

CITRAMOX 1000 mg/g

Powder for use in drinking water for chickens, turkeys, ducks and pigs
Amoxicillin Trihydrate



KARIZOO

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QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance: Amoxicillin 871.2 mg
(equivalent to 1000 mg amoxicillin trihydrate)

PHARMACEUTICAL FORM

Powder for use in drinking water.
A white powder. Clear and colourless liquid when in solution.

TARGET SPECIES

Chickens, ducks, turkeys, pigs.

INDICATIONS FOR USE

Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin. Pigs: For the treatment of pasteurellosis.

CONTRAINDICATIONS

This product should not be administered to horses or to rabbits, guinea pigs, hamsters, gerbils or any other small herbivore. Do not use in animals with known hypersensitivity to penicillins or other β -lactam antibiotics or to any of the excipients. Do not administer to animals with renal disease including anuria or oliguria.

ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

In drinking water use. Prepare the solution with fresh potable water immediately before use. Any medicated water which is not consumed within 24 hours should be discarded and the medicated drinking water replenished. In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated. The following formula may be used to calculate the required concentration of product (in milligrams of product per litre of drinking water):

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

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

Chickens: The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight (corresponding to 15 mg product/kg bodyweight/day). The total period of treatment should be for 3 days or in severe cases for 5 days.

Ducks: Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 20 mg product/kg bodyweight/day) for 3 consecutive days.

Turkeys: Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 15-20 mg product/kg bodyweight/day) for 3 days or in severe cases for 5 days.

Pigs: Administer in the drinking water to give 20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 20 mg product/kg bodyweight/day) daily for up to 5 days.

After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance. Solubility in drinking water varies depending on temperature and water quality. Maximum solubility is approximately 1 g/l at 4°C in soft water but increases to 2 g/l at 20°C in hard water. For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

INSTRUCTIONS FOR A CORRECT ADMINISTRATION

After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

WITHDRAWAL PERIOD

Meat and offal:

Chickens	1 day
Ducks	9 days
Turkeys	5 days
Pigs	2 days

Not authorised for use in laying birds producing eggs for human consumption and within 3 weeks before the onset of the laying period.

SPECIAL WARNINGS

Special warnings for each target species: None.

Special precautions for use in animals:

Not effective against beta-lactamase producing organisms. Pigs: The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead. Official, national and regional antimicrobial policies should be taken into account when the product is used. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the amoxicillin and may 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.

People with known hypersensitivity to the active substance or if you have been advised not to work with such preparations should avoid contact with the veterinary medicinal product. Handle this product with great care to avoid exposure, taking all recommended precautions. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention. Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143. Wear gloves during preparation and administration of medicated water. Wash any exposed skin after handling the product or medicated water. Wash hands after use.

Use during pregnancy, lactation or lay:

Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.

Use only according to the benefit-risk assessment of the responsible veterinarian.

Do not use in birds producing eggs for human consumption or within 3 weeks before the onset of the laying period.

Interaction with other medicinal products and other forms of interaction:

The product should not be administered with antibiotics that have a bacteriostatic mode of action, such as tetracyclines, macrolides, sulphonamides.

Overdose (symptoms, emergency procedures, antidotes), if necessary:

No problems with overdosage have been reported. Treatment should be symptomatic and no specific antidote is available.

Incompatibilities:

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

SHELF LIFE

Do not use this veterinary medicinal product after the expiration date shown on the label and the box

Shelf life after first opening the immediate packaging: 3 months

Shelf life after dilution or reconstitution according to directions: 24 hours

SPECIAL PRECAUTIONS FOR STORAGE

Keep the bags tightly closed.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM THE USE OF SUCH PRODUCTS

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

FOR ANIMAL TREATMENT ONLY.

TO BE SUPPLIED ONLY ON VETERINARY SUBSCRIPTION.

ADDITIONAL INFORMATION

Pack sizes: 200 g bag
50 g bag
1 kg bag
20 x 200 g

Not all pack sizes may be marketed.

Laboratorios Karizoo, s.a.
An Alivira Group Company

Polig. Industrial La Borda
Mas Pujades, 11-12
08140 Caldes de Montbui
Barcelona, Spain

T +34 938 654 148
F +34 938 654 648
karizoo@karizoo.com
www.karizoo.com



KARIZOO