

HFA-305

Date of Approval: APR 2 200

FREEDOM OF INFORMATION SUMMARY

ANADA 200-315

**Lincomycin Injection
(Lincomycin Hydrochloride)
25mg/mL, 100 mg/mL, 300 mg/mL**

Swine Antibiotic

Indications for use: 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.

Sponsored by:

**Veterinary Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215**

ANADA 200-315

FOIS

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AMERICAN

FREEDOM OF INFORMATION SUMMARY

1. General Information:

- a. *File Number:* ANADA 200-315
- b. *Sponsor:* Veterinary Laboratories, Inc.
12340 Santa Fe Trail Dr.
Lenexa, KS 66215

21 CFR 510.600: Drug Labeler Code: 000857
- c. *Established Name:* Lincomycin Hydrochloride Monohydrate
- d. *Proprietary Name:* Lincomycin Injection 25; Lincomycin Injection 100;
Lincomycin Injection 300
- e. *Dosage Form:* Liquid (solution)
- f. *How Supplied:* 100 mL vials containing 25, 100, and 300 mg
lincomycin hydrochloride per mL.
- g. *How Dispensed:* OTC
- h. *Amount of Active Ingredients:* 25, 100, 300 mg lincomycin hydrochloride per mL
of sterile finished product
- i. *Route of Administration:* Sterile Intramuscular Injection
- j. *Species/Class:* Swine
- k. *Recommended Dosage:* The usual daily dosage for arthritis or mycoplasma
pneumonia is 5.0 mg/lb. BW intramuscularly once
daily for 3-7 days as needed. When using
Lincomycin Injection containing 25 mg/mL, 1 mL/5
lb. BW will provide 5 mg/lb. When using
Lincomycin Injection containing 100 mg/mL, 1
mL/20 lb. BW will provide 5 mg/lb. When using
Lincomycin Injection containing 300 mg/mL, 1
mL/60 lb. BW will provide 5 mg/lb.
- 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[®] Injectable manufactured by Pharmacia & Upjohn Co., NADA 034-025, 25 mg/mL, 100 mg/mL, and 300 mg/mL.

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 data and drug 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 2000).

Safety and effectiveness for this generic animal drug, Lincomycin Injection, were established by demonstration of chemical equivalence to the pioneer product, Lincomix[®] Injectable (NADA 034-025). Based on this demonstrated equivalency, a waiver of the *in vivo* bioequivalence studies was granted on September 16, 1999. The generic and pioneer products contain the same active ingredients and are parenteral solutions intended for use in swine by the intramuscular route of administration.

3. HUMAN SAFETY

• Tolerance

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

• Withdrawal Time

When a waiver of the *in vivo* bioequivalence study is granted, then the withdrawal period established for the pioneer product will be assigned to the generic product. A 2-day (48 hr) withdrawal period is required for swine treated intramuscularly with lincomycin at 5 mg/lb BW.



• Human Safety Relative to Possession, Handling and Administration

Labeling contains adequate caution/warning statements. Human Warnings are provided on the product label as follows: “Not for human use.” “Keep out of reach of children.” “Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment.”

• Regulatory Method for Residues

The analytical method for detection of lincomycin residues 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 Abbreviated New Animal Drug Application (ANADA) filed 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 Lincomycin Injection, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Labeling: Pioneer Labeling for NADA 034-025:
Lincomix[®] Injectable – 25 mg/mL, 100 mg/mL, 300 mg/mL

Generic Labeling for ANADA 200-315:
Lincomycin Injection[™] – 25 mg/mL, 100 mg/mL, 300 mg/mL

Veterinary Laboratories, Inc. is the manufacturer and Sparhawk Laboratories, Inc. is the distributor of this generic product.

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.



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.

Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 25 mg; also Benzyl Alcohol, 9.45 mg added as preservative.

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

Lot No. _____ Exp. Date _____

L-6679-04 Rev. 1-03

LINCOMYCIN 25

INJECTION

25 mg/mL

**STERILE LINCOMYCIN
HYDROCHLORIDE INJECTION**

SWINE ANTIBIOTIC

NET CONTENTS: 100 mL

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

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

TAKE TIME OBSERVE LABEL DIRECTIONS

ANADA#: 200-315 Approved by F.D.A.

