scores or ≥ Grade 2 clinical impression scores, with at least one pig per pen expressing these criteria.
  - 1) Diarrhea was scored as follows: 1 = no diarrhea; 2 = semi-solid, no blood; 3 = watery stool, runs through the floor slats, no blood; 4 = blood tinged feces, loose or formed; 5 = profuse diarrhea with blood or very dark tarry feces.
  - 2) Clinical impression scores were obtained from the sum of the pig demeanor score (PDS) and the abdominal appearance score (AAS) divided by two. PDS were scored as follows: 1 = normal; 2 = slightly to moderately depressed, listless, will stand; 3 = severely depressed, recumbent, will not stand. AAS were scored as follows: 1 = normal; 2 = moderately gaunt; 3 = severely gaunt.

- f. Challenge: A total dose of  $5 \times 10^9$  cells of *Lawsonia intracellularis* was administered as an oral intestinal mucosal homogenate to each pig over the two challenge days (Days 0 and 1).
  - g. Study Duration: Treatment was initiated on Day 7. The test diets were then provided *ad libitum* for 21 consecutive days. The study duration was 28 days.
  - h. Variables Measured: The primary variables for determining effectiveness were a comparison of mortality, abnormal clinical impression days, and abnormal diarrhea days between the treated and control groups. Clinical impression score was considered abnormal if either pig demeanor scores were  $\geq 2$  or abdominal appearance scores were  $\geq 2$ . Diarrhea score was considered abnormal if  $\geq 2$ .
4. Statistical methods used: Mixed model ANOVA procedures were used to analyze the data. Rates per pen for mortality, abnormal diarrhea scores, and abnormal clinical impression scores were computed for the entire 21-day treatment period. Freeman-Tukey arcsine transformations were applied if necessary. Analyses were conducted using a model with Treatment as a fixed effect and Weight block as a random effect. Pairwise comparisons were made with each lincomycin treatment group and the nonmedicated control group. Two-sided tests were used for the pairwise comparisons.
5. Results: The results for the 21-day treatment period are summarized in Table 4.2.

Table 4.2: Summary of results for the 21-day treatment period

Study Group	Least Squares Mean Pen Rate (2-sided p-value vs. control)		
	Non-Medicated Controls	Lincomycin 40 g/ton	Lincomycin 100 g/ton
% mortality	22.9	21.6 (0.89)	14.1 (0.32)
% abnormal diarrhea score pig days	84.6	58.7 (<0.01)	55.5 (<0.01)
% abnormal clinical impression score pig days	76.5	52.7 (<0.01)	49.4 (<0.01)

Mortality was numerically lower in the 40 grams and 100 grams lincomycin per ton of feed treatment groups compared to the non-medicated group. There was a statistically significant decrease in % abnormal diarrhea score pig days for both the 40 grams ( $p < 0.01$ ) and 100 grams ( $p < 0.01$ ) lincomycin per ton of feed treatment groups relative to the non-medicated group. In addition, there was a statistically

significant decrease in % abnormal clinical impression score pig days for both the 40 grams ( $p < 0.01$ ) and 100 grams ( $p < 0.01$ ) lincomycin per ton of feed treatment groups relative to the non-medicated group.

There were no reports of drug-related adverse effects in this study.

6. Conclusions: Lincomycin, fed at a level of 40 g/ton of feed or 100 g/ton of feed for 21 consecutive days, was effective in the control of PPE in swine challenged with an oral *Lawsonia intracellularis* intestinal mucosal homogenate.

## V. ANIMAL SAFETY

No animal safety data were required for the approval of this supplement.

## VI. HUMAN FOOD SAFETY

No human safety data were required for the approval of this supplement. It was determined by the Agency that this submission, requesting an additional label claim for LINCOMIX® (lincomycin) Type A medicated article, has at this time satisfied the requirements for microbial safety with respect to resistance and pathogen load issues. No additional information was required for this supplemental approval.

