

Date of Approval FEB - 1 2002

## **FREEDOM OF INFORMATION SUMMARY**

### **ANADA 200-274**

Indication for use: It is used as a treatment of infectious arthritis and mycoplasma pneumonia in swine

Sponsored by:  
Alpharma, Inc.  
Fort Lee, NJ 007024

FOIS-1

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

ANADA Number	200-274
Sponsor:	Alpharma, Inc. One Executive Drive Fort Lee, NJ 007024
	21 CFR 510.600: Labeler Code 046573
Established Name:	Lincomycin HCL Injectable
Trade/Proprietary Name:	Lincomycin Injectable 30 %
Dosage Form:	Injectable
How Supplied:	100 mL multidose vials
How Dispensed:	Rx
Amount of Active Ingredients:	Each mL contains 300 mg of llincomycin HCL
Route of Administration:	Intramuscularly
Species:	Swine
Labeled Dosage	5 milligrams per pound of body weight per day
Indications for Use:	Infectious arthritis and mycoplasma pneumonia
Pharmacological Category:	Antibacterial

Pioneer Product: Lincomix<sup>®</sup> 300 Injection manufactured by  
Pharmacia & Upjohn Co. (NADA 034-025)

## 2. TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October, 2000).

Based upon the formulation characteristics of the generic product, Alpharma, Inc. was granted a waiver on May 27, 1993, from conducting an *in vivo* bioequivalence study for Lincomycin Injectable 30 %. The generic and pioneer products contain the same active and inactive ingredients and are injectable solutions.

## 3. HUMAN FOOD SAFETY:

### WITHDRAWAL TIME

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for Lincomycin is established under 21 CFR 522.1260- 48 hours in swine.

### TOLERANCE

Under section §556.360, **Lincomycin**, the tolerances for lincomycin of 0.6 part per million in liver and 0.1 part per million in muscle are established for swine. The ADI for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.

### HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 Injectable 30 % is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert

100 mL vial

Generic Labeling:

Package Insert

100 mL vials

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

Food and Drug Administration  
Freedom of Information Staff (HFI-35)  
5600 Fishers Lane  
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

(b) Approved Pioneer Bottle Label (magnified 150%):

For Intramuscular Use in Swine Over 300 lbs.

Restricted Drug—Use Only as Directed  
(California)

For Use in Animals Only

Dosage: Usual daily dose for arthritis or  
mycoplasma pneumoniae—5 mg per pound of  
body weight (1 mL per each 50 pounds of body  
weight) intramuscularly for three to seven days.

See package insert for complete product  
information.

Warnings: Not for human use. Keep  
out of the reach of children. Swine  
intended for human consumption  
should not be slaughtered within 18  
hours of latest treatment.

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

813 773 002

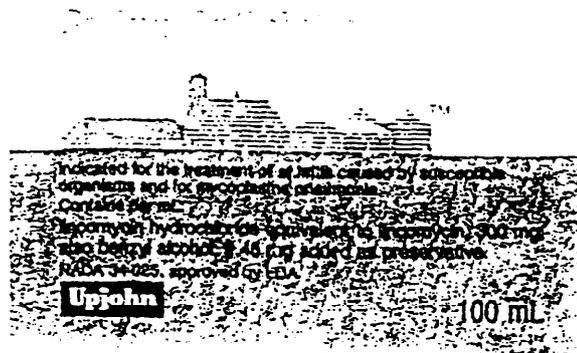
The Upjohn Company  
Kalamazoo, MI 49001 USA

NDC 0009-3256-01

**Lincomix**<sup>®</sup>

injectable

sterile lincomycin hydrochloride injection



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(b) Approved Pioneer Package Insert

**Upjohn**

**Lincomix®**

brand of lincomycin hydrochloride injectable

**For Intramuscular Use in Swine Only**

LINCOMIX Injectable contains lincomycin hydrochloride, an antibiotic produced by *Streptomyces lincolnensis* var. *lincolnensis*, which is chemically distinct from all other clinically available antibiotics and is isolated as a white crystalline solid.

**INDICATIONS FOR SWINE**

LINCOMIX Injectable is indicated for the treatment of infectious forms of arthritis caused by organisms sensitive to its activity. This includes most of the organisms responsible for the various infectious arthritides in swine, such as the staphylococci, streptococci, *Erysipelothrix* and *Mycoplasma* spp.

It is also indicated for the treatment of mycoplasma pneumonia.

**CONTRAINDICATIONS**

As with all drugs, the use of LINCOMIX Injectable is contraindicated in animals previously found to be hypersensitive to the drug.

**WARNING**

Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment. **Not for human use.**

**CAUTION**

If no improvement is noted within 48 hours, consult a veterinarian.

**ADVERSE REACTIONS**

The intramuscular administration to swine may cause a transient diarrhea or loose stools. Although this effect has rarely been reported, one must be alert to the possibility that it may occur.

