Belacol 100% Kompaktat

1000 mg/g, granules for oral administration

in cattle, pigs, chickens and turkeys

Active ingredient: Colistin sulphate





Name and address of the marketing authorisation holder and, if different, of the manufacturer responsible for batch release

Bela-Pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

Name of the veterinary medicinal product

Belacol 100% Kompaktat
1000 mg/g, granules for oral administration in *cattle, pigs, chickens,* and *turkeys*
Active ingredient: Colistin sulphate

Statement of the active substance(s) and other ingredient(s)

Each g granulate contains:
Pharmacological active substance:
Colistin sulphate 1000 mg

Indications

Cattle, pigs, chickens and *turkeys:*
Treatment of intestinal infections caused by non-invasive *E. coli* sensitive to colistin.
Treatment and metaphylaxis.
The presence of disease in the herd must be established before initiating metaphylactic treatment.

Contraindications

- Do not use in cases of resistance to polymyxins.
- Do not use in animals with manifest renal dysfunction.
- Do not use in case of known hypersensitivity to polymyxins.
- Do not use in horses, especially foals, as colistin may lead to the development of antimicrobial colitis (colitis X), typically caused by *Clostridium difficile*, due to disturbance of the gastrointestinal flora balance.

Adverse reactions

No data.

Target species

Cattle, pig, chicken, turkey.

Dosage for each species, route(s) and method of administration

For application via the drinking water of *cattle, pigs, chickens* and *turkeys*.
To ensure correct dosing and to avoid underdosing, the body weight of the animals should be determined as accurately as possible.
The necessary amount of the granules is to be weighed with a suitable balance.
The medicated drinking water must be prepared fresh every 24 hours.

For the treatment of individual animals.

· *Cattle:*
4 mg colistin sulphate/kg body weight/day equivalent to
2 g Belacol 100% Kompaktat per 500 kg body weight/day

For the treatment of parts of stock / entire stock
· *Pigs:*
5 mg colistin sulphate/kg body weight/day equivalent to
1 g Belacol 100% Kompaktat per 200 kg body weight of animals to be treated / day

· *Chickens:*
6 mg colistin sulphate/kg body weight/day equivalent to
6 g Belacol 100% Kompaktat per 1000 kg body weight of animals to be treated / day

· *Turkeys:*
6 mg colistin sulphate/kg body weight/day equivalent to
6 g Belacol 100% Kompaktat per 1000 kg body weight of animals to be treated / day

For the treatment of individual animals *(cattle)*:
Dissolve the needed amount of granules completely in part of the drinking water and administer immediately.
The body weight must be carefully determined before each treatment.
Administer half of the indicated daily dose at an interval of 12 hours, respectively.
Take care that the provided dose is taken in completely.

For the treatment of parts of stock / the entire stock *(pigs, chickens* and *turkeys)*:
The average body weight to be treated and the average daily drinking water intake must be carefully determined before each treatment.
Dissolve the needed amount of granules completely and every day a new 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.
No other source of water must be accessible to the animals during the entire treatment period.
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 (e.g. varying ambient temperature or different light patterns in case of chickens).
For the above mentioned dose, the amount of Belacol 100% Kompaktat to be mixed into the drinking water for the animals to be treated is calculated according to the following formula:

· *Pigs*:

$$\frac{\text{5 mg Belacol 100\% Kompaktat per kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg Belacol 100\% Kompaktat per l drinking water}$$

· *Chickens:*

$$\frac{\text{6 mg Belacol 100\% Kompaktat per kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg Belacol 100\% Kompaktat per l drinking water}$$

· *Turkeys:*

$$\frac{\text{6 mg Belacol 100\% Kompaktat per kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily intake of drinking water (l) per animal}} = \text{... mg Belacol 100\% Kompaktat per l drinking water}$$

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, residual amounts of the applied antibiotic supporting resistance formation.
In animals with obviously disturbed state of health, a preparation to be administered parenterally shall be preferred.

Withdrawal period(s)

Cattle:	edible tissues:	2 days
	milk:	0 days
Pig:	edible tissues:	2 days
Chicken:	edible tissues:	2 days
	eggs:	0 days
Turkey:	edible tissues:	2 days

Special storage precautions
Keep out of the reach and sight of children.
Do not use after the expiration date stated on the label.
Shelf life after first opening the container: 14 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 drinking water: 24 hours
Protect from moisture. Store tightly closed.

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 a concentration-dependent effect against gram-negative bacteria. Due to the poor absorption of the substance, high colistin concentrations are reached in the gastrointestinal tract, i.e. in the target region, after oral administration. These factors indicate that a longer duration of treatment than that described in section „Dosage and route of administration“, which leads to unnecessary exposure, is not recommended.
In addition to treatment, good farm management and hygiene practices should be followed to reduce the risk of infection and counteract the possible development of resistance.
There is complete cross-resistance between colistin and polymyxins.

Special precautions for use

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.

Susceptibility testing should be based on bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional or farm) epidemiological information on the susceptibility of the target bacteria.

When using the veterinary medicinal product, the official, national and local guidelines for the use of antibiotics must be observed.

Do not use colistin as a substitute for good husbandry conditions.

Colistin is a reserve antibiotic in human medicine for the treatment of infections caused by certain multidrug-resistant bacteria. To minimise any potential risks associated with the widespread use of colistin, its use should be limited to therapeutic and metaphylactic treatment of disease and the veterinary medicinal product should not be used for prophylaxis.

Whenever possible, colistin should be used exclusively on the basis of susceptibility testing.

Use deviating from the instructions for use or the summary of product characteristics may result in treatment failure and increase the prevalence of bacteria resistant to colistin.

In neonatal animals and animals with severe gastrointestinal or renal dysfunction, absorption of colistin may be increased. Neurotoxic and nephrotoxic changes may occur.

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

To avoid sensitisation or contact dermatitis, avoid direct skin, eye and mucous membrane contact as well as inhalation during processing and/or application. Wear a dust mask and gloves for this purpose. Wash hands after application.

Persons with known hypersensitivity to polymyxins, such as colistin, should avoid contact with the veterinary medicinal product.

In case of accidental contact with skin or eyes, rinse immediately with plenty of water.

If symptoms such as skin rash occur after handling, consult a doctor immediately and show the package leaflet or label.

Swelling of the face, lips or eyes or difficulty breathing are serious symptoms requiring immediate medical attention.

Use during pregnancy, lactation or lay

Pregnancy and lactation:

Laboratory studies in mice, rats and rabbits have not produced any evidence of teratogenic, fetotoxic or maternotoxic effects.

The safety of the veterinary medicinal product during pregnancy, lactation or laying has not been established in the target species. Use during pregnancy, lactation or the laying period should only take place after the benefit/risk assessment by the attending 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.

Colistin is antagonised in its antibacterial effect by divalent cations (such as iron, calcium, magnesium) as well as by fatty acids and polyphosphates.

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

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

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.

Date on which the package leaflet was last approved: 28.11.2020

Other informations

Marketing authorisation number: 402187.00.00

For veterinary use only.

Available on prescription only!