

**Brand or Product Name:** HINALIN 220 GRANULES

**Composition:** 22% Lincomycin Premix, 100g: 22g (22,000,000 IU of Lincomycin)

**Product Description:** white or almost white granules

**Pharmacodynamics:** Lincomycin is active mainly against Gram-positive bacteria. It exerts its antibiotic action by inhibiting RNA-dependent protein synthesis through action on the 50S subunit of the ribosome. Lincomycin has no activity against Gram-negative bacteria

**Pharmacokinetics:** Lincomycin is rapidly absorbed orally and reaches therapeutic plasma concentration.

After a single, oral administration of approximately 4.4 mg/kg and 11 mg/kg lincomycin to pigs resulted therapeutic plasma concentration for 12-16 hours, reaching peak plasma concentration after 4 hours. After a single, oral dose of 10 mg/kg lincomycin to pigs the maximum plasma concentration ( $C_{max}$ ) of 1.45 mg/kg was reached at 3.6 hours ( $T_{max}$ ). The elimination half-life ( $T_{1/2\beta}$ ) is about 3.36 hours. The oral administration of 22 mg/kg lincomycin for 3 days to pigs did not result in drug accumulation after 24 hours of administration and there was no therapeutic plasma concentration. After oral administration the absorbed lincomycin is eliminated through the bile and faeces in active form or as metabolites.

**Indication:** For treatment of swine dysentery caused by *Brachyspira hyodysenteriae*, *mycoplasmal pneumonia* associated with *Mycoplasma hyopneumoniae* and porcine proliferative enteropathy (ileitis) associated with *Lawsonia intracellularis*

**Recommended Dosage:**

To be administered orally, in dry medicated feeding stuff.

**Treatment of swine dysentery:**

Feed 110 mg lincomycin/kg complete feed (equivalent to 5.5 mg lincomycin/kg bodyweight) as the sole ration for three weeks or until clinical signs of disease (watery, mucoid or bloody stools) disappear.

**Treatment of mycoplasmal pneumonia:**

Feed 220 mg lincomycin/kg complete feed (equivalent to 11 mg lincomycin/kg bodyweight) as the sole ration for three weeks or until clinical signs of disease disappear.

**Treatment of porcine proliferative enteropathy:**

Feed 220 mg lincomycin/kg complete feed (equivalent to 11 mg lincomycin/kg bodyweight) as the sole ration for three weeks.

Medicated feed may be pelleted at temperatures not exceeding 85°C.

**Mode of Administration:** Usage: Mix with the feed

**Contraindications:** Do not use in case of hypersensitivity to the active substance or to any of the excipient. Do not use in horses, ruminants, rabbits, guinea pigs and hamsters. Do not use if resistance to lincosamides has been detected.

**Warnings and Precautions:** *Special precautions for use in animals*

Medicated feeding stuff uptake can be affected by the severity of the disease. In case of insufficient uptake of feed, animals should be treated parentally.

*Special precautions to be taken by the person administering the veterinary medicinal product to animals*

1. People with known hypersensitivity to lincomycin should avoid contact with the veterinary medicinal product.
2. Care should be taken not to inhale any dust. The wearing of approved dust masks gloves, overalls and safety glasses is recommended during the handling and mixing of this product.
3. Direct contact of the product with the skin, eyes and mucous membranes should be avoided.
4. In case of accidental exposure rinse abundantly with water. In case of allergic reaction (inflammation of the face, lips or eyes or respiratory difficulties) during handling or mixing of the product, seek medical advice immediately and show the package leaflet or the label to the physician.
5. Do not smoke, eat or drink when handling the product.
6. Wash hands and any exposed skin with soap and water immediately after use.

*Other precautions*

7. When spreading the manure of weaner pigs treated with the veterinary medicinal product at a dose of 10 mg/kg for 21 days, a minimum distance to surface water of 10 m should be applied.

**Interactions with Other Medicament:** Co-administration with macrolides (e.g. erythromycin) should be avoided.

**Statement on Usage during Pregnancy and Lactation:** None Known

**Adverse Effects/Undesirable Effects:** Lincomycin may occasionally cause transient soft stools and/or mild swelling of the anus within the first two days of treatment. Very rarely some pigs may show skin reddening and mildly irritable behaviour. These conditions are usually self-correcting within 5-8 days without discontinuing lincomycin treatment.

**Overdose and Treatment:** None Known

**Withdrawal Period(s):** Swine: Meat and offal: 5 days

**Storage Conditions:** Keep sealed and stored in cool and dry place below 25°C.

**Disposal of containers:** Unused material and packaging should be disposed of in accordance with all local and national legislation.

**Packaging available:** 1 kg packed into aluminium foil and 25 kg packed into drum.

**[Name and Address of manufacturer/marketing authorization holder]**

**Manufactured by:**

HINAPHARM PHARMACEUTICAL CO., LTD. FOSHAN

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**Marketing Authorization Holder:**

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