PARTICULARS TO APPEAR ON THE COMBINED LABEL/ LEAFLET

150 g Bag

1 kg Bag

OCNIL 400 mg/g powder for use in drinking water *(ES, CY, EL, IE, IT, PT, UK, HU)*

DOPHALIN 400 mg/g powder for use in drinking water *(AT, EE, FR, LT, LV, RO, PL)*

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Marketing authorisation holder:

VETPHARMA ANIMAL HEALTH, S.L

Les Corts, 23

08028 Barcelona

SPAIN

Manufacturer responsible for batch release:

MEVET S.A.U

Pol. Ind. El Segre, p.409-410

25191 Lleida

SPAIN

Distributed by:

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

OCNIL 400 mg/g powder for use in drinking water *(ES, CY, EL, IE, IT, PT, UK, HU)*

DOPHALIN 400 mg/g powder for use in drinking water *(AT, EE, FR, LT, LV, RO, PL)*

Lincomycin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT(S)

Each gram contains:

Active substance:

Lincomycin.....400 mg

(equivalent to 450 mg of lincomycin hydrochloride)

4. PHARMACEUTICAL FORM

Powder for use in drinking water

White powder without lumps.

5. PACKAGE SIZE

150 g

1 kg

6. INDICATIONS

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* susceptible to lincomycin.

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

7. 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 cases of known resistance to lincosamides.

Do not use in cases of hepatic dysfunction.

8. ADVERSE REACTIONS

On rare occasions, pigs given lincomycin-medicated water may develop diarrhoea/soft stools and/or mild swelling of the anus within the first 2 days after onset of treatment. On rare occasions some pigs may show reddening of the skin and mild irritable behaviour. These conditions are usually self-correcting within 5-8 days without discontinuing the lincomycin treatment. Allergic/hypersensitive reactions occur on rare occasions.

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).

If you notice any serious effects or other effects not mentioned in this label-leaflet, please inform your veterinary surgeon.

9. TARGET SPECIES

Pigs and Chickens.

10. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For use in drinking water.

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

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:

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

11. ADVICE ON CORRECT ADMINISTRATION

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.

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.

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.

12. WITHDRAWAL PERIOD

Pigs

Meat and offal: 1 day.

Chickens

Meat and offal: 5 days

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

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the bag after "EXP". The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 6 months
Once opened, use by...
Shelf life after dilution or reconstitution according to directions: 24 hours

14. SPECIAL WARNINGS

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

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. However, also see text under section *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 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 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 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.

Other precautions

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

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 pregnancy, lactation or lay in the target species. Use only according to the benefit-risk assessment by the responsible veterinarian.

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 the neuromuscular effects of anaesthetic and muscle relaxants.

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.

Incompatibilities

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

15. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dangerous to aquatic life (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.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

17. OTHER INFORMATION

Bag of 150 g or 1 Kg.

Not all pack sizes may be marketed.

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

To be supplied only on veterinary prescription.

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

20. EXPIRY DATE

EXP {month/year}

21. MARKETING AUTHORISATION NUMBER(S)

22. MANUFACTURER'S BATCH NUMBER

Lot {number}