Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

LINCOPHAR 400 mg/ml solution for use in drinking water for chickens

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Lincomycin (as hydrochloride monohydrate) 400 mg

Excipients:
Benzyl alcohol (E1519) 10.0 mg
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for use in drinking water.
Colourless to yellow clear solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens

4.2 Indications for use, specifying the target species

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 known 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 case 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.

There is a lack of clinical breakpoints for *C. perfringens*. Where possible, therapy should be based on local (regional, farm level) epidemiological information concerning the response of necrotic enteritis to treatment with lincomycin.

4.5 Special precautions for use

Special precautions for use in animals
Use of the veterinary medicinal product should be based on idenfication of the target pathogen(s) and on epidemiological information and knowledge of suceptiliity of the target bacteria at farm level, or at local/regional level. However, also see text under section 4.4. 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 summary of product characteristics (SPC) 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, which can cause allergic reactions in some people.
People with known hypersensitivity (allergy) to lincomycin or any other lincosamide or to any of the excipients should avoid contact with the veterinary medicinal product.
Contact with skin and eyes should be avoided.
Personal protective equipment consisting of impervious gloves should be worn when handling 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)

None described.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of teratogenic effects, although foetotoxicity has been reported. The safety of the veterinary medicinal product has not been established during lay in the target species.

4.8 Interaction with other medicinal products and other forms of interactions

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 anaethetics and muscle relaxants.

4.9 Amounts 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 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.

Dosage:

Chickens:
Necrotic enteritis: 5 mg lincomycin per kg of bodyweight per day (corresponding to 1.25 ml product/100 kg bodyweight/day) for 7 consecutive days.

Administration:

To be administered orally, in the drinking water.
The concentration to be used depends on the actual body weight and the water

consumption of the animals and can be calculated according to the following formula:

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

The use of suitably calibrated 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

In the 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)

Chickens: Meat and offal: 5 days.
Not authorised for use in laying birds producing eggs for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial 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 if 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 (*Clostridium perfringens*).
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. 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

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.

Environmental properties

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium hydroxide (for pH adjustment)
Purified water

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: 3 years
Shelf life after first opening the immediate packaging: 3 months
Shelf life after reconstitution according to directions: 24 hours

6.4 Special precautions for storage

Keep the bottle and barrel tightly closed.

6.5 Nature and composition of immediate packaging

Nature of the container
White opaque high density polyethylene bottle with transparent graduated scale closed with white opaque low density polyethylene screw-cap and white polyethylene tamper-evident ring (1 L).
White opaque high density polyethylene barrel, closed with white opaque high density polyethylene screw-cap and a white polyethylene tamper-evident ring (5 L).
Polypropylene measuring device is included in the packaging size of 1 L.

Pack sizes
Box with 1 bottle of 1 L
Barrel of 5 L
Not all pack sizes may be marketed

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

Dangerous for organisms of pure water (as 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

Ecuphar Veterinaria S.L.U.
Avenida Rio de Janeiro 60 - 66
Planta 13
08016 Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10389/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th September 2017

10 DATE OF REVISION OF THE TEXT

August 2018