

LINCOMYCIN - lincomycin injection
VetTek

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.

Not for Use in Humans
Keep out of reach of children

SWINE ANTIBIOTIC

For Intramuscular Use in Swine Over 300 lbs.
Restricted Drug - Use Only As Directed
(California). For Use in Animals Only

Indicated for the treatment of arthritis caused by susceptible organisms 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 available 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 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]

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].

L-4636-04 Rev. 07.24

Lot No. Exp. Date



NDC 60270-343-10

Lincomycin 300

300 mg/mL
STERILE LINCOMYCIN
INJECTION

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
SWINE ANTIBIOTIC
Net Contents: 100 mL (3.3 fl. oz.)

VET TEK™

Manufactured for: Vettek, Blue Springs, MO 64014

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 for
Vettek
Blue Springs, MO 64014, USA
ISS24XB07

Manufactured by
Sparhawk 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].

L-4636-04 Rev. 07.24

Lot No. Exp. Date



NDC 60270-343-10

Lincomycin 300

300 mg/mL
STERILE LINCOMYCIN
INJECTION

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SWINE ANTIBIOTIC
Net Contents: 100 mL (3.3 fl. oz.)

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Vettek
Blue Springs, MO 64014, USA
ISS24XB07

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

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.

L-4636-04 Rev. 07-24

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TAKE TIME  **OBSERVE LABEL DIRECTIONS**

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Manufactured by
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Lincomycin 300 Injection

For Intramuscular Use in Swine Only

Lincomycin 300 Injection 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. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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1

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

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.

3

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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,

4

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.

5

HOW SUPPLIED

Lincomycin 300 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.

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.

6

<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>L-4636-04 Rev. 07-24</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>Approved by FDA under ANADA # 200-315</p> <p>Manufactured for VetTek Blue Springs, MO 64014, USA ISS24XB07</p> <p>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA</p> <p>1</p>	<p>Lincomycin 300 Injection For Intramuscular Use in Swine Only</p> <p>Lincomycin 300 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. 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>5</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. 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>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: 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 necessary steps be taken to prevent the effects of dehydration.</p> <p>3</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>DOSEAGE 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. When using lincomycin injection containing 25 mg/mL,</p> <p>4</p>	<p>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.</p> <p>5</p>	<p>HOW SUPPLIED</p> <p>Lincomycin 300 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>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>6</p>
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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].

L-4636-04 Rev. 07.24
Lot No. Exp. Date

7 45801 12131 7

NDC 60270-343-10

Lincomycin 300

300 mg/mL
STERILE LINCOMYCIN INJECTION

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
SWINE ANTIBIOTIC
Net Contents: 100 mL (3.3 fl. oz.)

VET TEK

Manufactured for: VetTek, Blue Springs, MO 64014

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


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TAKE TIME  **OBSERVE LABEL DIRECTIONS**

Approved by FDA under ANADA # 200-315

Manufactured for **VetTek**
Blue Springs, MO 64014, USA
ISS24XB07

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

OPEN HERE 

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<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>L-4636-04 Rev. 07-24</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>Approved by FDA under ANADA # 200-315</p> <p>Manufactured for VetTek Blue Springs, MO 64014, USA ISS240607</p> <p>Manufactured by Sparhawk Laboratories, Inc. Lenexa, KS 66215, USA</p>	<p>Lincomycin 300 Injection For Intramuscular Use in Swine Only</p> <p>Lincomycin 300 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. 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>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. 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>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: 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 necessary steps be taken to prevent the effects of dehydration.</p> <p>3</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 once daily for three to seven days as needed. When using lincomycin injection containing 25 mg/mL,</p> <p>4</p>	<p>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.</p> <p>5</p>	<p>HOW SUPPLIED</p> <p>Lincomycin 300 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>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>6</p>
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Product Information				
Product Type		PREScription ANIMAL DRUG	Item Code (Source)	NDC:60270-343
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:60270-343-10	100 mL in 1 VIAL		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANADA	ANADA200315		08/08/2024	

Labeler - VetTek (056387798)

Registrant - Sparhawk Laboratories, Inc. (147979082)

Establishment			
Name	Address	ID/FEI	Business Operations
Sparhawk Laboratories, Inc.		147979082	analysis, manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
HEC PHARM CO., LTD		554546110	api manufacture