

For Veterinary Use Only

Active ingredient:

Each gram contains:

Lincomycin base (as Lincomycin Hydrochloride): 222mg

Spectinomycin base (as Spectinomycin Hydrochloride): 444.7mg

Product description:

An off white of buff color powder.

Pharmacodynamics:

The veterinary medicinal product is a combination of two antibiotics, lincomycin and spectinomycin, having a complementary spectrum of activity.

Lincomycin

Lincomycin is active against gram-positive bacteria, some anaerobic gram-negative bacteria and mycoplasmas. It has little or no action against gram-negative bacteria such as *Escherichia coli*.

Spectinomycin

Spectinomycin is an aminocyclitol antibiotic derived from *Streptomyces spectabilis*, it has bacteriostatic activity and is active against *Mycoplasma* spp. and against some gram-negative bacteria such as *E. coli*.

The mechanism by which spectinomycin administered orally acts on pathogens at the systemic level despite a poor absorption is not fully elucidated, and might rely partly on indirect effects on the gut flora.

In *E. coli* the MIC distribution appears to be bimodal, with a significant number of strains showing high MIC values; this could partly correspond to natural (intrinsic) resistance.

In vitro studies as well as clinical efficacy data show that the lincomycin-spectinomycin combination is active against *Lawsonia intracellularis*.

Due to technical constraints the susceptibility of *Lawsonia intracellularis* is difficult to test *in vitro*, and data about the resistance status in that species are lacking.

Pharmacokinetics:

Lincomycin

In chickens treated with the veterinary medicinal product in drinking water at the target dose of 50 mg/kg body weight of total activity (at a ratio of 1:2 lincomycin:spectinomycin) for seven consecutive days.

Spectinomycin

Studies performed in various animal species have demonstrated that spectinomycin undergoes limited absorption from the intestine (less than 4–7%) after oral administration. Spectinomycin exhibits little tendency to protein binding and is poorly liposoluble.

Indication:

Chickens

For the treatment and metaphylaxis of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to lincomycin and spectinomycin, and associated with a low mortality rate. The presence of the disease in the flock must be established before the product is used.

Contraindications:

Do not use in case of hypersensitivity to the active substances or any of the excipients. Do not use in case of hepatic dysfunction.

Do not allow rabbits, rodents (e.g. chinchillas, hamsters, guinea pigs), horses or ruminants to access to water or feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Do not use in laying hens.

Symptoms and treatment of overdose:

In chickens treated at several times the recommended dose, enlargement of the caecum and abnormal caecum content was observed.

In case of accidental overdose, the treatment should be interrupted and restarted at the recommended dose.

Recommended dose:

For use in drinking water.

The recommended dosage rates are:

Chickens: 16.65 mg lincomycin and 33.35 mg spectinomycin/kg bw/day, for 7 days. This amounts to 75 mg powder/kg bw/day for 7 days.

Treatment should be initiated as soon as first clinical signs occur.

For the preparation of drinking water, the incorporation rate of the veterinary medicinal product in water will depend on the body weight of the animals and their actual daily intake of water.

To ensure a correct dosage and avoid underdosing, mean body weights in the group of animals and daily water consumption should be determined as accurately as possible.

The medicated drinking water should be the sole source of drinking water for the treatment duration. Any medicated water which is not consumed within 24 hours should be discarded.

In case of disease accompanied with significant decrease in water intake, parenteral treatment may have to be initiated.

Use the following indications as a basis for the precise calculation of incorporation rate of the veterinary medicinal product in drinking water.

To determine the volume of dilution (in litres of drinking water) for 150 g of the veterinary medicinal product, use the following formula:

$$\text{Volume (L) for 150 g of the veterinary medicinal product} = \frac{2,000 \times [\text{daily water consumption per bird (L)}]}{\text{average body weight of one bird (kg)}}$$

150 g of the veterinary medicinal product corresponds to the dose for 2,000 kg of body weight per day.

Interaction with other medicaments:

In general mixture with other medicines should be avoided.

The combination of lincosamides and macrolides is antagonistic, due to competitive binding to their target sites. Combination with anaesthetics may lead to possible neuromuscular blocking.

Do not administer with kaolin or pectine as they impair lincomycin absorption. If co-administration is mandatory, respect a delay of two hours between intakes.

Pregnancy and lactation:

Do not use in birds in lay.

Side effects:

Cases of diarrhoea or soft faeces and/or perianal region inflammation have been encountered in healthy pigs at the start of treatment. The symptoms disappeared within 5 to 8 days without interruption of the treatment.

Rare cases of irritability/excitation, skin rash/pruritus were also observed.

Allergic/hypersensitive reactions are rare but can occur and require stopping treatment with the veterinary medicinal product. A symptomatic treatment must be implemented.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

Withdrawal period:

Meat and offal: 5 days.

Not authorised for use in birds producing eggs for human consumption, including replacement chicks which are intended to produce eggs for human consumption.

Animals must not be slaughtered for human consumption during treatment.

Warning and precautions:

Special warnings for each target species

In *E. coli*, a significant part of the strains show high MIC values (minimum inhibitory concentrations) against the lincomycin-spectinomycin combination and may be clinically resistant, although no breakpoint is defined.

Due to technical constraints the susceptibility of *L. intracellularis* is difficult to test *in vitro*, and data about the lincomycin-spectinomycin resistance status in that species are lacking.

Special precautions for use

Special precautions for use in animals

It is sound clinical practice to base treatment on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of target bacteria.

Use of the veterinary medicinal product deviating from the instructions may increase the risk of development and selection of resistant bacteria and decrease the effectiveness of treatment with macrolides due to the potential for cross-resistance.

The oral use of preparations containing lincomycin is only indicated in chickens. Do not leave access to the medicated water for other animals. Lincomycin may lead to severe gastrointestinal disturbances in other animal species.

The repeated or prolonged use should be avoided, by improving the farm management and disinfection practices.

Diagnosis should be reconsidered if improvement is not seen after 5 days.

Sick animals have a reduced appetite and an altered drinking pattern, and severely affected animals may therefore require parenteral treatment.

This powder is for use in drinking water only and should be dissolved before use.

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

People with known hypersensitivity to lincomycin, spectinomycin or soybean millfeed should avoid contact with the veterinary medicinal product. Care should be taken not to raise and inhale any dust.

Contact with skin and eyes should be avoided.

Personal protective equipment consisting of approved dust masks (either a disposable half mask respirator or a non-disposable respirator), gloves and safety glasses should be worn when handling and mixing the product.

Wash hands and any exposed skin with soap and water immediately after use. If symptoms such as skin rash or persistent eye irritation appear after exposure, seek medical advice immediately and show the package leaflet or label to the physician.

Shelf life and storage condition:

Shelf life: 36 months

Shelf life after first opening of container: 7 days

Shelf life after reconstitution/dilution: 24 hours

Store below 30°C.

Packaging: 150g aluminium pouch

Manufacturer: Nam Pharma Sdn Bhd

5, Lebuhr Perumahan Klebang 11,
Taman Perindustrian Antarabangsa IGB,
31200 Chemor, Perak.

Marketing Authorization Holder: F.E Venture Sdn Bhd

Lot 3 & 5, Jalan PJS 11/8,
Bandar Sunway, 46150 Petaling Jaya,
Selangor, Malaysia