

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:

Colistin (as colistin sulphate) 2 000 000 International Units

Excipients:

Benzyl alcohol 10 mg

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Solution for use in drinking water
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1. Target species

Chickens

4.2. Indications for use

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.

4.3. Contra-indications

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.

4.4. Special warnings for each 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 4.9, leading to unnecessary exposure, is not recommended.

4.5 Special precautions for use

i) 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 the SPC may lead to treatment failures and increase the prevalence of bacteria resistant to colistin.

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

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product can be used during lay.

4.8 Interaction with other medicinal products and other forms of interaction

The combination with aminoglycosides should be avoided.

4.9 Amounts to be administered and administration route

Administration via drinking water.

Chickens: 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.

4.10 Overdose (Symptoms, emergency procedures, antidotes)

None.

4.11 Withdrawal period

Meat and offal: 1 day.

Eggs: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: intestinal antiinfectives, antibiotics.

ATC vet code: QA07AA10.

5.1 Pharmacodynamic properties

Colistin is a polypeptide antibiotic belonging to the polymyxin class.

Colistin exerts a bactericidal action on susceptible bacteria strains by disruption of the bacteria cytoplasmic membrane leading to an alteration of cell permeability and then a leakage of intracellular materials.

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.

Colistin possesses virtually no activity against gram positive bacteria and fungi. Gram-positive bacteria are naturally resistant to colistin, as are some species of Gram-negative bacteria such as *Proteus* and *Serratia*.

However, acquired resistance of gram-negative enteric bacteria to colistin is rare and explained by a single step mutation.

The *in vitro* susceptibility of *Escherichia coli* strains isolated from poultry to colistin has been determined. The MIC₅₀ and MIC₉₀ values were 0.25 µg/ml and 0.38 µg/ml, respectively.

5.2 Pharmacokinetic particulars

Colistin is poorly absorbed from the gastro-intestinal tract. In contrast to the very low concentrations of colistin in serum and tissues, high and persistent amounts are present within the different sections of the gastro intestinal tract.

No significant metabolism is observed.

Colistin is almost exclusively eliminated via the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzyl alcohol.

Water, purified

6.2. Incompatibilities

None known.

6.3. Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after opening the immediate packaging: 3 months.

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

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

Nature of container:

- High density polyethylene bottle.
- Polypropylene screw caps fitted with a polypropylene dosing device and a poly(vinyl chloride/vinyl acetate) seal.

Package sizes:

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

Not all pack sizes may be marketed.

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

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

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

8. MARKETING AUTHORISATION NUMBER

Vm: 15052/4042

9. DATE OF FIRST AUTHORISATION

Date: 01 July 2010

10. DATE OF REVISION OF THE TEXT

Date: June 2015



Approved: 09 June 2015