## VII. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that LINCOMIX® Type A Medicated Article is effective for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* when administered as follows:

- 1) Feed 100 grams of lincomycin per ton of complete feed as the sole ration for three weeks, or until signs of disease (watery, mucoïd or bloody stools) disappear,
- 2) Feed 100 grams of lincomycin per ton of complete feed as the sole ration for three weeks, or until signs of disease (watery, mucoïd or bloody stools) disappear, followed by 40 grams of lincomycin per ton, or
- 3) Feed 40 grams of lincomycin per ton of complete feed as the sole ration.

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layman and the conditions for use prescribed on the label are likely to be followed in practice.

Under section 512(c)(2)(F)(iii) of the FDCA, this approval for food-producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant. The three years of marketing exclusivity applies only to the new claim for the control of porcine proliferative enteropathies (ileitis), for which the supplemental application was approved.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

There are currently no U.S. patents for LINCOMIX<sup>®</sup> 20 and LINCOMIX<sup>®</sup> 50 Type A Medicated Articles.

#### **VIII. APPROVED LABELING**

Copies of facsimile Type A medicated article labeling and specimen (Blue Bird) Type B and Type C medicated feed labels are attached to this document.

- A. LINCOMIX<sup>®</sup> 20 Type A Medicated Article
- B. LINCOMIX<sup>®</sup> 50 Type A Medicated Article
- C. Blue Bird Type B Medicated Feed Swine Mix
- D. Blue Bird Type C Medicated Feeds: Swine Ration L20, Swine Ration LC, Swine Ration L100, and Swine Ration PLC

Copies of applicable labels may be obtained by writing to the following:

Freedom of Information Staff (HFI-35)  
Food and Drug Administration, Room 12A16  
5600 Fishers Lane  
Rockville, Maryland 20857

NDC 0009-0494-17

# LINCOMIX® 20

Feed Medication  
(Type A Medicated Article)

## 20 grams/lb

For increase in rate of weight gain, for improved feed efficiency, and for the control of necrotic enteritis caused or complicated by *Clostridium spp.* or other organisms susceptible to lincomycin in broilers.

For the treatment and control of swine dysentery, and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.

For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.

For increase in rate of weight gain in growing-finishing swine.

**Each pound contains:**

**Active Drug Ingredient**

Lincomycin ..... 20 grams  
(as lincomycin hydrochloride agricultural grade)

**Inactive Ingredients**

Soybean hulls, #20 grind; mineral oil, USP.

**IMPORTANT:**

**Must be thoroughly mixed in feeds before use.  
Store opened bag in dry place to prevent caking.  
Store at room temperature.**

### NET WEIGHT 50 lb (22.6 kg)

**Pharmacia  
&Upjohn**



# LINCOMIX® 20



## Feed Medication (Type A Medicated Article)

20 grams/lb

### Broilers

For increase in rate of weight gain, for improved feed efficiency, and for the control of necrotic enteritis caused or complicated by *Clostridium spp.* or other organisms susceptible to lincomycin in broilers.

### DIRECTIONS FOR USE

#### For Increase in Rate of Weight Gain and Improved Feed Efficiency:

LINCOMIX 20, 20 grams/lb, should be mixed into the complete feed supplied to broiler chickens so that the final feed contains 2 to 4 grams of lincomycin per ton of feed.

#### For the Control of Necrotic Enteritis:

LINCOMIX 20, 20 grams/lb, should be mixed into the complete feed supplied to broiler chickens so that the final feed contains 2 grams of lincomycin per ton of feed.

### MIXING DIRECTIONS

**Intermediate Premix**  
Amount of LINCOMIX 20 per 1000 lb  
(454 kg) of Feed Ingredients

**Complete Feed**  
Amount of Intermediate Premix to use to Provide Desired  
Grams of lincomycin per ton of Type C Medicated Feed

	lincomycin per ton of feed		
	2 grams	3 grams	4 grams
50 lbs	2 lbs	3 lbs	4 lbs
10 lbs	10 lbs	15 lbs	20 lbs
5 lbs	20 lbs	30 lbs	40 lbs

### WARNING

When using LINCOMIX 20 in approved combinations with other drugs, follow the required withdrawal times for those drugs. No drug withdrawal period is required before slaughter of birds fed LINCOMIX 20 at approved concentrations (2 to 4 grams lincomycin per ton of feed).