Should this occur, it is important that the necessary steps be taken to prevent the effects of dehydration.

**DOSAGE AND ADMINISTRATION**

For arthritis or mycoplasma pneumonia—5 mg per pound of body weight intramuscularly once daily for three to seven days as needed. When using LINCOMIX Injectable containing 25 mg/ml, 1 ml/5 lb body weight will provide 5 mg/lb. When using LINCOMIX Injectable containing 100 mg/ml, 1 ml/20 lb body weight will provide 5 mg/lb. When using LINCOMIX Injectable containing 300 mg/ml, 1 ml/60 lb body weight will provide 5 mg/lb.

For optimal results, initiate treatment as soon as possible.

As with any multi-dose vial, practice aseptic techniques in withdrawing each dose. Adequately clean and disinfect the vial closure prior to entry with a sterile needle and syringe. No vial closure should be entered more than 20 times.

**HOW SUPPLIED**

LINCOMIX Injectable is available in three concentrations: 300 mg/ml, 100 mg/ml, and 25 mg/ml.

**300 mg/ml:** For use in swine weighing 300 pounds or more. Each ml contains lincomycin hydrochloride equivalent to lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 ml vials.

**100 mg/ml:** Each ml contains lincomycin hydrochloride equivalent to lincomycin, 100 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 ml vials.

**25 mg/ml:** Special baby pig concentration. Each ml contains lincomycin hydrochloride equivalent to lincomycin, 25 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 ml vials.

NADA 34-025, approved by FDA

The Upjohn Company  
Kalamazoo, Michigan 49001, USA

Revised May 1988

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3.75" x 1.875" landscape  
Black, PMS 307 (blue), PMS 1485 (orange)

For intramuscular use in swine over 300 lbs.

Restricted drug - use only as directed (CA)

For use in animals only

Dosage: Usual daily dose for arthritis or mycoplasma pneumonia - 5 mg per pound of body weight (1 ml per each 60 pounds of body weight) intramuscularly for three to seven days.

See package insert for complete product information.

Warnings: Not for human use.  
Keep out of the reach of children.  
Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment.

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

Lot #  
EXP.

Swine  
Antibiotic

**Lincomycin**  
Injectable 30%

Sterile lincomycin hydrochloride injection  
100 ml

Indicated for the treatment of arthritis caused by susceptible organisms and for mycoplasma pneumonia.

Contains per ml:  
lincomycin hydrochloride equivalent to lincomycin, 300 mg; also benzyl alcohol, 9.45 mg added as a preservative.

Manufactured for  
**ALPHARMA.**  
Alpharma Inc.  
One Executive Drive, Fort Lee, New Jersey 07024

ANADA 200-274,  
approved by FDA  
AHL-479 0111

## **LINCOMYCIN INJECTABLE 30%** (Lincomycin hydrochloride injectable)

### **For intramuscular use in swine only.**

Lincomycin Injectable 30% contains lincomycin hydrochloride, an antibiotic produced by *Streptomyces lincolnensis* var. *lincolnensis*, which is chemically distinct from all other clinically available antibiotics and is isolated as a white crystalline solid.

### **Indications for swine**

Lincomycin Injectable 30% is indicated for the treatment of infectious forms of arthritis caused by organisms sensitive to its activity. This includes most of the organisms responsible for the various infectious arthritides in swine, such as staphylococci, streptococci, *Erysipelothrix* and *Mycoplasma spp.*

It is also indicated for the treatment of mycoplasma pneumonia.

### **Contraindications**

As with all drugs, the use of Lincomycin Injectable 30% is contraindicated in animals previously found to be hypersensitive to the drug.

### **Warning**

Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment. **Not for human use.**

### **Caution**

If no improvement is noted within 48 hours, consult a veterinarian.

### **Adverse reactions**

The intramuscular administration to swine may cause a transient diarrhea or loose stools. Although this effect has rarely been reported, one must be alert to the possibility that it may occur. Should this occur, it is important that the necessary steps be taken to prevent the effects of dehydration.

### **Dosage and administration**

For arthritis or mycoplasma pneumonia - 5 mg per pound of body weight intramuscularly once daily for three to seven days as needed. When using Lincomycin Injectable 30% containing 300 mg/ml, 1 ml/60 lb body weight will provide 5 mg/lb.

For optimal results, initiate treatment as soon as possible.

As with any multi-dose vial, practice aseptic techniques in withdrawing each dose. Adequately clean and disinfect the vial closure prior to entry with a sterile needle and syringe. No vial closure should be entered more than 20 times.

### **How supplied**

Lincomycin Injectable 30% is available in 300 mg/ml, concentration.

For use in swine weighing 300 pounds or more. Each ml contains lincomycin hydrochloride equivalent to lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 ml vials.

Manufactured for

 **ALPHARMA.**

AlphaPharma Inc.  
One Executive Drive, Fort Lee, New Jersey 07024

ANADA 200-274, approved by FDA  
AHI-001 0111