1.B.2 LABELLING AND PACKAGE LEAFLET

COMBINED LABEL-LEAFLET FOR 150 g and 1.5 Kg PACKAGE SIZES:

Lismay 444.7 mg/g + 222.0 mg/g powder for use in drinking water [AT, CZ, DK, HU, ES, NL, PL, PT, RO, SK,]
Lismay 444.7 mg/g + 222.0 mg/g powder for use in drinking water for pigs [IE, IT]

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder and Manufacturer responsible for batch release:
Laboratorios Maymó, S.A.
Vía Augusta, 302
08017 Barcelona (Spain)

2. Name of the veterinary medicinal product

Lismay 444.7 mg/g + 222.0 mg/g powder for use in drinking water [AT, CZ, DK, ES, HU, NL, PL, PT, RO, SK,]
Lismay 444.7 mg/g + 222.0 mg/g powder for use in drinking water for pigs [IE, IT]

Spectinomycin (as spectinomycin sulfate tetrahydrate)
Lincomycin (as lincomycin hydrochloride

3. Statement of the active substance and other ingredients

Each g contains:
Active Substance
Spectinomycin (as spectinomycin sulfate tetrahydrate) ……444.7 mg
Lincomycin (as lincomycin hydrochloride) ……...222.0 mg
Excipients
Sodium Benzoate (E-211)……..…. 10.67 mg
Whitish powder

4. Pharmaceutical form

Powder for use in drinking water

5. Package size

Bag of 150 g and 1.5 kg

6. Indication (s)

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.

7. Contraindications

Do not use in known cases of hypersensitivity to the active substances or 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

8. Adverse reactions

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}

9. Target species

Pigs

10. Dosage for each species, route(s) and method of administration

For use in drinking water.

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.

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.
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.

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) required for 150 g of the veterinary medicinal product, use the following formula:

$$\text{Volume (L) for 150 g of the veterinary medicinal product} = \frac{10{,}000 \times [\text{daily water consumption per animal (L)}]}{\text{Average body weight of one pig (kg)}}$$

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

11. Advice on correct administration

12. Withdrawal period(s)

Meat and offal: Zero days.
Animals must not be slaughtered for human consumption during treatment.

13. Special storage precautions

This veterinary medicinal product does not require any special storage conditions.

14. Special warnings

<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 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 -spectinomaycin resistance status in that species are lacking.

<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 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.
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 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.

<Pregnancy and lactation>:
The safety of the veterinary medicinal product has not been established during 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 in accordance with the benefit-risk assessment by the responsible veterinarian.

<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.

<Overdose (symptoms, emergency procedures, 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.

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

15. Special precautions for the disposal of unused product or waste materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Lincomycin is toxic for 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.

16. Date on which the label was last approved

MM/YYYY

<17. Other information>

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.

Package sizes:
Bag of 150 g
Bag of 1.5 kg

Not all pack sizes may be marketed

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

19. The words "Keep out of the sight and reach of children

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

Once opened use by:…….
Shelf life after first opening the container: 6 months.
Shelf life after dissolution according to directions: 24 hours
Medicated drinking water should be refreshed or replaced every 24 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

21. Marketing Authorisation Number

XXXXX

22. Manufacturer's batch number

Lot {number}