1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Linco-Spectin 100, 222/444.7 mg/g powder for use in drinking water for pigs and chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:

Lincomycin (as lincomycin hydrochloride)	222 mg
Spectinomycin (as spectinomycin sulphate)	444.7 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium benzoate
Lactose

White pale powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs and chickens.

3.2 Indications for use for each target species

Pigs:
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 veterinary medicinal product is used.

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 veterinary medicinal 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 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.

3.4 Special warnings

In *Escherichia 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 *Lawsonia intracellularis is* difficult to test *in vitro*, and data about the 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 and 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 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.
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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

Rare	Allergic reaction[1], Hypersensitivity reaction[1]

(1 to 10 animals / 10,000 animals treated):	

[1]Require stopping treatment with the veterinary medicinal product. Symptomatic treatment must be implemented.

Pigs:

Very common (>1 animal / 10 animals treated):	Diarrhoea[1], Loose stool[1] Skin inflammation[1,2]
Rare (1 to 10 animals / 10,000 animals treated):	Excitation, Irritability Allergic reaction[3], Hypersensitivity reaction[3] Pruritus, Rash

[1]Usually self-correcting within 5-8 days without discontinuing the treatment.
[2]Affecting perianal region.
[3]Require stopping treatment with the veterinary medicinal product. Symptomatic treatment must be implemented.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Pigs:
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 accordingly to benefit-risk assessment by the responsible veterinarian.

Laying birds:

Chickens:
Do not use in birds in lay.

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 pectin as they impair lincomycin absorption. If co-administration is mandatory, respect a delay of two hours between intakes.

3.9 Administration routes and dosage

For use in drinking water.

The recommended dosage rates are:

Pigs: 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.

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

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:

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

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 dissolution of 150 g of the veterinary medicinal product.

Water consumption	150 g of powder = 100 g antibiotic activity should be dissolved 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

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.

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

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:

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

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.

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

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

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

Pigs:
Meat and offal: Zero days.
Chickens:
Meat and offal: 5 days.

Not for use in birds producing or intended to produce eggs for human consumption.

4. PHARMACOLOGICALINFORMATION

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 *Escherichia 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 *Escherichia 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% ± 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.

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, C_{max} after first offering of medicated water was calculated to be 0.0631 µg/ml. C_{max} occurred at 4 hours after introduction of the medicated water.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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: 5 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

White high density polyethylene (HDPE) bottle containing 1.5 kg powder for use in drinking water with a white tamper evident low density polyethylene (LDPE) lid.

White high density polyethylene (HDPE) bottle containing 150 g powder for use in drinking water with a white tamper evident low density polyethylene (LDPE) lid with an aluminium cap.

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.

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

Phibro Animal Health (Poland) Sp. z o.o.

7. MARKETING AUTHORISATION NUMBER

VPA25497/004/001

8. DATE OF FIRST AUTHORISATION

01/10/2003

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

29/08/2025

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).