

**LINCOMYCIN 300- lincomycin injection**  
**MWI Veterinary Supply, Inc.**

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**Linco-Bac 300**

**(lincomycin)**

**brand of Lincomycin hydrochloride injectable**

**300 mg/mL**

**SWINE ANTIBIOTIC**

**STERILE LINCOMYCIN HYDROCHLORIDE INJECTION**

**Not for Use in Humans**

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

**Approved by FDA under ANADA # 200-315**

**For Intramuscular Use in Swine Over 300 lbs.**

**Restricted Drug - Use Only As Directed (California).**  
**For Use in Animals Only.**

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.

**INDICATIONS FOR SWINE**

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

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.

It is also indicated for the treatment of mycoplasma pneumonia.

**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 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

### 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:

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 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. 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 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.

**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]**

**TAKE TIME OBSERVE LABEL DIRECTIONS**

## Warning

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

## CONTACT INFORMATION

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data sheet (SDS), 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><b>For Intramuscular Use in Swine Over 300 lbs.</b> Restricted Drug - Use Only As Directed (California). For Use in Animals Only.</p> <p><b>Dosage:</b> 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.</p> <p><b>Warning:</b> 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><b>Store at controlled room temperature: 20° to 25°C (68° to 77°F) [see USP].</b></p> <p>Lot No.                      Exp. Date</p>	<p>NDC 13985-577-10</p> <p><b>VETone</b> <b>LincoBac™ 300</b> (lincomycin) Injection 300 mg/mL</p> <p><b>SWINE ANTIBIOTIC</b> <b>STERILE LINCOMYCIN HYDROCHLORIDE INJECTION</b> Not for Use in Humans</p> <p><b>Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</b></p> <p>Approved by FDA under ANADA # 200-315</p> <p>VI 510621                      Net Contents: 100 mL</p>	<p>100 mL</p> <p>Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative.</p> <p>Indicated for the treatment of arthritis caused by susceptible organisms and for mycoplasma pneumonia.</p> <p>Approved by FDA under ANADA # 200-315</p> <p>Distributed by: MWI Boise, ID 83705                      L-4636-04                      Rev. 03/2024 <a href="http://www.VetOne.net">www.VetOne.net</a></p> <p><b>TAKE TIME</b> <b>OBSERVE LABEL DIRECTIONS</b></p> <p><b>OPEN HERE</b></p> <p>3 13985 57710 9</p>
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<p><b>25 mg/mL:</b> 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><b>Warning:</b> 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>7</p>	<p>Contains per mL: Lincomycin Hydrochloride equivalent to Lincomycin, 300 mg; also Benzyl Alcohol, 9.45 mg added as preservative.</p> <p>Indicated for the treatment of arthritis caused by susceptible organisms and for mycoplasma pneumonia.</p> <p>Approved by FDA under ANADA # 200-315</p> <p>Distributed by: MWI Boise, ID 83705                      L-4636-04                      Rev. 03/2024 <a href="http://www.VetOne.net">www.VetOne.net</a></p> <p><b>TAKE TIME</b> <b>OBSERVE LABEL DIRECTIONS</b></p> <p>3 13985 57710 9</p>	<p><b>VETone</b> <b>LincoBac™ 300</b> brand of Lincomycin hydrochloride injection <b>For Intramuscular Use in Swine Only</b></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><b>Caution:</b> 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</p> <p>1</p>	<p><b>INDICATIONS FOR SWINE</b> 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 spp.</i></p> <p>It is also indicated for the treatment of mycoplasma pneumonia.</p> <p><b>CONTRAINDICATIONS</b> 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><b>WARNING</b> Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment. <b>Not for human use.</b></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>3</p>	<p><b>CONTACT INFORMATION:</b> To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data sheet (SDS), 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 <a href="http://www.fda.gov/reportanimalae">http://www.fda.gov/reportanimalae</a></p> <p><b>DOSE AND ADMINISTRATION</b> 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 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, 1 mL/20 lb body weight will provide 5 mg/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 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><b>HOW SUPPLIED</b> Lincomycin Injection 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 Alcohol, 9.45 mg added as preservative. Supplied in 100 mL vials.</p> <p>6</p>
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**LINCOMYCIN 300**  
lincomycin injection

**Product Information**

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:13985-577
<b>Route of Administration</b>	INTRAMUSCULAR		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LINCOMYCIN HYDROCHLORIDE (UNII: M6T05Z2B68) (LINCOMYCIN - UNII:BOD072YW0F)	LINCOMYCIN	300 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
BENZYL ALCOHOL (UNII: LKG8494WBH)	9.45 mg in 1 mL

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:13985-577-10	100 mL in 1 VIAL		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANADA	ANADA200315	04/07/2014	

**Labeler** - MWI Veterinary Supply, Inc. (019926120)**Registrant** - Sparhawk Laboratories, Inc. (147979082)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Sparhawk Laboratories, Inc.		147979082	manufacture, analysis

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
HEC Pharm Co., Ltd.		554546110	api manufacture