**CAUTION:** Not for use in layers, breeders, or turkeys. (For additional Cautions, see below.)

### SWINE

For the Treatment and Control of Swine Dysentery, and the Control of Porcine Proliferative Enteropathies (ileitis) caused by *Lawsonia intracellularis*. For Reduction in the Severity of Swine Mycoplasmal Pneumonia caused by *Mycoplasma hyopneumoniae*. For increase in Rate of Weight Gain in Growing-Finishing Swine.

### DIRECTIONS FOR USE

**For the treatment of swine dysentery, and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*:**

Feed 100 grams of lincomycin per ton of complete feed as the sole ration for three weeks, or until signs of disease (watery, mucoid or bloody stools) disappear.

**For the treatment and control of swine dysentery, and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*:**

Feed 40 grams of lincomycin per ton of complete feed as the sole ration for three weeks, or until signs of disease (watery, mucoid or bloody stools) disappear, followed by 40 grams of lincomycin per ton.

**For the control of swine dysentery and porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*:**

Feed 40 grams of lincomycin per ton of complete feed as the sole ration. For use in animals or on premises with a history of swine dysentery, but where symptoms have not yet occurred.

**For Reduction in the Severity of Swine Mycoplasmal Pneumonia:**

Feed 200 grams of lincomycin per ton of complete feed as the sole ration for 21 days.

**For Increase in Rate of Weight Gain in Growing-Finishing Swine:**

Feed 20 grams of lincomycin per ton of complete feed as the sole ration from weaning to market weight.

**MIXING DIRECTIONS**

**Type C Medicated Feeds**

**For Treatment of Swine Dysentery, and the Control of Porcine Proliferative Enteropathies (ileitis) caused by *Lawsonia intracellularis*:**

To make complete feed containing 100 grams of lincomycin, add 5 lbs of LINCOMIX 20 per ton.

**For Control of Swine Dysentery and Porcine Proliferative Enteropathies (ileitis) caused by *Lawsonia intracellularis*:**

To make complete feed containing 40 grams of lincomycin, add 2 lbs of LINCOMIX 20 per ton.

**For Reduction in the Severity of Mycoplasmal Pneumonia:**

To make complete feed containing 200 grams of lincomycin, add 10 lbs of LINCOMIX 20 per ton.

**For Increase in Rate of Weight Gain in Growing-Finishing Swine:**

To make complete feed containing 20 grams of lincomycin, add 1 lb of LINCOMIX 20 per ton.

### WARNING

When using LINCOMIX 20 in approved combinations with other drugs, follow the required withdrawal times for those drugs. No drug withdrawal period is required before slaughter of swine fed LINCOMIX 20 at approved concentrations (20, 40, 100 or 200 grams lincomycin per ton of feed).

