MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

250 ml, 500 ml, 1 litre, 2 litres and 5 litres bottles.

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

Marketing Authorisation Holder: Ceva Animal Health Ltd, Unit 3, Anglo Office Park White Lion Road, Amersham, Bucks, HP7 9FB, UK
Manufacturer responsible for batch release: Ceva Sante Animale,Zone Industrielle de Tres-le-Bois, 22600 Loudeac, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Coliscour oral solution of colistin sulphate 2MIU/ml

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

1 ml contains: 2 MIU colistin (as colistin sulphate). 10 mg benzyl alcohol (E1519)

4. PHARMACEUTICAL FORM

Solution for use in drinking water

5. PACKAGE SIZE

250 ml, 500 ml, 1 litre, 2 litres or 5 litres.

6. INDICATION(S)

Treatment and metaphylaxis of gastrointestinal infections caused by noninvasive *E. coli* susceptible to colistin. The presence of the disease in the herd should be established before metaphylactic treatment.

7. CONTRAINDICATIONS

Do not use in horses, particularly in foals, since colistin, due to a shift in the gastrointestinal microflora balance could lead to the development of antimicrobial associated colitis (Colitis X), typically associated with *Clostridium difficile*, which may be fatal.

8. ADVERSE REACTIONS

None known. If you notice any serious effects or any other effects not mentioned in this product literature, please inform your veterinary surgeon.

9. TARGET SPECIES

Pigs: in particular suckling and post weaning.

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

Oral use.
Administration via drinking water or direct application by mouth, after dilution with drinking water.
Dosage: 50 000 IU of colistin per kg body weight twice a day for 5 days, i.e. 0.25 ml of COLISCOUR® per 10 kg of body weight twice a day for 5 consecutive days.

Individual administration: For sucking piglets the product should be administered only on an individual basis. COLISCOUR® should be diluted in drinking water. Take 1 ml of COLISCOUR® and dilute to 40 ml with drinking water. Administer this diluted solution by direct application in the mouth with a syringe at: 1 ml per kg bodyweight twice a day for 5 consecutive days. The syringe must be accurate to 0.2 ml.

Administration via drinking water: The medicated water should be the only source of drinking water for the animals for the entire duration of the treatment period (2 to 6 hours). In order to ensure that the product is effectively consumed in less than 6 hours, it might be advisable to either:
• restrict water for one hour just before the treatment period, if the clinical condition of the animals allows this.
Or,
• to slightly underestimate the consumption of water which will ensure a shortened treatment period.

Administration without a dosing pump: The treatment is distributed in a tank in a pulse mode over a period of 2 to 6 hours, twice a day, for 5 consecutive days. COLISCOUR® is added to a volume of the drinking water corresponding to the volume consumed by the animals over the treatment period (2 to 6 hours) to achieve a dose rate of 50 000 IU of colistin per kg body weight.
The following sequential steps should be followed:
- From the dosage regimen, and the total weight of pigs to be treated, determine the necessary quantity of active ingredient, and deduce the necessary quantity of commercial product.

- Determine the mean water consumption of the animals to be treated over the treatment period (2 to 6 hours), and deduce the total quantity of supplemented water to prepare.

The following formulae can be applied:

Calculation of COLISCOUR® volume at each distribution (V):

V (ml) = (50 000*W)/(2 000 000)

where W (kg) = total weight of pigs to treat

Or 0.025 ml x W (kg) of bodyweight.

Calculation of the quantity of supplemented drinking water to prepare (Q):

Q (L) = A x N

where A = mean individual water consumption of the animals during the scheduled treatment period in litres.

where N = number of animals to be treated

Administration via a dosing pump: The treatment is distributed in a pulse mode over a period of 2 to 6 hours, twice a day, for 5 consecutive days. A dosing pump is used to add a stock solution at a pre-determined concentration to the drinking water.

The pumped volume is constant, but the drinking frequency depends on the flow rate of the circuit. The flow rate (F) through the pump is a proportion. Thus, the concentration of the stock solution corresponds to the concentration of the solution to be distributed to the animals divided by the flow rate through the pump.

If the product is administered with an automated drinking water system, the following sequential steps should be followed:

- Determine the quantity of COLISCOUR® to achieve a dose rate of 50 000 IU of colistin per kg body weight.
- Determine the mean water consumption of the animals to be treated over the scheduled treatment period (2 to 6 hours).
- Calculate the concentration of the solution to be distributed to the animals
- Calculate from this, the concentration of the stock solution, knowing the flow rate of the dosing pump.

1 ml of COLISCOUR® contains 2 000 000 IU.

The following calculation must be applied:

Calculation of COLISCOUR® volume at each distribution (V):

V (ml) = (50 000 x W)/(2 000 000)

where W (kg) = total weight of pigs to treat

Or 0.025 ml x W(kg) of bodyweight.

Calculation of the drinking water concentration (C):

C (ml/L) = V/B

where B = total volume of water consumed by the pigs during the scheduled treatment period (2 to 6 hours) in litres.

Calculation of the stock solution volume (V'): V' (ml) = B*F where F = flow rate through the dosing pump as a percentage.

Calculation of the stock solution concentration (C'): C' (ml/L) = C/F

The veterinary surgeon should provide suitable advice to the farmer including prevention, by vaccination of sows, and hygiene methods that might aid in prevention of the disease such as adoption of all-in-all-out procedures in farrowing units.
Duration of treatment should be limited to the minimum time necessary for the treatment of the disease.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat and offal:1 day.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25° C. Once opened use within 3 months.
Any medicated drinking water or stock solution which is not consumed within 24 hours should be discarded.

14. SPECIAL WARNING(S)

SPECIAL WARNINGS FOR THE TARGET SPECIES: Colistin exerts concentration-dependent activity against Gram-negative bacteria. Following oral administration high concentrations are achieved in the gastrointestinal tract, i.e. the target site, due to the poor absorption of the substance. These factors indicate that a longer duration of treatment than the one indicated in section «Dosage», leading to unnecessary exposure, is not recommended.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS: Do not use colistin as a substitute for good management practices. Colistin is a last resort drug in human medicine for treatment of infections caused by certain multi-drug resistant bacteria. In order to minimise any potential risk associated with widespread use of colistin, its use should be limited to treatment or treatment and metaphylaxis of diseases, and should not be used for prophylaxis. Whenever possible, colistin should only be used based on susceptibility testing. Use of the product deviating from the instructions given in this label may lead to treatment failures and increase the prevalence of bacteria resistant to colistin.

USER WARNINGS: People with known hypersensitivity to polymyxins, such as colistin, should avoid contact with this product. In case of accidental eye exposure, wash with plenty of water, seek medical attention immediately and show the label to the physician. Wash hands after use.

USE DURING PREGNANCY AND LACTATION: The safety of colistin during pregnancy or lactation was not investigated in target species. However, the colistin is poorly absorbed after oral administration, therefore the use of colistin during pregnancy, lactation or lay should not lead to particular problems.

15. EXPIRY DATE

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

POM-V

To be supplied only on veternary prescription.

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

20. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4017

21. MANUFACTURER'S BATCH NUMBER

Approved: 24/05/2017