

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

OCNIL 400 mg/g powder for use in drinking water

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Lincomycin 400 mg
(equivalent to 450 mg of lincomycin hydrochloride)

Excipients:

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for use in drinking water.

White powder without lumps.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (broilers).

4.2 Indications for use, specifying the target species

Chickens (broilers): Treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

The presence of the disease in the group must be established before the product is used.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not administer the product to hamsters, rabbits, guinea-pigs, chinchillas, horses or ruminants, and do not allow these species to access the product, since it can cause severe gastrointestinal disturbances.

4.4 Special warnings for each target species

As an adjunct to treatment, good management and hygiene practices should be introduced in order to reduce the risk of infection.

Medicated drinking water uptake can be affected by the severity of the disease.

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based 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 the target bacteria. Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the 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 streptogramins due to potential for cross-resistance.

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

This product contains lincomycin, which can cause allergic reactions in some people. People with known hypersensitivity (allergy) to lincomycin or any other lincosamide 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), impervious gloves and safety glasses should be worn when handling and mixing the product.

In case of accidental exposure to the skin, eyes or mucous membranes, wash the affected area thoroughly with plenty of water.

In case of allergic reaction (inflammation of the face, lips or eyes, or respiratory difficulties), or persistent eye irritation occurring 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.

Other precautions

Lincomycin is known to be toxic to terrestrial plants and cyanobacteria.

4.6 Adverse reactions (frequency and seriousness)

Not described.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of teratogenic effects.

4.8 Interaction with other medicinal products and other forms of interaction

Antagonism may exist between lincomycin and other antibiotics that act by binding to the 50S ribosomal subunit, e.g. macrolides.

Lincomycin may potentiate the neuromuscular effects of anaesthetic and myorelaxant products.

The bioavailability of lincomycin may decrease in the presence of gastric antacids, activated charcoal, pectin or kaolin.

4.9 Amounts to be administered and administration route

Administration in drinking water. Medicated water should be refreshed every 24 hours.

Chickens (broilers): 3 – 6 mg of lincomycin per kg body weight per day (equivalent to 7.5 – 15 mg product/kg body weight/ day) for 7 consecutive days.

Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of the veterinary product should be calculated according to the following formula:

$$\frac{\text{Dose (mg product per kg body weight per day)} \times \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (litre) per animal per day}} = \text{___ mg product per litre drinking water}$$

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

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.

For accurate dosing, use a suitably calibrated measuring device.

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.

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

In chickens, no effects were observed following administration of five times the recommended dose over a 21 day period.

4.11 Withdrawal period(s)

Meat: 5 days

Eggs: Not authorised for use in laying birds producing eggs for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use, Lincosamides.

ATC Vet Code: QJ01FF02

5.1 Pharmacodynamic properties

Lincomycin is a lincosamide antibiotic and mainly has activity against aerobic Gram-positive bacteria. Lincomycin is also active against some anaerobic bacterial species.

Depending on the susceptibility of the organism and the antibiotic concentration, lincomycin may act as a bactericidal or bacteriostatic agent. Lincomycin acts by

binding to the 50S ribosomal subunit of susceptible bacteria, thereby inhibiting peptide bond formation and protein synthesis. Lincosamides have the same binding site as macrolides and streptogramins B.

Lincomycin is active against anaerobic microorganisms such as *Clostridium perfringens*.

The most common resistance mechanism is a target site modification mediated by different rRNA methylases (*erm* genes). A post-transcriptional modification of the 23S rRNA by adenine-methyl-transferases (methylases) occurs. This modification reduces the binding of the antimicrobials to the ribosomal target site. These genes can be horizontally transferred. Transfer of different *erm* and *mef* genes carried on a plasmid or in a transposon together with other resistance determinants has been shown between strains of *Clostridium* species.

5.2 Pharmacokinetic properties

Both parent compound and metabolites are excreted in bile and subsequently eliminated via the faeces.

5.3 Environmental properties

Lincomycin is known to be toxic to terrestrial plants and cyanobacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica colloidal anhydrous
Lactose monohydrate

6.2 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: 3 years.
Shelf-life after first opening the immediate packaging: 6 months.
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

Thermosealed bags made of polypropylene/metallized polyester/low density polyethylene.

Pack size:

Bag of 1kg

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

Dangerous for organism of pure water (cyanobacteria). Do not contaminate surface waters or ditches with product or used container.

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

Vetpharma Animal Health, S.L.
Les Corts, 23
08028 Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10516/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th July 2017

10 DATE OF REVISION OF THE TEXT