Belacol Doser

7.5 mg/ml, suspension for oral administration

in pigs (piglets)

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 Doser
7.5 mg/ml, suspension for oral administration in pigs (piglets)
Active ingredient: Colistin sulphate

Statement of the active substance(s) and other ingredient(s):
1 ml suspension contains:

Pharmacological active substance:	
Colistin sulphate	7.50 mg
Adjuvants:	
Methyl parahydroxybenzoate	2.0 mg
Propyl parahydroxybenzoate	0.2 mg

Indications:
Treatment of intestinal infections in piglets 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 (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:
Piglets.

Dosage for each species, route(s) and method of administration:
Suspension for oral administration.
Piglet: 5 mg Colistin sulphate/kg body weight/day
equivalent to
1 ml Belacol Doser per 1.5 kg body weight/day.

1 pump stroke = 1 ml suspension
Prior to the first application, the originality closure must be removed and replaced by the dosage device added.
Shake well before use.
Introduce the dosage device into the lateral mouth of the piglet and apply the amount recommended according to the body weight.
The duration of treatment is in general 5 to 7 days.
Following cessation of clinical symptoms it is recommended to continue therapy for 2 additional days.
Should there be no significant improvement of the state of health after 3 days of treatment, review diagnosis and change therapy, if necessary.
Duration of treatment should be limited to the minimum time necessary for the treatment of the disease.

Advice on correct administration:

Special warnings for each target species
In case of septicaemic course, in chronically diseased animals, or animals with inappetence or disease-related reduced water intake 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 clarified by an antibiogram.
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 the direct contact with skin or mucous membranes to reduce the risk of sensitisation.

Use during pregnancy, lactation or lay
Not indicated.

Interaction with other medicinal products and other forms of interaction
Following application of colistin, interactions with anaesthetics and muscle relaxants cannot be precluded in single cases.
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.
Mixing with other medicinal products should be avoided due to possible incompatibilities.

Withdrawal period(s):
Piglets: edible tissues: 2 days

Special storage precautions:
Do not store at temperatures exceeding 30 °C. Keep out of the 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.
Do not use after the expiration date stated on the label.

Special warnings:
None.

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:
04.08.2015

Other informations:
Marketing authorisation number: 6027275.00.00
For veterinary use only.
Available on prescription only!