### NOT FOR HUMAN USE

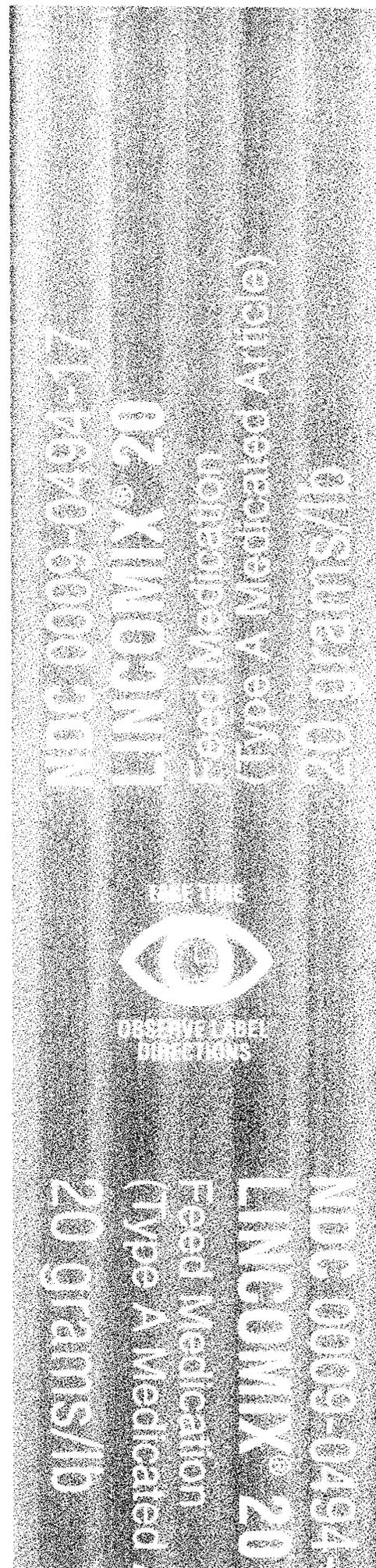
**CAUTION:** Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. Not to be fed to swine that weigh more than 250 pounds.

Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

Good Manufacturing Practices Should Be Observed in Preparing Feeds Containing LINCOMIX 20.  
This Includes Appropriate Clean-out Procedures to Avoid Cross-Contamination.

Restricted Drug—Use Only as Directed (California)

Made in Canada for  
Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, USA  
By Pharmacia & Upjohn Animal Health  
Ottawa, Ontario CANADA K1W 3T3



NDC 0009-0487-05

# LINCOMIX<sup>®</sup> 50

Feed Medication  
(Type A Medicated Article)

## 50 grams/lb

For increase in rate of weight gain, for improved feed efficiency, and for the control of necrotic enteritis caused or complicated by *Clostridium spp.* or other organisms susceptible to lincomycin in broilers.

For the treatment and control of swine dysentery, and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.

For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.

For increase in rate of weight gain in growing-finishing swine.

**Each pound contains:**

**Active Drug Ingredient**

Lincomycin . . . . . 50 grams  
(as lincomycin hydrochloride agricultural grade)

**Inactive Ingredients**

Soybean hulls, #20 grind; mineral oil, USP.

**IMPORTANT:**

Must be thoroughly mixed in feeds before use.  
Store opened bag in dry place to prevent caking.  
Store at room temperature.

### NET WEIGHT 50 lb (22.6 kg)

**Pharmacia  
&Upjohn**

NDC 0009-0487-05

LINCOMIX<sup>®</sup> 50

Feed Medication  
(Type A Medicated Article)

TAKE TIME



OBSERVE LABEL  
DIRECTIONS

50 grams/lb

LINCOMIX<sup>®</sup> 50  
Feed Medication  
(Type A Medicated Article)



# LINCOMIX® 50

## Feed Medication (Type A Medicated Article) 50 grams/lb

### Broilers

For increase in rate of weight gain, for improved feed efficiency, and for the control of necrotic enteritis caused or complicated by *Clostridium spp.* or other organisms susceptible to lincomycin in broilers.

### DIRECTIONS FOR USE

#### For Increase in Rate of Weight Gain and Improved Feed Efficiency:

LINCOMIX 50, 50 grams/lb, should be mixed into the complete feed supplied to broiler chickens so that the final feed contains 2 to 4 grams of lincomycin per ton of feed.

#### For the Control of Necrotic Enteritis:

LINCOMIX 50, 50 grams/lb, should be mixed into the complete feed supplied to broiler chickens so that the final feed contains 2 grams of lincomycin per ton of feed.