Distributed by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA Manufactured by Veterinary Laboratories, Inc. Lenexa, KS 66215, USA

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.

Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 25 mg; also Benzyl Alcohol, 9.45 mg added as preservative.

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

Lot No. _____ Exp. Date _____

L-6679-04 Rev. 1-03

LINCOMYCIN 25

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

TAKE TIME OBSERVE LABEL DIRECTIONS

ANADA#: 200-315 Approved by F.D.A.

Distributed by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA Manufactured by Veterinary Laboratories, Inc. Lenexa, KS 66215, USA

CUSTOMER PROOF • pdf format • CHECK CAREFULLY!

Customer: SPARHAWK / VETLABS P.O. #: RACHEL CYREL #: 28244 (ts)

Date 3/4/02 1/10/03

Design: Lincomycin injection 25mg colors: _____ size: 1.875 x 5.75

Yes No 202 red black 877 silver

pattern

flood

Unwind #: 4

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Approved by: _____ Date approved: _____

**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 complete product information.

Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 100 mg; also Benzyl Alcohol, 9.45 mg added as preservative.

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

Lot No. Exp. Date

L-6739-04 Rev. 1-03

LINCOMYCIN 100

INJECTION

100 mg/mL

**STERILE LINCOMYCIN
HYDROCHLORIDE INJECTION**

SWINE ANTIBIOTIC

NET CONTENTS: 100 mL

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

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

TAKE TIME OBSERVE LABEL DIRECTIONS

ANADA#: 200-315 Approved by F.D.A.

Distributed by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA Manufactured by Veterinary Laboratories, Inc. Lenexa, KS 66215, USA

**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 complete product information.

Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 100 mg; also Benzyl Alcohol, 9.45 mg added as preservative.

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

Lot No. Exp. Date

L-6739-04 Rev. 1-03

LINCOMYCIN 100

INJECTION

100 mg/mL

**STERILE LINCOMYCIN
HYDROCHLORIDE INJECTION**

SWINE ANTIBIOTIC

NET CONTENTS: 100 mL

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

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

TAKE TIME OBSERVE LABEL DIRECTIONS

ANADA#: 200-315 Approved by F.D.A.

Distributed by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA Manufactured by Veterinary Laboratories, Inc. Lenexa, KS 66215, USA

CUSTOMER PROOF • pdf format • CHECK CAREFULLY!

Customer: SPARHAWK / VETLABS P.O. #: RACHEL CYREL #: 28245 (ts)

Date 3/4/02 1/10/03

desc.: Lincomycin injection 25mg size: 1.875 x 5.75

| | | | | |
|----------------------------------|-----------------------------|----------------|--------------|-------------------|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | <u>202 red</u> | <u>black</u> | <u>877 silver</u> |
| <input type="checkbox"/> pattern | | | | |
| <input type="checkbox"/> flood | | | | |

Unwind #: 4

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Approved by: _____ Date approved: _____

**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.

Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative.

Store at controlled room temperature:
20° to 25° C (68° to 77° F) [see USP].
Lot No. Exp. Date

L-4636-04 Rev. 1-03

LINCOMYCIN 300

INJECTION

300 mg/mL
**STERILE LINCOMYCIN
HYDROCHLORIDE INJECTION**

SWINE ANTIBIOTIC

NET CONTENTS: 100 mL



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

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

TAKE TIME  OBSERVE LABEL DIRECTIONS

ANADA#: 200-315 Approved by F.D.A.

Distributed by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA Manufactured by Veterinary Laboratories, Inc. Lenexa, KS 66215, USA

**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.

Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative.

Store at controlled room temperature:
20° to 25° C (68° to 77° F) [see USP].
Lot No. Exp. Date

L-4636-04 Rev. 1-03

LINCOMYCIN 300

INJECTION

300 mg/mL
**STERILE LINCOMYCIN
HYDROCHLORIDE INJECTION**

SWINE ANTIBIOTIC

NET CONTENTS: 100 mL



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

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

TAKE TIME  OBSERVE LABEL DIRECTIONS

ANADA#: 200-315 Approved by F.D.A.

