PACKAGE LEAFLET

Colistin 2MIU/mL SOGEVAL concentrate for oral solution for calves, lambs, pigs, chickens and turkeys(FR)
Sogecoli 2 000 000 IU/ml concentrate for oral solution for calves, lambs, pigs, chickens and turkeys (UK)
Sogecoli 2 000 000 IU/ml concentrate for oral solution (PL, BE, DE)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer responsible for batch release:

Laboratoires Biove
3 rue de lorraine
62510 Arques
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colistin 2MIU/mL SOGEVAL concentrate for oral solution for calves, lambs, pigs, chickens and turkeys(FR)
Sogecoli 2 000 000 IU/ml concentrate for oral solution for calves, lambs, pigs, chickens and turkeys (UK)
Sogecoli 2 000 000 IU/ml concentrate for oral solution (PL, BE)

Colistine sulphate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One ml contains
Colistin (as sulphate).....2000 000 IU
Excipients:
Benzyl alcohol (E1519).....0,01 ml

Concentrate for oral solution. Clear , yellowish to orange solution

4. INDICATION(S)

Calves - lambs – pigs – , chickens - turkeys:

Treatment and metaphylaxis of gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin.
The presence of the disease in the herd should be established before metaphylactic treatment.

5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to polypeptide antibiotics or to any of the excipients.
Do not use in case of resistance to polymyxins.
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.

6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this label, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (calves) – Sheep (lambs) – pigs – chickens – turkeys.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

To be administered orally

Calves, lambs and pigs:
100 000 IU of colistin per kilogram body weight i.e 0.5 ml of product per 10 kg body weight daily for 3-5 consecutive days. The recommended daily dose should be divided into two if the product is to be administered directly into the mouth of the animal.

Chickens and turkeys:
75 000 IU of colistin per kilogram body weight i.e 37.5 ml of product per 1000 kg body weight daily for 3-5 consecutive days.

Duration of treatment should be limited to the minimum time necessary for the treatment of the disease.

9. ADVICE ON CORRECT ADMINISTRATION

Administration via drinking water and milk/milk replacer.
The uptake of medicated water/milk 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 average body weight to be treated and the average daily water consumption before each treatment. Medicated water should be prepared every day. Medicated milk should be prepared immediately prior to provision.

The medicated water should be the only source of drinking water for the animals for the entire duration of the treatment period.

$$\frac{\text{ml of the product per kg body weight and day} \times \text{Average body weight (kg)}}{\text{Average daily water intake (l/animal)}} = \text{...ml of the product per litre of drinking water}$$

- Administration without a dosing pump:

The treatment is distributed in a tank over a period of 24 hours, for 3 to 5 consecutive days. The product is added to a volume of the drinking water corresponding to the volume consumed by the animals over the treatment period (24 hours) to achieve a dose of 100 000 IU of colistin per kg body weight for pigs lambs and calves and 75 000 IU of colistin per kg body weight for chickens and turkeys .

- Administration via a dosing pump

The treatment is distributed over a period of 24 hours, for 3 to 5 consecutive days.
A dosing pump is used to add a stock solution at a pre-determined concentration to the drinking water.

10. WITHDRAWAL PERIOD

Calves, lambs and pigs
Meat and offal: 1 day

Chickens and turkeys
Meat and offal: 1 day

Eggs: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30 °C.

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution in drinking water according to directions: 24 hours
Shelf life after incorporation in milk or milk substitute according to directions: 6 hours
Any medicated water which is not consumed within 24 hours should be discarded.
Any medicated milk which is not consumed within 6 hours should be discarded.

Once opened, use by:…

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

In the case of newborn animals and of animals with severe gastrointestinal and renal disorders the absorption of colistin may be increased. Neurological or nephrotoxic symptoms may occur.

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.
It is recommended to wear gloves when handling or administering the product.
Do not eat, drink or smoke while handling the product.

In case of accidental contact with eyes, wash with plenty of water, seek medical advice immediately and show the label to the physician.
Wash hands after use.

Use during pregnancy, lactation or lay
The safety of colistin during pregnancy, lactation or lay was not investigated in target species. 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.

Interaction with other medicinal products and other forms of interaction:
If possible, the combination with aminoglycosides should be avoided.

Overdose (symptoms, emergency procedures, antidotes):
None.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

100 ml bottle

250ml bottle
500ml bottle
1 litre bottle
5 litres barrel

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

For animal treatment only
To be supplied only on veterinary prescription

Marketing Authorisation Number

BATCH NUMBER:

EXPIRY DATE:


16 June 2016