

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colipro 2 000 000 IU/ml concentrate for oral solution for pigs and poultry [FR]
Colivet 2 000 000 IU/ml concentrate for oral solution for pigs and poultry [AT, PT]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance:

- Colistin (as sulphate)..... 2 000 000 IU

Excipient:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Benzyl alcohol (E1519).	10 mg
Purified water.	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs and poultry.

3.2 Indications for use for each target species

Treatment and metaphylaxis of gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin.

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

3.3 Contraindications

Do not use in cases 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.

3.4 Special warnings

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 3.9, leading to unnecessary exposure, is not recommended.

3.5 Special precautions for use

Special precautions for safe use in the target species

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 veterinary medicinal 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.

Special precautions for the protection of the environment

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. 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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal:

Pigs: 1 day

Poultry: 1 day

Eggs: 0 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QA07AA10.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 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.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Nature of container:

- High density polyethylene bottle.
- Polypropylene screw caps fitted with a polypropylene dosing device and a polyethylene seal.

Package sizes:

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

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

LABELLING AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

250 ml, 500 ml, 1 litre, 2 litres and 5 litres labels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colipro 2 000 000 IU/ml concentrate for oral solution, pigs, poultry [FR]
Colivet 2 000 000 IU/ml concentrate for oral solution, pigs, poultry [AT, PT]

2. COMPOSITION

1 ml contains 2 000 000 IU colistine (as sulphate)
10 mg benzyl alcohol (E1519)

3. PACKAGE SIZE

250 ml
500 ml
1 l
2 l
5 l

4. TARGET SPECIES

Pigs and poultry.

5. INDICATIONS FOR USE

Indications for use

Treatment and metaphylaxis of gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin.

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

6. CONTRAINDICATIONS

Contraindications

Do not use in cases 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.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

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 safe use in the target species:

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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

Pregnancy, lactation or lay:

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. 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.

Interactions with other medicinal products and other forms of interaction:

None known.

Overdose:

None.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

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

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not

worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal:

Pigs: 1 day

Poultry: 1 day

Eggs: 0 days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

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 label after Exp.

Shelf life after first opening the immediate packaging: 3 months.

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

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.

These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

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

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Tel: +800 35 22 11 51

Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:

Ceva Santé Animale - Z.I. Très le Bois - 22600 - Loudéac - France