## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OCNIL 400 mg/g powder for use in drinking water

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

**Active substances:**
Lincomycin 400 mg
(equivalent to 450 mg of lincomycin hydrochloride)

**Excipients:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Silica colloidal anhydrous |
| Lactose monohydrate |

White powder without lumps.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs and chickens.

### 3.2 Indications for use for each 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.

### 3.3 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 gastrointestinal disturbances.
Do not use in cases of resistance to lincosamides.
Do not use in cases of hepatic dysfunction.

### 3.4 Special warnings

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

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

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. However, also see text under section 3.4.
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 SPC may increase the prevalence of bacteria resistant to lincomycin and may decrease the effectiveness of treatment with other lincosamides, macrolides or streptogramin B due to 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 veterinary medicinal 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 EN 149 or a non-disposable respirator conforming to European Standard EN 140 with a filter to EN 143), gloves and safety glasses should be worn when handling and mixing the veterinary medicinal 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:

Lincomycin is known to be toxic to terrestrial plants, cyanobacteria and groundwater bacteria.

### 3.6 Adverse events

Pigs:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10 000 animals treated): | Diarrhoea[1]<br>Soft stool[1]<br>Anal swelling[1]<br>Reddening of the skin[2]<br>Irritability[2]<br>Allergic reaction<br>Hypersensitivity reaction |

[1] Mild, within the first 2 days after onset of treatment.
[2] These conditions are usually mild and self-correcting within 5-8 days without discontinuing the lincomycin treatment.

Chickens:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10 000 animals treated): | Allergic reaction<br>Hypersensitivity reaction |

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, lactation or lay in the target species.

Pregnancy:

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

### 3.8 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 anaesthetic and muscle relaxants.

### 3.9 Administration routes and dosage

In drinking water use
To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of the lincomycin (lincomycin hydrochloride) may need to be adjusted accordingly.
The use of suitably calibrated measuring equipment is recommended.
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 of lincomycin per kg body weight (corresponding to 12.5 mg product per kg body weight) 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

| | | | |
|---|---|---|---|
| mg veterinary medicinal product/ kg body weight per day | X | average body weight (kg) of animals to be treated | = mg veterinary medicinal product per litre of drinking water |
| average daily water intake (l/animal) | | | |

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.
The maximum solubility of finished product is 50 g/l in soft and hard water. For stock solutions and when using a dosing pump, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

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

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.

### 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: 1 day.

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

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:

QJ01FF02

### 4.2 Pharmacodynamics

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-positive 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.

### 4.3 Pharmacokinetics

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 ($t½$ = 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.

## 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: 3 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

Thermosealed bags made of polypropylene/metallized polyester/low density polyethylene, with the polyethylene layer being in direct contact with the product.

Pack sizes:
Bag of 150 g
Bag of 1 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 (cyanobacteria). Do not contaminate surface waters or ditches with product or used container.

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

VETPHARMA ANIMAL HEALTH, S.L.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10516/015/001

## 8. DATE OF FIRST AUTHORISATION

28/07/2017

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

20/10/2026

## 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*).