LINCOMED 100- lincomycin injection Bimeda, Inc.

LincoMed® 100 (lincomycin injection) For Intramuscular Use in Swine Only

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

LincoMed 100 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 100 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, use of LincoMed 100 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.

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 1-888-524-6332. 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 20 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 100 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.

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.

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

Approved by FDA under ANADA # 200-368

1 NDC:61133-6000-1 100 mL in 1 VIAL, MULTI-DOSE



LINCOMED 100 lincomycin injection **Product Information** Item Code (Source) **Product Type** PRESCRIPTION ANIMAL DRUG NDC:61133-6000 **Route of Administration INTRAMUSCULAR Active Ingredient/Active Moiety** Basis of **Ingredient Name** Strength Strength LINCOMYCIN HYDROCHLORIDE (UNII: M6T05Z2B68) (LINCOMYCIN -100 mg LINCOMYCIN UNII:BOD072YW0F) in 1 mL **Packaging Item Code** Package Description **Marketing Start Date Marketing End Date**

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 Animal Health		256232216	manufacture			

Revised: 3/2024 Bimeda, Inc.