Belacol 12% Powder

120 mg/g, powder for oral administration with the feed, drinking water, milk or milk substitute

Active ingredient: Colistin sulphate

Target species: Cattle, calves, pigs, chickens






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

Statement of the active substance(s) and other ingredient(s):
1 g powder contains:
Pharmacological active substance:
Colistin sulphate 120.0 mg

Indications:
Cattle, calves, pigs, and *chickens:*
Treatment of intestinal infections caused by non-invasive *E. coli* sensitive to colistin.
Treatment and metaphylaxis.
The presence of the disease in the herd 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:
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*, *calf*, *pig*, *chicken*

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

Cattle:
4.0 mg colistin sulphate/kg body weight/day equivalent to
33.3 mg Belacol 12% Powder per kg body weight/day equivalent to
15.0 g Belacol 12% Powder per 450 kg body weight/day

Calves, *pigs*:
5.0 mg colistin sulphate/kg body weight/day equivalent to
41.6 mg Belacol 12% Powder per kg body weight/day equivalent to
2.1 g Belacol 12% Powder per 50 kg body weight/day.

Chicken:
6.0 mg colistin sulphate/kg body weight/day equivalent to
50.0 mg Belacol 12% Powder per kg body weight/day

For the treatment of individual animals (*cattle, calves, pigs*):
Colistin sulphate is sensitive to high temperatures. When mixing into the milk or milk substitute of *calves*, the needed amount of powder is to be solved completely in a small amount of drinking water. The medicated drinking water is then to be mixed with the milk or ready-to-use milk substitute, cooled down to below 38 °C, and to be given immediately.
When given with the drinking water, the needed amount of powder must be solved completely in a part of the drinking water, and to be given immediately.
The needed amount of powder must be mixed for each application freshly into a part of the food or dissolved completely in the milk or ready-to-use milk substitute. Ensure a complete mixing and administer prior to the feeding.
Administer half of the indicated daily dose at an interval of 12 hours, respectively.

For the treatment of parts of stock (*chickens*):
Dissolve the needed amount of powder completely and every day fresh in a small part of water and add to 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 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.
For the above mentioned dose, the amount of Belacol 12% Powder to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

Chicken:

$$\frac{\text{50 mg Belacol 12\% Powder per kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg Belacol 12\% Powder per l drinking water}$$

Take care that the provided dose is taken in completely.
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, residual amounts of the applied antibiotic supporting resistance formation.
In animals with obviously disturbed state of health and/or in animals showing inappetence, a preparation to be administered parenterally shall be preferred.

Advice on correct administration:

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.

Special precautions for use in animals:

On account of the limited antibacterial spectrum of colistin sulfate, diagnosis should be secured bacteriologically and the sensitivity of the germs should be ensured by a susceptibility testing.

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 skin contact and inhalation during handling and application due to the risk of sensitisation or contact dermatitis. Wear a dust mask and gloves when handling the veterinary medicinal product.

Use during pregnancy, lactation or lay:

Not indicated.

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:

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.

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

Special storage precautions:
Protect from moisture.
Do not store at temperatures exceeding 30 °C.
Keep out of reach and sight of children.
Shelf life after first opening the container: 28 days
Residuals of the pharmaceutical remaining in the packing after ending of this period must be wasted.
Stability of the medicated drinking water: 24 hours
Stability of the medicated milk/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.
Do not use after the expiration date stated on the label.

Special precautions for the disposal of unused veterinary medicinal product or waste materials, if any:
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.

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For animal treatment only.

Available on prescription only!

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