SUMMARY OF PRODUCT CHARACTERISTICS

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 gram contains:

Active substances:

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

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
White pale powder

4. CLINICAL PARTICULARS

4.1 Target species

Pigs and chickens.

4.2 Indications for use, specifying the 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 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 product is used.

4.3 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.

4.4 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.

4.5 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

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 treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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.

Chickens
Do not use in birds in lay.

4.8 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.

4.9 Amounts to be administered and administration route

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.
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.

Pigs:

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

Chickens:

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

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.

Animals must not be slaughtered for human consumption during treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, lincomycin combinations.
ATCvet code: QJ01FF52.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate
Lactose

6.2 Major incompatibilities

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

6.3 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 dilution according to directions: 24 hours.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions

6.5 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.

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

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

7. MARKETING AUTHORISATION HOLDER

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 43877/4001

9. DATE OF FIRST AUTHORISATION

24 June 2015

10. DATE OF REVISION OF THE TEXT

January 2021

Approved 08 January 2021