PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Bags of 100 g and 1 kg

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 responsible for batch release
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 - CALDES DE MONTBUI (Barcelona)
Spain

2. Name of the veterinary medicinal product

CITRAMOX 100 mg/g powder for use in drinking water for pre-ruminant calves, broilers and pigs [ES, PT]
KARIMOX 100 mg/g powder for use in drinking water for pre-ruminant calves, broilers and pigs [EL]Amoxicillin trihydrate

3. Statement of the active substance (s) and other ingredients

Each g contains:

Active substance:
Amoxicillin 100 mg
(Equivalent to 114.78 mg amoxicillin trihydrate)

Excipients: q.s.
White powder.

4. Pharmaceutical form

Powder for use in drinking water.

5. Package size

100 g
1 kg

6. Indication(s)

Treatment of infections caused by bacteria sensitive to amoxicillin; colibacillosis, salmonellosis (except in broilers), streptococci, staphylococci.

7. Contraindications

Do not use in cases of hypersensitivity to penicillins, other beta-lactams or to any of the excipients.
Do not use in rabbits, guinea pigs, hamsters and horses, since amoxicillin, like all penicillins, has an important action on the cecal bacterial population.
Do not use in ruminants with a functional rumen.

8. Adverse reactions

Hypersensitivity reactions may occur in very rare cases. The severity can range from simple urticaria to anaphylactic shock.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

9. Target species

Cattle (pre-ruminant), chicken (broiler) and pig.

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

In drinking water use.

Dosage in drinking water: 10 mg of amoxicillin per kg b.w. every 12 hours for 5 consecutive days, equivalent to 1 g of the veterinary medicinal product / 10 kg of b.w. / every 12 hours.

If no improvement is observed in 48 hours, reconsider the diagnosis.
According to the recommended dose and the number and weight of the animals that should receive the treatment, the exact daily dose of product should be calculated using the following formula:

$$\frac{\text{x mg product per kg bodyweight per day} \times \text{mean bodyweight (kg) of animals to be treated}}{\text{Mean daily water consumption (litres) per animal}} = \text{mg of product / litre of drinking water}$$

11. Advice on correct administration

The uptake of medicated water depends on the clinical and physiological conditions of the animals and season. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted taking into account the daily water intake.
To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
Medicated water should be the only source of drinking water during the treatment period.

12. Withdrawal period(s)

Broilers:
- Meat and offal: 6 days
- Eggs: Not for use in birds producing or intended to produce eggs for human consumption. Do not use within 4 weeks of the start of the laying period.

Pigs:
- Meat and offal: 10 days

Pre-ruminant calves:
- Meat and offal: 2 days

13. Special storage precautions

Keep the bag tightly closed.

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.

14. Special warning(s)

Special warnings for each target species:
The medicated water intake by animals can be modified as a consequence of the disease. In case of insufficient water intake, administer an alternative parenteral treatment.

Special precautions for use in animals:
Good clinical practice requires basing treatment on susceptibility tests of bacteria isolated from sick animals. If this is not possible, the treatment should be based on local epidemiological information (regional, farm level) on the sensitivity of the different strains of the bacterial species usually involved in the infectious process.
The use of veterinary (antimicrobial) medicinal product in poultry must be in accordance with regulation (EC) 1177/2006 and subsequent national requirements.
When using this veterinary medicinal product, the official recommendations (national or regional) on the use of antimicrobials should be taken into account.
The use of the veterinary medicinal product under conditions other than those recommended in the SPC may increase the prevalence of bacteria resistant to amoxicillin and decrease the effectiveness of the treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact.
Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Do not handle the product if you are allergic to penicillins and/or cephalosporins.
Handle this product with care to avoid inhaling dust and contact with skin and eyes during its incorporation into water taking all recommended precautions:
Take appropriate measures to avoid the dust spread during the product incorporation into drinking water.
Wear a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with a filter to EN 143 and protective gloves when handling the product.
Avoid skin and eyes contact. In case of skin and eyes contact, wash thoroughly with clear water.
Do not smoke, eat or drink while handling the product.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Pregnancy:
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
Do not use simultaneously with neomycin because it blocks oral penicillin absorption.

Overdose (symptoms, emergency procedures, antidotes):
In cases of several allergic reactions the treatment should be discontinued, and corticosteroids and adrenalin should be administered. In all other cases a symptomatic treatment should be established.

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

15. 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 or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

17. Other information

Not all pack sizes may be marketed.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}
Once opened use within…

Shelf life after first opening the container: 3 months.
Shelf life after dilution according to directions: 24 hours.

21. Marketing authorisation number(s)

22. Manufacturer's batch number

Batch {number}