### MIXING DIRECTIONS

Intermediate Premix Amount of LINCOMIX 50 per 1000 lb (454 kg) of Feed Ingredients		Complete Feed Amount of Intermediate Premix to use to Provide Desired Grams of lincomycin per ton of Type C Medicated Feed		
		lincomycin per ton of feed		
		2 grams	3 grams	4 grams
20 lbs		2 lbs	3 lbs	4 lbs
4 lbs		10 lbs	15 lbs	20 lbs
2 lbs		20 lbs	30 lbs	40 lbs

### WARNING

When using LINCOMIX 50 in approved combinations with other drugs, follow the required withdrawal times for those drugs. No drug withdrawal period is required before slaughter of birds fed LINCOMIX 50 at approved concentrations (2 to 4 grams lincomycin per ton of feed).

CAUTION: Not for use in layers, breeders, or turkeys. (For additional Cautions, see below.)

### SWINE

For the Treatment and Control of Swine Dysentery, and the Control of Porcine Proliferative Enteropathies (ileitis) caused by *Lawsonia intracellularis*. For Reduction in the Severity of Swine Mycoplasma Pneumonia caused by *Mycoplasma hyopneumoniae*. For Increase in Rate of Weight Gain in Growing-Finishing Swine.

### DIRECTIONS FOR USE

For the treatment of swine dysentery, and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.

Feed 100 grams of lincomycin per ton of complete feed as the sole ration for three weeks, or until signs of disease (watery, mucoid or bloody stools) disappear.

For the treatment and control of swine dysentery, and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.

Feed 100 grams of lincomycin per ton of complete feed as the sole ration for three weeks, or until signs of disease (watery, mucoid or bloody stools) disappear, followed by 40 grams of lincomycin per ton.

For the control of swine dysentery and porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*. Feed 40 grams of lincomycin per ton of complete feed as the sole ration. For use in animals or on premises with a history of swine dysentery, but where symptoms have not yet occurred.

For Reduction in the Severity of Swine Mycoplasma Pneumonia: Feed 200 grams of lincomycin per ton of complete feed as the sole ration for 21 days.

For Increase in Rate of Weight Gain in Growing-Finishing Swine: Feed 20 grams of lincomycin per ton of complete feed as the sole ration from weaning to market weight.

### MIXING DIRECTIONS

#### Type C Medicated Feeds

For Treatment of Swine Dysentery, and the Control of Porcine Proliferative Enteropathies (Ileitis) caused by *Lawsonia intracellularis*: To make complete feed containing 100 grams of lincomycin, add 2 lbs of LINCOMIX 50 per ton.

For Control of Swine Dysentery and Porcine Proliferative Enteropathies (Ileitis) caused by *Lawsonia intracellularis*: To make complete feed containing 40 grams of lincomycin, add 0.8 lbs of LINCOMIX 50 per ton.

For Reduction in the Severity of Mycoplasma Pneumonia: To make complete feed containing 200 grams of lincomycin, add 4 lbs of LINCOMIX 50 per ton.

For Increase in Rate of Weight Gain in Growing-Finishing Swine: To make complete feed containing 20 grams of lincomycin, add 0.4 lbs of LINCOMIX 50 per ton.

Additional mixing directions to make complete feed containing 20 or 40 grams of lincomycin per ton are provided below.

MIXING DIRECTIONS Intermediate Premix Amount of LINCOMIX 50 per 1000 lb (454 kg) of Feed Ingredients		Complete Feed Amount of Intermediate Premix to use to Provide Desired Grams of lincomycin per ton of Type C Medicated Feed	
		lincomycin per ton of feed	
		20 grams	40 grams
50 lbs		8 lbs	16 lbs
40 lbs		10 lbs	20 lbs
20 lbs		20 lbs	40 lbs

### WARNING

When using LINCOMIX 50 in approved combinations with other drugs, follow the required withdrawal times for those drugs. No drug withdrawal period is required before slaughter of swine fed LINCOMIX 50 at approved concentrations (20, 40, 100 or 200 grams lincomycin per ton of feed).

### NOT FOR HUMAN USE

CAUTION: 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. Not to be fed to swine that weigh more than 250 pounds.

Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

Good Manufacturing Practices Should Be Observed in Preparing Feeds Containing LINCOMIX 50. This Includes Appropriate Clean-out Procedures to Avoid Cross-Contamination.

