SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lincocin Soluble Powder, 400 mg/g powder for use in drinking water for pigs and chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Lincomycin (as lincomycin hydrochloride) 400 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
White, free-flowing, fine powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs and chickens.

4.2 Indications for use, specifying the target species

Pigs:
Treatment and metaphylaxis of enzootic pneumonia caused by *Mycoplasma hyopneumoniae*.
The presence of the disease in the group must be established before the product is used.

Chickens:
Treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens*.
The presence of the disease in the group must be established before the product is used.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer, and do not allow access to water containing lincomycin, to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants as this could result in severe gastro-intestinal disturbance.
Do not use in cases of known resistance to lincosamides.
Do not use in cases of hepatic dysfunction.

4.4 Special warnings for each target species

Medicated drinking water uptake can be affected by the severity of the disease. In case of insufficient uptake of water, pigs should be treated parenterally.

The susceptibility of *Mycoplasma hyopneumoniae* to antimicrobial agents is difficult to test *in vitro* owing to technical constraints. In addition, there is a lack of clinical breakpoints for both *M. hyopneumoniae* and *C. perfringens*. Where possible, therapy should be based on local (regional, farm level) epidemiological information concerning the response of enzootic pneumonia/necrotic enteritis to treatment with lincomycin.

4.5 Special precautions for use

Special precautions for use in animals

Use of the veterinary medicinal product preferably should be based on identification of the target pathogen and susceptibility testing of the bacteria isolated from the animal. See also the above special warnings for each target species.
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal product deviating from the instructions given in the summary of product characteristics may increase the prevalence of bacteria resistant to the lincomycin and may decrease the effectiveness of treatment with other lincosamides, macrolides and streptogramin B due to the potential for cross-resistance.
Repeated or prolonged use should be avoided by improving the farm management and hygiene practices.

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

This product contains lincomycin and lactose monohydrate, either of which can cause allergic reactions in some people. People with known hypersensitivity to lincomycin or any other lincosamide, or to lactose monohydrate, 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 EN140 with a filter EN143), gloves and safety glasses should be worn when handling and mixing the product. If respiratory symptoms develop following exposure, seek medical advice and show this warning to the physician.
In case of accidental exposure to the skin, eyes or mucous membranes, wash the affected area thoroughly with plenty of water. 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.
Wash hands and any exposed skin with soap and water immediately after use.
Do not eat, drink or smoke while handling the product.

Special precautions for the protection of the environment

None.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Chickens:

None known.

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Irritability[1,2] Diarrhoea[3] Hypersensitivity reaction, Anal oedema (swelling)[2,3] Reddening of the skin[1]

[1] Usually self-correcting within 5-8 days without discontinuing the lincomycin treatment.
[2] Mild.
[3] Within the first 2 days after onset of 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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay.

Laboratory studies in rats have not produced any evidence of teratogenic effects, although foetotoxicity has been reported. Use only according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Antagonism may exist between lincomycin and macrolides such as erythromycin and other bactericidal antibiotics; concurrent use is therefore not recommended due to competitive binding at the 50S ribosomal subunit of the bacterial cell.
The bioavailability of lincomycin may decrease in the presence of gastric antacids or activated charcoal, pectin or kaolin.
Lincomycin can potentiate neuromuscular effects of anaesthetics and muscle relaxants.

4.9 Amount(s) to be administered and administration route

For use in drinking water.

Dosing guidance and recommended doses:
To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake of medicated water depends on the physiological and clinical condition of the animals. In order to obtain the correct dosage, the concentration of the lincomycin has to be adjusted accordingly.
The uptake of water should be monitored frequently.
The medicated water should be the only source of drinking water for the animals for the entire duration of the treatment period.
After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

Dosage:

Pigs:
Enzootic pneumonia: 10 mg lincomycin per kg of body weight (corresponding to 25 mg product per kg bodyweight) for 21 consecutive days.

