

LINCOBAC 300- lincomycin injection MWI/VetOne

LincoBac™ 300

(lincomycin injection)

For use in swine weighing 300 pounds or more.

For Intramuscular Use in Swine Only

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

LincoBac 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.

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.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Bimeda, Inc. at 1-888-524-6322. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

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 preservative.

HOW SUPPLIED: LincoBac 300, 300 mg/mL: *For use in swine weighing 300 pounds or more.* Supplied in 100 mL multiple dose vial.

INDICATIONS FOR SWINE:

LincoBac 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.

Store at 20°-25°C (68°-77°F). Keep from freezing.

CONTRAINDICATIONS: As with all drugs, the use of LincoBac 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.



LINCOBAC 300

lincomycin injection

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:13985-576
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

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	9.45 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-576-10	100 mL in 1 VIAL, GLASS		

Marketing Information

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

Labeler - MWI/VetOne (019926120)

Registrant - Bimeda, Inc. (060492923)

Establishment

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