

Date of Approval: 7/13/2004

**FREEDOM OF INFORMATION SUMMARY**  
**ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION**

**ANADA 200-351**

**Lincomycin Injectable, USP**  
**25 mg/mL; 100 mg/mL; 300 mg/mL**  
**(lincomycin hydrochloride monohydrate)**

**Swine Antimicrobial**

**For the treatment of infectious forms of arthritis caused by organisms sensitive to its activity and for mycoplasma pneumonia.**

**Sponsored by:**

**Phoenix Scientific, Inc.**

**FREEDOM OF INFORMATION SUMMARY**

**1. GENERAL INFORMATION:**

- a. File Number: ANADA 200-351
- b. Sponsor: Phoenix Scientific, Inc.  
3915 South 48<sup>th</sup> St. Terrace  
St. Joseph, MO 64503
- Drug Labeler Code: 059130
- c. Established Name: Lincomycin hydrochloride monohydrate
- d. Proprietary Name: Lincomycin Injectable, USP
- e. Dosage Form: Sterile Solution
- f. How Supplied: 100 mL vials
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 25, 100, and 300 mg lincomycin hydrochloride per mL of sterile finished product
- i. Route of Administration: Intramuscular
- j. Species/Class: Swine; 300 mg/mL concentration is for use in swine weighing 300 lb or more.
- k. Recommended Dosage: The usual daily dosage for arthritis or mycoplasma pneumonia is 5.0 mg/lb of body weight (bwt) intramuscularly once daily for 3-7 days as needed. When using Lincomycin Injectable containing 25 mg/mL, 1 mL/5 lb bwt will provide 5 mg/lb. When using Lincomycin Injectable containing 100 mg/mL, 1 mL/20 lb bwt will provide 5 mg/lb. When using Lincomycin Injectable containing 300 mg/mL, 1 mL/60 lb bwt will provide 5 mg/lb. Do not treat within 48 hours of slaughter.
- l. Pharmacological Category: Antimicrobial
- m. Indications: 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.

- n. Pioneer Product: LINCOMIX 25, 100, and 300 Injectable; lincomycin hydrochloride monohydrate; NADA 034-025; Pharmacia & Upjohn Co.

## **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 (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Lincomycin Injectable, USP. The generic product is administered as an intramuscular injection, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product LINCOMIX Injectable (lincomycin hydrochloride monohydrate), the subject of Pharmacia & Upjohn Co., NADA 034-025, was approved on June 6, 1967.

## **3. HUMAN SAFETY:**

- **Tolerance**

The tolerances established for the pioneer product apply to the generic product. Tolerances of 0.6 part per million in liver and 0.1 part per million in muscle are established for lincomycin residues in swine under 21 CFR 556.360. An acceptable daily intake (ADI) for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.

- **Withdrawal Time**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal time of 2 days has been established for Lincomycin Injectable, USP in swine treated intramuscularly at a dose of 5 mg/lb bwt (21 CFR 522.1260).

- **Regulatory Method for Residues**

The analytical method for determination of Lincomycin Injectable, USP in tissues is the test using *Sarcina lutea* (ATCC 9341). This method is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

**4. AGENCY CONCLUSIONS:**

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

**5. ATTACHMENTS:**

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

Generic Labeling for ANADA 200-351:

Lincomycin Injectable, USP – 25 mg/mL, 100 mg/mL, and 300 mg/mL; vial labels and package insert

Pioneer Labeling for NADA 034-025:

LINCOMIX Injectable – 25 mg/mL, 100 mg/mL, and 300 mg/mL; vial labels and package insert

For Intramuscular Use In Swine.  
Restricted Drug-Use Only as Directed  
(California). 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  
5 pounds of body weight)  
intramuscularly for three to  
seven days.

See package insert for complete  
product information.



Lot No.

Exp. Date

600115

NDC 59130-749-01

**Lincomycin Injectable, USP**  
**25 mg/mL**  
**Swine Antibiotic**

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

Contains per mL:  
lincomycin hydrochloride equivalent to lincomycin, 25  
mg; also benzyl alcohol, 9.45 mg added as preservative.

ANADA 200-351, Approved by FDA

**Net Contents: 100 mL (3.3 fl oz)**

**Amtech**<sup>®</sup>  
Group, Inc.

**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.

OPEN  
HERE



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

TAKE TIME



OBSERVE LABEL  
DIRECTIONS

Manufactured by  
Phoenix Scientific Inc.  
St. Joseph, MO 64503

Iss. 8-01

For Intramuscular Use in Swine.  
Restricted Drug-Use Only as Directed  
(California). 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  
20 pounds of body weight)  
intramuscularly for three to  
seven days.  
See package insert for com-  
plete product information.



Lot No.

Exp. Date

600113

NDC 59130-747-01

**Lincomycin Injectable, USP**  
**100 mg/mL**  
**Swine Antibiotic**

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

Contains per mL:  
Lincomycin hydrochloride equivalent to lincomycin, 100  
mg; also benzyl alcohol, 9.48 mg added as preservative.

ANADA 200-351, Approved by FDA

**Net Contents: 100 mL (3.3 fl oz)**

**AmTech**<sup>®</sup>  
Group, Inc.

**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.

OPEN  
HERE

Store at controlled room temp-  
erature 20° to 25° C (68° to 77°F)



Manufactured by  
Phoenix Scientific Inc.  
St. Joseph, MO 64503

Iss. 8-01

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 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.



Lot No.

Exp. Date

600114

NDC 59130-748-01

**Lincomycin Injectable, USP**  
**300 mg/mL**  
**Swine Antibiotic**

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 preservative.