Chickens:
Necrotic enteritis: 5 mg lincomycin per kg of body weight (corresponding to 12.5 mg product per kg bodyweight) for 7 consecutive days.

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:

$$\frac{\text{Dosage (mg product per kg body weight per day)} \times \text{Mean body weight (kg) of animals to be treated}}{\text{Average daily water intake (litre/animal)}} = \text{mg product per litre drinking water}$$

The use of suitably calibrated weighing equipment is recommended if part packs are used. The daily amount is to be added to the drinking water in such a way that all medication will be consumed within 24 hours. Medicated drinking water should be freshly prepared every 24 hours. No other source of drinking water should be available.

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

A dosage greater than 10 mg lincomycin per kg of body weight may cause diarrhoea and loose stools in pigs.
In case of accidental overdose, the treatment must be stopped and restarted at the recommended dose level.
There is no specific antidote, treatment is symptomatic.

4.11 Withdrawal period(s)

Pigs:
Meat and offal: 1 day.

Chickens:
Meat and offal: 5 days.
Not for use in birds producing or intended to produce eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Lincosamides.

ATCvet code: QJ01FF02

5.1 Pharmacodynamic properties

Lincomycin is a lincosamide antibiotic derived from *Streptomyces lincolnensis* which inhibits protein synthesis. Lincomycin binds to the 50S sub-unit of the bacterial ribosome close to the peptidyl transfer centre and interferes with the peptide chain elongation process by causing premature peptidyl-tRNA dissociation from the ribosome.
Lincomycin is active against some gram-negative bacteria (*Clostridium perfringens*) and mycoplasmas (*Mycoplasma hyopneumoniae*).
While the lincosamides are generally considered to be bacteriostatic agents, the activity depends on the sensitivity of the organism and concentration of the antibiotic. Lincomycin may be either bactericidal or bacteriostatic.
Resistance to lincomycin is frequently conferred by plasmid-borne factors (*erm* genes) coding for methylases modifying the ribosomal binding site and frequently leading to cross-resistance to other antimicrobials of the macrolides, lincosamides and streptogramins group. However, the most prevalent mechanism in mycoplasmas is the alteration of the binding site through mutational events (chromosomal resistance). Lincomycin resistance mediated by efflux pumps, or by inactivating enzymes, has also been described. There is often complete cross-resistance between lincomycin and clindamycin.

5.2 Pharmacokinetic particulars

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.

Crossing the intestinal barrier, lincomycin is widely distributed to all tissues, especially the lungs and joint cavities; the volume of distribution is about 1 litre. The elimination half-life of lincomycin is greater than 3 hours. Approximately 50% of lincomycin is metabolised in the liver. Lincomycin undergoes enterohepatic circulation. Lincomycin is eliminated unchanged or in the form of various metabolites in bile and urine. High concentrations of the active form are observed in the intestine.

Chickens were administered lincomycin hydrochloride in the drinking water at a level of approximately 34 mg/litre (5.1-6.6 mg/kg body weight) for seven days. Metabolites comprised more than 75% of total residues in the liver. Unmetabolised lincomycin declined at a slightly faster half-life ($t_{½}$ = 5.8 hours) than total residue. Lincomycin and one unknown metabolite comprised >50% of the muscle residue at zero hours. The excreta contained mostly unmetabolised lincomycin (60-85%) during treatment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica
Lactose monohydrate

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

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: use immediately.
Shelf life after dilution or reconstitution 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

Medicines should not be disposed of via wastewater.

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

7. MARKETING AUTHORISATION HOLDER

Phibro Animal Health (Poland) Sp z.o.o.
ul. Towarowa 28
00-839 Warsaw
Poland

8. MARKETING AUTHORISATION NUMBER

Vm 61652/5001

9. DATE OF FIRST AUTHORISATION

21 January 1993

10. DATE OF REVISION OF THE TEXT

November 2025

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 16 January 2026