

PACKAGE LABEL - LEAFLET

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AQUACOLI 2 000 000 IU/ml, Solution for use in drinking water or milk

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

Marketing authorisation holder and manufacturer:

LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla del Ramassà)
LES FRANQUESES DEL VALLÈS, (Barcelona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AQUACOLI 2 000 000 IU/ml, Solution for use in drinking water or milk
AQUACOLI 2 000 000 IU/ml, Oral solution for cattle, sheep, swine and poultry (DE)

Colistin sulfate

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

Each 1 ml of solution contains:

Colistin (as sulfate)..... 2 MIU
Benzyl alcohol (E1519)..... 10 mg

Clear yellow-brown solution

4. INDICATION(S)

Treatment of gastrointestinal infections caused by non-invasive *E. coli* susceptible to colistin.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

Do not use in case of resistance to the polymyxin.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Cattle (calves), sheep (lambs), swine and poultry

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

In drinking water/milk use

For calves, lambs and pigs the recommended dose is 100 000 IU of colistin per kilogram body weight daily for 3-5 consecutive days via drinking water or milk replacer, i.e. 0.5 ml of Solution per 10 kg of body weight per day 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.

For poultry the recommended dose is 75 000 IU of colistin per kilogram body weight daily for 3-5 consecutive days via drinking water, i.e. 37.5 ml of Solution per tonne of body weight per day for 3 - 5 consecutive days.

With the following formula we can calculate an exact dosage:

$$\frac{\text{ml Veterinary medicinal product/kg bw day} \times \text{Average body weight (kg)}}{\text{Average daily water intake (l/animal)}} = \text{ml Veterinary Medicinal product per litre of drinking water}$$

If it is not possible to obtain sufficient uptake of medicated water, animals should be treated parenterally.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. Carefully calculate the total body mass to be treated and the total daily water consumption before each treatment.

Medicated water should be made every day, 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

10. WITHDRAWAL PERIOD

Meat and offal: 1 day

Eggs: Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use after the expiry date stated on the label.

Shelf-life after dilution or reconstitution according to directions: 24 hours after dilution in drinking water and 6 hours in milk replacer

Any medicated water which is not consumed within 24 hours should be discarded safely

12. SPECIAL WARNING(S)

Special precautions for use in animals

Using the veterinary medicinal product (antimicrobials) in poultry should be in accordance with Commission Regulation EC 1177/2006 and subsequent national requirements. Whenever possible, colistin should only be used based on susceptibility testing.

In the case of newborn animals and of animals with severe gastrointestinal and renal disorders the absorption of colistin may be increased. Neuro- and nephrotoxic alterations 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.

Avoid direct contact with skin and eyes while handling the product. The use of gloves while handling and dosing is recommended.

Wash splashes from skin immediately with soap and plenty of water.

In case of accidental eye exposure, wash with plenty of water and seek medical attention immediately and show the label to the physician.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

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

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment..

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only - to be supplied only on veterinary prescription.

Marketing authorisation number(s):

Manufacturer's batch number:

Expiry date: EXP {month/year}

Once opened, use by:...

Bottles of 1 and 5 l