ANADA 200-351, Approved by FDA

**Net Contents: 100 mL (3.3 fl oz)**

**Amftech**<sup>®</sup>  
Group, Inc.

**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 20° to 25° C (68° to 77° F)

TAKE TIME



OBSERVE LABEL DIRECTIONS

Manufactured by  
Phoenix Scientific Inc.  
St. Joseph, MO 64503

Iss. 8-01

OPEN  
HERE

30198, 30199, 30200

	<p><b>WARNINGS:</b> 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.</p> <p>Store at controlled room temperature 20° to 25° C (68° to 77° F)</p> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p> <p>Manufactured by Phoenix Scientific Inc. St. Joseph, MO 64503 Iss. 8-01</p>	<p>ANADA 200-351, Approved by FDA</p> <p><b>Lincomycin Injectable, USP</b></p> <p>For Intramuscular Use in Swine Only Lincomycin Injectable contains lincomycin hydrochloride, an antibiotic produced by <i>Streptomyces lincolnensis</i> var. <i>lincolnensis</i>, which is chemically distinct from all other clinically available antibiotics and is isolated as a white crystalline solid.</p> <p><b>INDICATIONS FOR SWINE</b> Lincomycin 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</p>	<p>for the various infectious arthritides in swine, such as the staphylococci, streptococci, <i>Erysipelothrix</i> and <i>Mycoplasma spp.</i> It is also indicated for the treatment of mycoplasma pneumonia.</p> <p><b>CONTRAINDICATIONS</b> As with all drugs, the use of Lincomycin Injectable is contraindicated in animals previously found to be hypersensitive to the drug.</p> <p><b>WARNING</b> Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment. Not for human use.</p>
<p><b>CAUTION</b> If no improvement is noted within 48 hours, consult a veterinarian.</p> <p><b>ADVERSE REACTIONS</b> 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.</p> <p><b>DOSAGE AND ADMINISTRATION</b> For arthritis or mycoplasma pneumonia - 5 mg per pound of body</p>	<p>weight intramuscularly once daily for three to seven days as needed. When using Lincomycin Injectable containing 25 mg/mL, 1 mL/5 lb body weight will provide 5 mg/lb. When using Lincomycin Injectable containing 100 mg/mL, 1 mL/20 lb body weight will provide 5 mg/lb. When using Lincomycin 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.</p> <p>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</p>	<p>vial closure should be entered more than 20 times.</p> <p><b>HOW SUPPLIED</b> Lincomycin Injectable is available in three concentrations: 300 mg/mL, 100 mg/mL, and 25 mg/mL.</p> <p><b>300 mg/mL:</b> 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.</p> <p><b>100 mg/mL:</b> Each mL contains lincomycin hydrochloride equivalent to lincomycin, 100 mg; also Benzyl</p>	<p>Alcohol, 9.45 mg added as preservative. Supplied in 100 mL vials.</p> <p><b>25 mg/mL: Special baby pig concentration.</b> Each mL contains lincomycin hydrochloride equivalent to lincomycin, 25 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 100 mL vials.</p>

LOT/EXP

81376206  
 For Intramuscular Use in Swine.  
 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 5 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

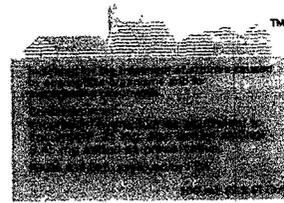
Store at controlled room temperature  
 20° to 25° C (68° to 77° F) [see USP].  
 Pharmacia & Upjohn Company  
 Kalamazoo, MI 49001, USA

NDC 0009-3072-06

**Lincomix® 25**

Injectable

lincomycin injection, USP

**Swine Antibiotic**

LOT/EXP

813778206  
 For Intramuscular Use in Swine.  
 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 20 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.

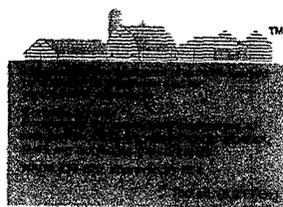
Store at controlled room temperature  
 20° to 25° C (68° to 77° F) [see USP].  
 Pharmacia & Upjohn Company  
 Kalamazoo, MI 49001, USA

NDC 0009-0617-13

**Lincomix® 100**

Injectable

lincomycin injection, USP

**Swine Antibiotic**

LOT/EXP

813773206  
 For Intramuscular Use in Swine  
 Over 200 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  
 60 pounds of body weight) intramus-  
 cularly 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.

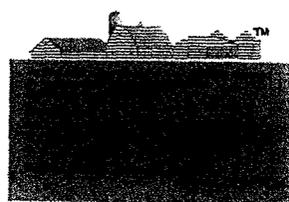
Store at controlled room temperature  
 20° to 25° C (68° to 77° F) [see USP].  
 Pharmacia & Upjohn Company  
 Kalamazoo, MI 49001, USA

NDC 0009-3256-01

**Lincomix® 300**

Injectable

lincomycin injection, USP

**Swine Antibiotic**



## Lincomix

brand of lincomycin injection, USP

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.

*(continued below)*

**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.

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

NADA #34-025, Approved by FDA

Pharmacia & Upjohn Company  
Kalamazoo, Michigan 49001, USA

Revised August 1999

810 601 211

691461

**Lincomix®**  
brand of lincomycin injection, USP

Pharmacia  
& Upjohn

**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.

Lincomix  
lincomycin  
injection, USP



Lincomix  
lincomycin  
injection, USP



**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.

*see back*