Belacol 24% Liquid

240 mg/ml, solution for oral administration

cattle, calves, pigs, chickens and turkeys

Active ingredient: Colistin sulphate






Name and address of the marketing authorisation holder:
bela-pharm GmbH & Co. KG
Lohner Str. 19
49377 Vechta / Germany

Name of the veterinary medicinal product:
Belacol 24% Liquid
240 mg/ml, solution for oral administration in cattle, calves, pigs, chickens and turkeys.
Active ingredient: Colistin sulphate

Statement of the active substance(s) and other ingredient(s):
1.0 ml solution contains:
Pharmacological active substance:
Colistin sulphate 240,00 mg
Adjuvants:
Benzyl alcohol 9,45 mg

Indications:
Cattle, pigs, chickens and turkeys:
Treatment of intestinal infections caused by non-invasive *E. coli* sensitive to colistin (individual animals).
Treatment and metaphylaxis of intestinal infections caused by non-invasive *E. coli* sensitive to colistin (herds/flocks).
The presence of the disease in the herd or flock should be established before metaphylactic treatment.

Contraindications:
Resistance to polymyxins (total cross-resistance between colistin and polymyxin B).
Colistin should not be administered to animals suffering from manifest renal dysfunction.
The antibiotic should also be avoided in case of intolerance to polymyxins.
Do not use in horses, particularly in foals, since colistin, due to a shift in the gastro-intestinal microflora balance could lead to the development of antimicrobial associated colitis (Colitis X), typically associated with *Clostridium difficile*, which may be fatal.

Adverse reactions (frequency and seriousness):
It cannot be precluded that neurotoxic and nephrotoxic changes occur in newborns as well as in animals with severe intestinal diseases and renal dysfunction due to an increased enteral rate of absorption.
Allergic reactions in animals have not been described.

Target species:
Cattle, pig, chicken, turkey.

Dosage for each species, route(s) and method of administration:
For application via the drinking water for cattle, pigs, chickens and turkeys.
For application via the milk or milk substitute for calves.

- *Cattle:*
  2 x 2 mg colistin sulphate/kg body weight/day equivalent to
  2 x 0.008 ml Belacol 24% Liquid per kg body weight/day equivalent to
  2 x 3.75 ml Belacol 24% Liquid per 450 kg body weight/day.
- *Calves, pigs:*
  2 x 2.5 mg colistin sulphate/kg body weight/day equivalent to
  2 x 0.01 ml Belacol 24% Liquid per kg body weight/day equivalent to
  2 x 0.5 ml Belacol 24% Liquid per 50 kg body weight/day.
- *Chicken:*
  2 x 3 mg colistin sulphate/kg body weight/day equivalent to
  2 x 0.0125 ml Belacol 24% Liquid/kg body weight/day equivalent to
  2 x 0.5 ml Belacol 24% Liquid per 40 kg body weight/day.
- *Turkeys:*
  6 mg colistin sulphate/kg body weight/day equivalent to
  0.025 ml Belacol 24% Liquid/kg body weight/day equivalent to
  1 ml Belacol 24% Liquid per 40 kg body weight/day.

It has to be guaranteed that the recommended dosage is taken up completely.
In animals with obviously disturbed state of health and/or in animals showing inappetence or reduced water-intake due to illness, a preparation to be administered parenterally shall be preferred.

For the treatment of individual animals (cattle, calves, pigs):
The prescribed amount of Belacol 24% Liquid must be mixed for each application freshly into a part of the milk or the ready-to-use cooled down milk substitute. Ensure a complete mixing and administer prior to the feeding. When administering with the drinking water, the needed amount of Belacol 24% Liquid is to be mixed with part of the water and to be administered immediately. Administer half of the indicated daily dose at an interval of 12 hours, respectively.

For the treatment of parts of stock (pigs, chickens and turkeys):
Dissolve the needed amount of Belacol 24% Liquid completely and every day fresh in a small part of water per dosage interval (12 hours in pigs and chickens, 24 hours in turkeys) and add to the drinking water. To ensure an equable water intake by all animals to be treated, sufficient watering places have to be provided. In case of outdoor housing, the animals should be kept in the stable during the duration of treatment.
The feed resp. water intake may vary considerably between day and night.
The dosage has to be adjusted to the actual, real daily intake of drinking water by the animals as this varies in dependence on the age, state of health, purpose of the animals and the way of rearing.

