

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

Colibird 2 MIU/ml solution for use in drinking water for chickens

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

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

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 enteric infections caused by non-invasive *Escherichia coli* susceptible to colistin.

The presence of the disease in the flock should be established before metaphylactic treatment.

7. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance or any of the excipients. Do not use in known cases of resistance to polymyxins. Do not use in horses 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

Chickens

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

Administration via drinking water. 75 000 IU of colistin per kg body weight per day for 3-5 consecutive days by oral route, i.e. 37.5 ml of product per tonne of body weight per day for 3-5 consecutive days. Duration of treatment should be limited to the minimum time necessary for the treatment of the disease. The quantity of product to be mixed in drinking water depends on the total weight of the animals to be treated: Total number of birds x Average body weight in tonne x 37.5 = Total volume of product (ml) to be used per day. This volume of product should be added to the actual volume of drinking water consumed by the animals for each day of the treatment period. The medicated water should be the only source of drinking water for the birds for the entire duration of the treatment period. The uptake of medicinal water depends on the physiological and clinical conditions of the animals. In order to obtain the correct dosage, it is essential to record the live weight and actual water consumption accurately.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat and offal: 1 day. Eggs: zero days.

13. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions. Do not use after the expiry date which is stated on the label after EXP. Shelf-life after opening the container: 3 months.

Shelf-life after dilution according to directions: 24 hours after dilution in drinking water.

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 the veterinary medicinal product. Do not eat, drink or smoke while handling the product. In case of accidental eye exposure, wash with plenty of water. If irritation occurs seek medical advice immediately and show the label to the physician. Wash hands after use.

USE DURING LAY: The product can be used during lay.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION: The combination with aminoglycosides should be avoided.

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 veterinary prescription.

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

20. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4042

21. MANUFACTURER'S BATCH NUMBER

Approved: 12/05/2017