Distributed by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA Manufactured by Veterinary Laboratories, Inc. Lenexa, KS 66215, USA

CUSTOMER PROOF • pdf format • CHECK CAREFULLY!

Customer: SPARHAWK / VETLABS P.O. #: RACHEL CYREL #: 20246 (ts)

Date 3/4/02 1/10/03

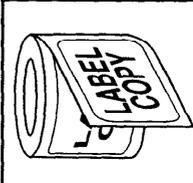
desc.: Lincomycin injection 25mg size: 1.875 x 5.75

Yes No 202 red black 877 silver

pattern _____

flood _____

Unwind #: 4



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Approved by: _____ Date approved: _____

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| <p>preservative. Supplied in 100 mL vials.</p> <p>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.</p> <p>7</p> | <p>Indicated for the treatment of arthritis caused by susceptible organisms and for mycoplasma pneumonia.</p> <p>Warning: Not for human use. Keep out of reach of children. Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment.</p> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p> <p>ANADA#: 200-315 Approved by F.D.A.</p> <p>Distributed by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA</p> <p>Manufactured by Veterinary Laboratories, Inc. Lenexa, KS 66215, USA</p> | <p>Lincomycin Injectable</p> <p>brand of Lincomycin hydrochloride injectable</p> <p>For Intramuscular Use in Swine Only</p> <p>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>INDICATIONS FOR SWINE</p> <p>Lincomycin injectable is indicated for the treatment of infectious</p> <p>1</p> | <p>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, <i>Erysipelothrix</i> and <i>Mycoplasma spp.</i></p> <p>It is also indicated for the treatment of mycoplasma pneumonia.</p> <p>CONTRAINDICATIONS</p> <p>As with all drugs, the use of Lincomycin Injectable is contraindicated in animals previously found</p> <p>2</p> |
|--|--|--|---|

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| <p>to be hypersensitive to the drug.</p> <p>WARNING</p> <p>Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment. Not for human use.</p> <p>CAUTION</p> <p>If no improvement is noted within 48 hours, consult a veterinarian.</p> <p>ADVERSE REACTIONS</p> <p>The intramuscular administration to swine may cause a transient diarrhea or loose stools. Although</p> <p>3</p> | <p>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>DOSAGE AND ADMINISTRATION</p> <p>For arthritis or mycoplasma pneumonia-5mg per pound of body weight intramuscularly once daily for three to seven days as needed.</p> <p>When using Lincomycin Injectable containing 25 mg/mL, 1 mL/5 lb. body weight will provide 5 mg/lb.</p> <p>4</p> | <p>When using Lincomycin Injectable containing 100 mg/mL, 1mL/20lb body weight will provide 5mg/lb. When using Lincomycin Injectable containing 300 mg/mL, 1 mL/60 lb. body weight will provide 5 mg/lb.</p> <p>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.</p> <p>5</p> | <p>HOW SUPPLIED</p> <p>Lincomycin Injectable is available in three concentrations: 300 mg/mL, 100 mg/mL, and 25 mg/mL.</p> <p>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.</p> <p>100 mg/mL: Each mL contains lincomycin hydrochloride equivalent to lincomycin, 100 mg; also Benzyl Alcohol, 9.45 mg added as</p> <p>6</p> |
|---|---|--|--|

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Lincomix®

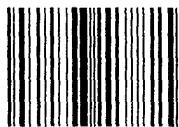
brand of lincomycin injection, USP

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

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Lincomix
lincomycin
injection, USP

0810601211

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.





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

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LOT/EXP

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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.

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

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

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

NADA #34-025, approved by FDA

100 mL (3.3 Fl Oz)

LOT/EXP

813776206

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 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

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

Contains per mL: lincomycin hydrochloride equivalent to lincomycin, 100 mg; also benzyl alcohol, 9.45 mg added as preservative.

NADA #34-025, approved by FDA

100 mL (3.3 Fl Oz)

LOT/EXP

813773206

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.

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

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.

NADA #34-025, approved by FDA

100 mL (3.3 Fl Oz)