

HAN-LINSPEC Injectable Solution

HAN-LINSPEC Injectable Solution appears to be a clear, colorless to yellowish light solution.

Composition:

Each ml contains	
Lincomycin (as hydrochloride)	50 mg
Spectinomycin (as dihydrochloride pentahydrate)	100 mg
Benzyl alcohol (as preservative)	10mg

Pharmacodynamics:

This is a combination of lincomycin (belongs to the lincosamides) and spectinomycin (which is related to the aminoglycosides).

Mechanism: At normal dosage, both components have a bacteriostatic effect. Lincomycin: Lincomycin inhibits protein synthesis in sensitive organisms by binding to the 50-S ribosomal subunit and by inhibition of the peptidyl transferase enzyme. Many Gram negative bacteria are resistant due to their impermeability and methylation of the ribosome binding site. Spectinomycin: Spectinomycin also inhibits protein synthesis in susceptible organisms, but by binding to the 30-S subunit of ribosomes. The action is similar to that of the aminoglycosides, but spectinomycin does not erroneously overwrite the polyribonucleotides ("codon misreading") like the aminoglycosides. Spectinomycin works only under aerobic conditions.

Spectrum: The combination results in a broad-spectrum activity against various gram-positive and gram-negative bacteria, mycoplasmas and spirochetes of animal origin. Lincomycin is active against gram-positive bacteria, gram-positive and gram-negative anaerobes and Mycoplasmas. Spectinomycin is active against mycoplasmas and aerobic or facultative aero-anaerobic Gram-negative bacteria, although natural resistance frequently occurs in Gram-negative strains of bacilli. The following organisms in particular, which are mainly responsible for pathologies in pigs, may be sensitive to the action of lincomycin and / or spectinomycin: *Mycoplasma spp.*, *Streptococcus spp.*, *Arcanobacterium pyogenes*, *Erysipelothrix rhusiopathiae*. With regard to particularly *E.coli*, higher MIC values were noted, making oral treatment more appropriate.

Resistance: The incidence of lincomycin resistance can be high in some animal pathogens. In Belgian *Streptococcus suis* strains, 50% were shown to be resistant. A common mechanism of resistance is methylation of the binding site due to methylases transferred by plasmids. This mechanism is linked to cross resistance to macrolides and streptogramins B antibiotics. Enzymatic inactivation of lincomycin may occur due to plasmid-borne factors. A progressive chromosomal modification of the ribosome has also been described. Cross-resistance with clindamycin is common. One-step chromosomal resistance to spectinomycin can occur, such as with streptomycin, especially with *Staphylococcus spp.* Transmissible resistance involving inactivating enzymes has also been observed. Cross-resistance with true aminoglycosides is unlikely to occur. In *E. coli* the MIC distribution appears to be bimodal, with a significant number of strains showing high MIC values; this could partially correspond to the natural (intrinsic) resistance.

Pharmacokinetics:

Lincomycin:

Absorption and plasma concentrations: Lincomycin is rapidly and completely absorbed after IM injection. Maximum plasma concentrations are reached within 30 minutes.

Distribution: Lincomycin has a high lipid solubility and therefore has a high apparent volume of distribution. Tissue concentrations are usually (often several times) higher than plasma concentrations. After parenteral administration, the highest concentrations are found in the kidneys and lungs. Lincomycin has also been shown to remain in the lungs longer than suggested by plasma levels.

Excretion: After parenteral administration, lincomycin is mainly excreted via the liver, the rest via the urine. The elimination half-life is 2 to 3 hours.

Spectinomycin:

Absorption and plasma concentrations: Spectinomycin is also rapidly absorbed after IM injection. Maximum plasma concentrations are reached within 30 minutes.

Distribution: Spectinomycin has a low lipid solubility so that tissue concentrations are usually lower than the respective plasma concentrations. There is no accumulation of spectinomycin in any tissue (except the kidneys).