· *Pigs and chickens:*
For the above mentioned dose, the amount of Belacol 24% Liquid to be mixed into the drinking water for the animals to be treated is calculated per dosage interval (12 hours) according to the following formula:

· *Pigs:*

$$\frac{\text{0.010 ml Belacol 24\% Liquid per kg body weight/ dosage interval} \times \text{average body weight (kg) of animals to be treated}}{\text{average intake of drinking water (l) per animal per dosage interval}} = \text{... ml Belacol 24\% Liquid per litre drinking water}$$

· *Chickens:*

$$\frac{\text{0.0125 ml Belacol 24\% Liquid per kg body weight/ dosage interval} \times \text{average body weight (kg) of animals to be treated}}{\text{average intake of drinking water (l) per animal per dosage interval}} = \text{... ml Belacol 24\% Liquid per litre drinking water}$$

· *Turkeys:*
For the above mentioned dose, the amount of Belacol 24% Liquid to be mixed into the drinking water for the animals to be treated is calculated per dosage interval (24 hours) according to the following formula:

$$\frac{\text{0.025 ml Belacol 24\% Liquid per kg body weight/ dosage interval} \times \text{average body weight (kg) of animals to be treated}}{\text{average intake of drinking water (l) per animal per dosage interval}} = \text{... ml Belacol 24\% Liquid per litre drinking water}$$

Duration of treatment: 5 - 7 days.
Duration of treatment should be limited to the minimum time necessary for the treatment of the disease.
Should there be no significant improvement of the state of health after 3 days of treatment, review diagnosis and change therapy, if necessary.
After conclusion of the treatment, the drinking equipment has to be cleaned thoroughly in a suitable manner to avoid the intake of subtherapeutic, especially resistance-causing residual amounts of the applied antibiotic.
To ensure an adequate body-weight related dose of Belacol 24% Liquid, a suitable dosage device is to be used.
A scaled dosage device with a maximal volume of 30 ml is added to the 250 ml packing.
Volumes of less than 10 ml should be measured with a suitable disposable syringe.

Advice on correct administration:
Not indicated.

Withdrawal period(s):

Cattle:	*edible tissues:*	*2 days*
	milk:	*0 days*
Calf, pig:	*edible tissues:*	*2 days*
Chicken:	*edible tissues:*	*2 days*
	eggs:	*0 days*
Turkeys:	*edible tissues:*	*2 days*

Special storage precautions:
Store protected from light.
Keep out of reach and sight of children.
Shelf life after first opening the container: 7 days.
Residuals of the pharmaceutical remaining in the container after the period to be used up is terminated are to be wasted.
Stability of the medicated solution in drinking water: 12 hours.
Stability of the medicated milk or milk substitute: 3 hours.
Solutions of the pharmaceutical in the milk or milk substitute must be prepared immediately prior to its use and must be fed instantly.

Special warnings:
Special warnings for each target species:
In case of septicaemic forms, chronical ill animals, or in animals with inappetence or reduced water-intake due to illness an additional treatment should be carried out.

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.

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 safety precautions to be taken by the person administering the medicinal product to animals
Avoid direct contact with skin or mucous membranes to reduce the risk of sensitisation.

Use during pregnancy, lactation or lay:
The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Interactions with anaesthetics and muscle relaxants cannot be precluded in single cases after application of colistin.

Avoid combinations with aminoglycosides and levamisole.

Overdose (symptoms, emergency procedures, antidotes):
Stop therapy instantly and treat symptomatically. No specific antidote known.

Incompatibilities:
Colistin is chemico-physically incompatible with ampicillin, cephalosporines, erythromycin and kanamycin.
The antibacterial effect of colistin will be antagonised by bivalent cations (e.g. iron, calcium, magnesium) as well as by fatty acids and polyphosphates.
Due to possible incompatibilities, mixing with other medicinal products should be avoided.

Special precautions for the disposal of unused product or waste materials:
Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

Marketing authorisation number:
402261.00.00 (Germany)

For veterinary use only.

Available on prescription only!

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