Made in Canada for  
Pharmacia & Upjohn Company  
Kalamazoo, MI 49001, USA  
By Pharmacia & Upjohn Animal Health  
Orangeville, Ontario CANADA L9W 3T3

Restricted Drug—Use Only as Directed (California)

NDC 0009-0487-05

LINCOMIX® 50

Feed Medication  
(Type A Medicated Article)

50 grams/lb

TAKE TIME



OBSERVE LABEL  
DIRECTIONS

50 grams/lb

Feed Medication  
(Type A Medicated Article)

LINCOMIX® 50

NDC 0009-0487-05

**NET WEIGHT 50 POUNDS**

**SWINE MIX  
Medicated  
(Type B Medicated Feed)**

For the treatment and control of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*. For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*. For increase in rate of weight gain in growing-finishing swine.

**ACTIVE DRUG INGREDIENT**

Each pound contains:

Lincomycin (lincomycin hydrochloride) 0.1-20 grams

**GUARANTEED ANALYSIS**

Minimum percentage of Crude Protein	_____ %
Minimum percentage of Lysine	_____ %
Minimum percentage of Crude Fat	_____ %
Maximum percentage of Crude Fiber	_____ %
Minimum and maximum percentage of Calcium	_____ %
Minimum percentage of Phosphorus	_____ %
Minimum and maximum percentage of Salt (if added)	_____ %
Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee	_____ %
Minimum Selenium in parts per million (ppm)	_____ ppm
Minimum Zinc in parts per million (ppm)	_____ ppm

**INGREDIENTS**

Each ingredient must be specifically named in accordance with the names and definitions adopted by the AAFCO.

**SEE FEEDING DIRECTIONS AND MIXING DIRECTIONS  
ON BACK OF TAG**

**IMPORTANT**

Must be thoroughly mixed in feeds before use.  
Store opened bag in dry place to prevent caking.  
Store at room temperature.

**MANUFACTURED BY**

Blue Bird Feed Company  
Robin, Indiana 11111

**SWINE MIX  
Medicated  
(Type B Medicated Feed)**

**MIXING DIRECTIONS**

Indication	Drug Level in complete Type C medicated feed g/ton	Type B medicated feed* lb	Mix Non medicated Feed lb
For increased rate of weight gain in growing-finishing swine	20	200-1	1800-1999
For control of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i>	40	400-2	1600-1998
For treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i>	100	1000-5	1000-1995
For reduction in the severity of mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i>	200	2000-10	0-1990

\*Lincomycin 0.1 - 20 g/lb

**CAUTION**

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. Not to be fed to swine that weigh more than 250 pounds.

Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

Good Manufacturing Practices Should Be Observed in Preparing Feeds Containing SWINE MIX Medicated.  
This includes appropriate clean-out procedures to avoid cross-contamination.

**BAG OR BULK**

**SWINE RATION L20  
Medicated  
(Type C Medicated Feed)**

For increase in rate of weight gain in growing-finishing swine.

**ACTIVE DRUG INGREDIENT**

Lincomycin (lincomycin hydrochloride) 20 g/ton

**GUARANTEED ANALYSIS**

Minimum percentage of Crude Protein	_____ %
Minimum percentage of Lysine	_____ %
Minimum percentage of Crude Fat	_____ %
Maximum percentage of Crude Fiber	_____ %
Minimum and maximum percentage of Calcium	_____ %
Minimum percentage of Phosphorus	_____ %
Minimum and maximum percentage of Salt (if added)	_____ %
Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee	_____ %
Minimum Selenium in parts per million (ppm)	_____ ppm
Minimum Zinc in parts per million (ppm)	_____ ppm

**INGREDIENTS**

Each ingredient must be specifically named in accordance with the names and definitions adopted by the AAFCO.

**FEEDING DIRECTIONS**

Feed 20 grams of lincomycin per ton of complete feed as the sole ration from weaning to market weight.

**CAUTION**

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. Not to be fed to swine that weigh more than 250 pounds.

Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

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Blue Bird Feed Company  
Robin, Indiana 11111

**BAG OR BULK**  
**SWINE RATION LC**  
**Medicated**  
**(Type C Medicated Feed)**

For control of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.

**ACTIVE DRUG INGREDIENT**

Lincomycin (lincomycin hydrochloride) 40 g/ton

**GUARANTEED ANALYSIS**

Minimum percentage of Crude Protein	_____ %
Minimum percentage of Lysine	_____ %
Minimum percentage of Crude Fat	_____ %
Maximum percentage of Crude Fiber	_____ %
Minimum and maximum percentage of Calcium	_____ %
Minimum percentage of Phosphorus	_____ %
Minimum and maximum percentage of Salt (if added)	_____ %
Minimum and maximum percentage of total Sodium	_____ %
shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee	_____ %
Minimum Selenium in parts per million (ppm)	_____ ppm
Minimum Zinc in parts per million (ppm)	_____ ppm

**INGREDIENTS**

Each ingredient must be specifically named in accordance with the names and definitions adopted by the AAFCO.

**FEEDING DIRECTIONS**

1. Feed this complete feed as the sole ration on premises with a history of swine dysentery but where symptoms have not yet occurred.
2. Feed this complete feed as the sole ration for the control of swine dysentery or porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.
3. Feed this complete feed as the sole ration after using feed containing 100 grams of lincomycin per ton for the treatment of swine dysentery or the control of porcine proliferative enteropathies (ileitis).

**CAUTION**

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. Not to be fed to swine that weigh more than 250 pounds.

Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

**MANUFACTURED BY**  
Blue Bird Feed Company  
Robin, Indiana 11111

**BAG OR BULK**

**SWINE RATION L100  
Medicated  
(Type C Medicated Feed)**

For treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*.

**ACTIVE DRUG INGREDIENT**

Lincomycin (lincomycin hydrochloride) 100 g/ton

**GUARANTEED ANALYSIS**

Minimum percentage of Crude Protein	_____%
Minimum percentage of Lysine	_____%
Minimum percentage of Crude Fat	_____%
Maximum percentage of Crude Fiber	_____%
Minimum and maximum percentage of Calcium	_____%
Minimum percentage of Phosphorus	_____%
Minimum and maximum percentage of Salt (if added)	_____%
Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee	_____%
Minimum Selenium in parts per million (ppm)	_____ppm
Minimum Zinc in parts per million (ppm)	_____ppm

**INGREDIENTS**

Each ingredient must be specifically named in accordance with the names and definitions adopted by the AAFCO.

**FEEDING DIRECTIONS**

Feed as the sole ration for three weeks or until clinical signs of the disease (watery, mucoid, or bloody stools) disappear.

**CAUTION**

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. Not to be fed to swine that weigh more than 250 pounds.

Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

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Blue Bird Feed Company  
Robin, Indiana 11111

**BAG OR BULK**

**SWINE RATION PLC  
Medicated  
(Type C Medicated Feed)**

For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.

**ACTIVE DRUG INGREDIENT**

Lincomycin (lincomycin hydrochloride) 200 g/ton

**GUARANTEED ANALYSIS**

Minimum percentage of Crude Protein	_____ %
Minimum percentage of Lysine	_____ %
Minimum percentage of Crude Fat	_____ %
Maximum percentage of Crude Fiber	_____ %
Minimum and maximum percentage of Calcium	_____ %
Minimum percentage of Phosphorus	_____ %
Minimum and maximum percentage of Salt (if added)	_____ %
Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee	_____ %
Minimum Selenium in parts per million (ppm)	_____ ppm
Minimum Zinc in parts per million (ppm)	_____ ppm

**INGREDIENTS**

Each ingredient must be specifically named in accordance with the names and definitions adopted by the AAFCO.

**FEEDING DIRECTIONS**

Feed as the sole ration for 21 days.

**CAUTION**

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. Not to be fed to swine that weigh more than 250 pounds.

Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

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