

LINCOMYCIN 300- lincomycin injection
MWI Veterinary Supply, Inc.

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.

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>For Intramuscular Use in Swine Over 300 lbs.</p> <p>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.</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>Store at controlled room temperature: 20° to 25°C (68° to 77°F) [see USP].</p> <p>Lot No. Exp. Date</p>	<p>NDC 13985-577-10</p> <p>VETone™</p> <p>LincoBac™ 300</p> <p>(lincomycin)</p> <p>Injection</p> <p>300 mg/mL</p> <p>SWINE ANTIBIOTIC</p> <p>STERILE LINCOMYCIN HYDROCHLORIDE INJECTION</p> <p>Not for Use in Humans</p> <p>Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Approved by FDA under ANADA # 200-315</p> <p>V1 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>Distributed by: MWI Boise, ID 83705 L-4636-04 www.VetOne.net Rev. 07/2023</p> <p>TAKE TIME</p> <p>OBSEVE LABEL DIRECTIONS</p> <p>OPEN HERE</p> 
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<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>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> <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>Distributed by: MWI Boise, ID 83705 L-4636-04 www.VetOne.net Rev. 07/2023</p> 	<p>VETone™</p> <p>LincoBac™ 300</p> <p>brand of Lincomycin hydrochloride injectable</p> <p>For Intramuscular Use in Swine Only</p> <p>Not for Use in Humans</p> <p>Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</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>1</p>	<p>INDICATIONS FOR SWINE</p> <p>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, <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 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</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 necessary steps be taken to prevent the effects of dehydration.</p> <p>3</p>	<p>DOSAGE AND ADMINISTRATION</p> <p>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, 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</p> <p>4</p>	<p>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>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>5</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>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>6</p>
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LINCOMYCIN 300
lincomycin injection

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:13985-577
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:13985-577-10	100 mL in 1 VIAL		

Marketing Information

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

Labeler - MWI Veterinary Supply, Inc. (019926120)

Registrant - Sparhawk Laboratories, Inc. (147979082)

Establishment

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

Establishment

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

Revised: 8/2023

MWI Veterinary Supply, Inc.