

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lismay 444.7 mg/g + 222.0 mg/g powder for use in drinking water for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances

Spectinomycin444.7 mg
(equivalent to 672.4 mg of spectinomycin sulfate tetrahydrate)

Lincomycin222.0 mg
(equivalent to 251.7 mg of lincomycin hydrochloride)

Excipients

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium Benzoate (E-211)	10.67 mg
Lactose monohydrate	

Whitish powder

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

For the treatment and metaphylaxis of porcine proliferative enteropathy (ileitis) caused by *Lawsonia intracellularis* and associated enteric pathogens (*Escherichia coli*) susceptible to lincomycin and spectinomycin.

The presence of the disease in the group must be established before the product is used.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients. Do not use in known cases of hepatic dysfunction. Do not allow rabbits or rodents (eg chinchillas, hamsters, guinea pigs), horses or ruminants to access to water or feed containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

3.4 Special warnings

In *E. coli*, a significant part of the strains show high MIC values (minimum inhibitory concentrations) against the lincomycin and 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 lincomycin -spectinomycin resistance status in that species are lacking.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 in the SPC 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 swine. 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. Wash hands and any exposed skin with soap and water immediately after use.

Personal protective equipment consisting of approved dust masks (either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN 140 with a filter EN 143), gloves and safety glasses should be worn when handling and mixing the veterinary medicinal product.

In case of accidental spillage onto skin or persistent eye irritation, seek medical advice immediately and show the package leaflet or label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Rare (1 to 10 animals / 10 000 animals treated):	Allergic reaction ¹ , hypersensitive reaction ¹ Irritability, excitation Rash, pruritus
Undetermined frequency (cannot be estimated from the available data)	Diarrhoea or soft faeces ² , perianal inflammation ²

¹ Treatment with the veterinary medicinal product should be stopped, and symptomatic treatment must be implemented

² In healthy pigs at the start of treatment. The symptoms disappeared within 5 to 8 days without interruption of the treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation

holder or its local representative or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Laboratory studies in dogs and rats have not produced any evidence of reproductive, foetotoxic or teratogenic effects for lincomycin or spectinomycin.

Lincomycin is excreted in milk.

Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

In drinking water use.

The recommended dosage rates are: 3.33 mg lincomycin and 6.67 mg spectinomycin/kg bw/day, for 7 days. This amounts to 15 mg powder/kg bw/day for 7 days.

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

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of lincomycin and spectinomycin may need to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{mg of veterinary medicinal product} \times \text{average bodyweight (kg)}}{\text{/kg bodyweight/day} \times \text{Average daily water intake (L/ animal)}} \times \text{of animals to be treated} = \text{mg of veterinary medicinal product per litre of drinking water}$$

In pigs 150 g of the veterinary medicinal product corresponds to the dose for 10,000 kg of body weight per day.

As an indication, standard water intake varies around 0.15 L/kg bw/day. The table below shows the volume of water to be used for dilution of 150 g of the veterinary medicinal product.

Water consumption	150 g of powder = 100 g antibiotic activity should be diluted in...
0.1 L/kg bw/day	1,000 L of drinking water
0.15 L/kg bw/day	1,500 L of drinking water
0.2 L/kg bw/day	2,000 L of drinking water
0.25 L/kg bw/day	2,500 L of drinking water

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.

Sufficient medicated drinking water should be prepared to cover only the daily requirements.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In the event of overdose, a change in the consistency of the faeces (soft faeces and/or diarrhoea) may be observed.

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.

Animals must not be slaughtered for human consumption during treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QJ01FF52.

4.2 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.

4.3 Pharmacokinetics

Lincomycin

In pigs, lincomycin is rapidly absorbed following oral administration. A single oral administration of lincomycin hydrochloride, at dose levels of approximately 22, 55 and 100 mg/kg body weight in pigs, resulted in dose related lincomycin serum levels, detected for 24–36 hours after administration. Peak serum levels were observed at 4 hours after dosing. Similar results were observed following single oral

doses of 4.4 and 11.0 mg/kg body weight in pigs. Levels were detectable for 12 to 16 hours, with peak concentrations occurring at 4 hours. A single oral dose of 10 mg/kg body weight was administered to pigs to determine the bioavailability. The oral absorption of lincomycin was found to be $53\% \pm 19\%$. Repeated dosing of pigs with daily oral doses of 22 mg lincomycin/kg body weight for 3 days indicated no accumulation of lincomycin in the species, with no detectable serum levels of antibiotic after 24 hours post administration.

Lincomycin pharmacokinetic studies in pigs show that lincomycin is bioavailable when given intravenously, intramuscularly or orally. The average of the half-lives of elimination of all routes of administration is 2.82 hours in pigs.

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.

Environmental properties

Lincomycin is toxic for terrestrial plant species including crop species such as Cruciferous vegetables (*Brassicaceae*), and for aquatic organisms such as, cyanobacteria.

Although spectinomycin is not persistent in the environment, some degradation products produced in the environment from spectinomycin might be classified as persistent or very persistent.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 6 months

Shelf life after dissolution according to directions: 24 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions

5.4 Nature and composition of immediate packaging

Triple complex film formed by a polyester film, an aluminum film and a sheet of low density polyethylene joined by a polyurethane base adhesive. The sealing is performed by thermal system.

Package sizes:

Bag of 150 g

Bag of 1.5 kg

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as lincomycin may be dangerous for fish and other aquatic organisms (such as cyanobacteria). Do not contaminate surface waters or ditches with the veterinary medicinal product or used container, to avoid adverse effects on aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Maymó, S.A.U.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10436/004/001

8. DATE OF FIRST AUTHORISATION

06/03/2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/02/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).