1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Coliscour 2 000 000 IU/ml, concentrate for oral solution, pigs, poultry.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Colistin (as sulphate)	2,000,000 IU

Excipients:

Benzyl alcohol (E1519)	10 mg
Excipients qs	1 ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for oral solution.
Clear yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs and poultry.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in case of hypersensitivity to polypeptide antibiotics or to any of the excipients.
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.

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

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to polymyxins should avoid contact with the veterinary medicinal product.
In case of accidental eye exposure, wash with plenty of water and seek medical attention 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 safety of colistin during pregnancy, lactation or lay 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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To be administered orally.

Pigs: 100 000 IU of colistin per kg body weight daily for 3-5 consecutive days, i.e. 0.50 ml of product per 10 kg of body weight per day for 3-5 consecutive days. The recommended daily dose should be divided into two if the product is to be administered directly into the mouth of the animal.

Poultry: 75 000 IU of colistin per kg body weight daily for 3-5 consecutive days, i.e. 37.5 ml of product per tonne of body weight per day for 3-5 consecutive days.

Administration via drinking water.
The uptake of medicated water depends on the physiological and clinical conditions of the animals. In order to obtain the correct dosage the concentration of colistin has to be adjusted accordingly.
Carefully calculate the total body mass to be treated and the total daily water consumption before each treatment.
Medicated water should be made every day, immediately prior to provision.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
Duration of treatment should be limited to the minimum time necessary for the treatment of the disease.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None.

4.11 Withdrawal period(s)

Meat and offal:
Pigs: 1 day
Poultry: 1 day
Eggs: 0 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: intestinal antiinfectives, antibiotics.
ATCvet 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 is bactericidal and is primarily effective against a range of gram negative bacteria, in particular enterobacteriaceae.
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.

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.

5.2 Pharmacokinetic particulars

Colistin is poorly absorbed from the gastro-intestinal tract. In contrast to very low concentration 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 (E1519).
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 product as packaged for sale: 3 years.
Shelf-life after first 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

The 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 veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10815/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th September 2007
Date of last renewal: 22nd June 2012

10 DATE OF REVISION OF THE TEXT

April 2018