

LINCOMED 300- lincomycin injection
Bimeda, Inc.

LincoMed® 300

lincomycin injection, USP
SWINE ANTIBIOTIC

Restricted Drug (California) - Use only as Directed.

For Use in Animals Only

ANADA 200-368, Approved by FDA

Net Content: 100 mL (3.3 fl oz)

For use in swine weighing 300 pounds or more.

For Intramuscular Use in Swine Only

LincoMed® 300 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:

LincoMed® 300 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 *Mycoplasmaspp*.

It is also indicated for the treatment of mycoplasma pneumonia.

CONTRAINDICATIONS:

As with all drugs, the use of LincoMed® 300 is contraindicated in animals previously found to be hypersensitive to the drug.

Residue Warning: Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment.

Human Warnings: Not for human use. Keep out of reach of children.

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/lb body weight intramuscularly once daily for three to seven days as needed. One mL per 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.

Each mL contains:

Lincomycin hydrochloride equivalent to lincomycin 300mg; also benzyl alcohol 9.45 mg added as a

preservative.

HOW SUPPLIED:

LincoMed® is available in two concentrations: 100 mg/mL and 300 mg/mL.

100mg/mL: Supplied in 100 mL multiple dose vial.

300 mg/mL: For use in swine weighing 300 pounds or more. Supplied in 100 mL multiple dose vial.

STORAGE: Store at 20°C - 25°C (68°F - 77°F).

KEEP FROM FREEZING



For Intramuscular Use in Swine Over 300 lbs.

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.

Residue Warning: Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment.

Human Warnings: Not for use in humans. Keep out of reach of children.

STORE AT 20°C - 25°C (68°F - 77°F). KEEP FROM FREEZING.

Net Contents: 100 mL (3.3 fl oz)

Contains per mL: Lincomycin hydrochloride equivalent to lincomycin 300 mg, also benzyl alcohol 9.45 mg added as a preservative.

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

LincoMed® is a registered trademark of Bimeda, Inc.

Manufactured by: Bimeda-MTC Animal Health Inc. Cambridge, ON Canada N3C 2W4

Manufactured for: Bimeda, Inc. Le Sueur, MN 56058 www.bimeda.com

Product No. LIN005 BURN000 Rev. 0313

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SEE THE EXP. LABS ENCLOSED

ANADA 200-368, Approved by FDA

LincoMed® 300 lincomycin injection, USP

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INDICATIONS FOR SWINE: LincoMed® 300 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 LincoMed® 300 is contraindicated in animals previously found to be hypersensitive to the drug.

Residue Warning: Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment.

Human Warnings: Not for use in humans. Keep out of reach of children.

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. One mL per 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.

Each mL contains: Lincomycin hydrochloride equivalent to lincomycin 300 mg; also benzyl alcohol 9.45 mg added as a preservative.

HOW SUPPLIED: LincoMed® is available in two concentrations: 100 mg/mL and 300 mg/mL.

300 mg/mL: For use in swine weighing 300 pounds or more. Supplied in 100 mL multiple dose vial.

100 mg/mL: Supplied in 100 mL multiple dose vial.

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Manufactured for: Bimeda, Inc. Le Sueur, MN 56058 www.bimeda.com

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LINCOMED 300

lincomycin injection

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:61133-6001
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lincomycin (UNII: BOD072YW0F) (Lincomycin - UNII: BOD072YW0F)	Lincomycin	300 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-6001-1	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200368	08/02/2006	

Labeler - Bimeda, Inc. (060492923)

Registrant - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda-MTC		256232216	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Jiangxi Guo Yao Pharmaceutical		420560294	api manufacture

Revised: 12/2018

Bimeda, Inc.