

LINCOMYCIN - lincomycin injection
Sparhawk Laboratories, Inc.

LINCOMYCIN 300 INJECTION

300 mg/mL

STERILE LINCOMYCIN INJECTION

Caution: Federal law restricts this drug to use by or on the order of a licenced veterinarian.

SWINE ANTIBIOTIC

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

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

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Not for Use in Humans

Keep out of reach of children

INDICATIONS FOR SWINE

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 for the various infectious arthritides in swine, such as staphylococci, streptococci, *Erysipelothrix* and *Mycoplasma spp.*

CONTRAINDICATIONS

As with all drugs, the use of Lincomycin 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 had 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.

CONTACT INFORMATION

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Sparhawk Laboratories Inc at 1-800-255-6388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

DOSAGE AND ADMINISTRATION

For arthritis or mycoplasma pneumonia-5mg per pound of body weight intramuscularly once daily for three to seven days as needed. When using lincomycin injection containing 25 mg/mL, 1 mL/5 lb. body weight will provide 5 mg/lb.

When using lincomycin injection containing 100 mg/mL, 1mL/20lb body weight will provide 5mg/lb. When using lincomycin injection 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.

Lincomycin 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 Benyl 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]

Lincomycin 300

**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. 08-23

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INJECTION

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STERILE LINCOMYCIN
INJECTION**

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**Not for Use in Humans
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SWINE ANTIBIOTIC

NET CONTENTS: 100 mL



MANUFACTURED FOR

LENEXA, KS 66215 USA

**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

Approved by FDA under ANADA # 200-315

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

OPEN
HERE



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.

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Lincomycin Injection

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INDICATIONS FOR SWINE

Lincomycin injection 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 injection is contraindicated in animals previously found to be hypersensitive to the drug.

2

WARNING

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CAUTION

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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

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necessary steps be taken to prevent the effects of dehydration.

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DOSAGE AND ADMINISTRATION
For arthritis or mycoplasma pneumonia-5mg per pound of body weight intramuscularly

4

once daily for three to seven days as needed. When using lincomycin injection containing 25 mg/mL, 1 mL/5 lb. body weight will provide 5 mg/lb.

When using lincomycin injection containing 100 mg/mL, 1mL/20lb body weight will provide 5mg/lb. When using lincomycin injection 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

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closure prior to entry with a sterile needle and syringe. No vial closure should be entered more than 20 times.

HOW SUPPLIED

Lincomycin injection 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.

6

**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].**

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TAKE TIME



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DOSAGE AND ADMINISTRATION
For arthritis or mycoplasma pneumonia - 5mg per pound of body weight intramuscularly

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<p>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.</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 style="text-align: center;">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> <div style="text-align: center;">  </div> <p>Approved by FDA under ANADA # 200-315</p> <p>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA L-4636-04 Rev. 08-23</p>	<p>Lincomycin Injection</p> <p>For Intramuscular Use in Swine Only</p> <p>Lincomycin injection 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>Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Not for Use in Humans Keep out of reach of children</p> <p style="text-align: center;">1</p>	<p>INDICATIONS FOR SWINE</p> <p>Lincomycin injection 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, <i>Erysipelothrix</i> and <i>Mycoplasma</i> spp.</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 injection is contraindicated in animals previously found to be hypersensitive to the drug.</p> <p style="text-align: center;">2</p>
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<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 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</p> <p style="text-align: center;">3</p>	<p>necessary steps be taken to prevent the effects of dehydration.</p> <p>CONTACT INFORMATION: To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Sparhawk Laboratories Inc at 1-800-255-6388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae</p> <p>DOSAGE AND ADMINISTRATION</p> <p>For arthritis or mycoplasma pneumonia-5mg per pound of body weight intramuscularly</p> <p style="text-align: center;">4</p>	<p>once daily for three to seven days as needed. When using lincomycin injection containing 25 mg/mL, 1 mL/5 lb. body weight will provide 5 mg/lb.</p> <p>When using lincomycin injection containing 100 mg/mL, 1mL/20lb body weight will provide 5mg/lb. When using lincomycin injection 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</p> <p style="text-align: center;">5</p>	<p>closure prior to entry with a sterile needle and syringe. No vial closure should be entered more than 20 times.</p> <p>HOW SUPPLIED</p> <p>Lincomycin injection 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 style="text-align: center;">6</p>
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LINCOMYCIN				
lincomycin injection				
Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG		Item Code (Source)	NDC:58005-636
Route of Administration	INTRAMUSCULAR			
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
LINCOMYCIN HYDROCHLORIDE (UNII: M6T05Z2B68) (LINCOMYCIN - UNII: BOD072YW0F)			LINCOMYCIN	300 mg in 1 mL
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58005-636-04	100 mL in 1 VIAL		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANADA	ANADA200315		01/21/2004	

Labeler - Sparhawk Laboratories, Inc. (147979082)

Revised: 11/2023

Sparhawk Laboratories, Inc.