Excretion: After parenteral administration, spectinomycin is mainly excreted via the kidneys by glomerular filtration, therefore renal insufficiency may lead to

Contraindication:

Do not use in case of known hypersensitivity to the active substance or to any of the excipients. Do not administer at the same time as erythromycin, tylosin or tilmicosin (or other macrolides). Do not use in animal species other than pigs (lincomycin is particularly dangerous in rabbits, guinea pigs, hamsters, horses and ruminants).

Warning and Precautions:

Special warnings for each target species

See *Contraindications* and *Special precautions for use*. A significant proportion of *E. coli* strains exhibit high MICs (minimal inhibitory concentrations) against the lincomycin-spectinomycin combination and these strains may be clinically resistant, although no critical threshold is defined.

Special precautions for use

i) Special precautions for use in animals

Antimicrobial resistance selection is evolving in some pathogenic microorganisms; the use of the product should be based on susceptibility testing. Due to the nephrotoxicity of aminoglycosides, renal function should be monitored. Due to the limited safety margin of aminoglycosides, the dose should be reduced in overweight or dehydrated animals or in animals with impaired renal function. Use of the product deviating from the instructions given in the SPC may increase the incidence of bacteria resistant to the active ingredients and reduce the effectiveness of treatment with antimicrobial agents belonging to the same or related class.

ii) Special precautions to be taken by the person administering the product to the animals

Avoid any contact with the skin, eyes and mucous membranes. Be careful to avoid self-injection. Wash off any spills immediately. Do not eat or drink while using the product. Wash hands thoroughly after contact with the product.

Other precautions

The veterinary medicinal product is known to be toxic to terrestrial plants and cyanobacteria.

Interactions with Other Medicaments:

The combination with macrolides has an antagonistic effect in vitro. Do not administer at the same time with these veterinary medicinal products. General anesthetics and muscle relaxants potentiate the neuromuscular blocking effect of aminoglycosides, which can lead to acute paralysis and apnea.

Statement on Usage During Pregnancy and Lactation:

Laboratory studies using lincomycin in laboratory animals have shown evidence of foetotoxic effects, but at doses higher than recommended. Use only in accordance with the benefit / risk assessment made by the treating veterinarian.

Adverse Effects / Undesirable Effects:

Slight local irritation at the injection site may occur but disappears after a few days.

Spectinomycin can cause ototoxicity and nephrotoxicity.

Lincomycin can cause neuromuscular blockade and allergic reactions.

The frequency of adverse reactions is defined as follows:

- Very common (side effects in more than 1 animal out of 10 treated animals)
- Common (between 1 and 10 animals out of 100 treated animals)
- Uncommon (between 1 and 10 animals in 1000 treated animals)
- Rare (between 1 and 10 animals out of 10,000 treated animals)
- Very rare (less than one animal in 10,000 treated animals, including isolated cases).

Overdose and Treatment:

Very high doses could lead to neuromuscular block.

Withdrawal Period (s):

Meat and offal: 14 days.

Incompatibilities:

Mixing with other veterinary medicinal products may lead to possible incompatibilities. Do not mix other substances in the same syringe.

Storage Condition:

Store at 30°C. Protect from heat and sunlight exposure.

Keep medicine out of reach of children / Jauhkan obat dari kanak-kanak.

Unused veterinary medicinal products or residues thereof should be disposed of in accordance with local requirements.

Shelf life packaged for sale: 2 years.

accumulation. A biphasic elimination of spectinomycin was noted bringing the total elimination half-life to 39 hours.

Indications:

Pig: Treatment of mixed infections caused by bacteria sensitive to lincomycin and spectinomycin.

Administration and Dosage:

Pigs: solution for intramuscular injection

1 ml per 10 kg body weight (corresponding to 10 mg spectinomycin and 5 mg lincomycin per kg bw) for 3 to 7 days.

To ensure correct dosing and to avoid underdosing, body weight should be determined as accurately as possible.

Shelf-life after first opening: 28 days.

Packaging Available: 100 mL

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Manufacturer:

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