1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Citramox 1000 mg/g powder for use in drinking water for chickens, ducks, turkeys and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substances:
Amoxicillin trihydrate.....1000 mg
(equivalent to 871.2 mg Amoxicillin)

A white powder. Clear and colourless liquid when in solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens, ducks, turkeys, pigs.

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not effective against beta-lactamase producing organisms.
Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.
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 veterinary medicinal product is used.

Use of the veterinary medicinal 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 veterinary medicinal 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 who have been advised not to work with such preparations should avoid contact with the veterinary medicinal product.
Handle this veterinary medicinal 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 ENl43.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product or medicated water.
Wash any exposed skin after handling the veterinary medicinal product or medicated water. Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Chickens, ducks, turkeys, pigs:

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction[1]

[1] May occasionally be serious.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Laboratory studies in rats have not produced any evidence of a teratogenic effect.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration route and dosage

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.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

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. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of amoxicillin may need to be adjusted accordingly.

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:
Recommended dosage is 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 ºC in soft water but increases to 2 g/l at 20 ºC 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal:

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

Do not use in birds in lay and within 3 weeks before the start of the laying period.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA04

4.2 Pharmacodynamics

Amoxicillin is a time-dependent bactericidal antibiotic which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. It inhibits the formation of bridges between the chains of linear polymers constituting the peptidoglycan cell wall of Gram positive bacteria.
Amoxicillin is a broad-spectrum penicillin. It is also active against a limited range of Gram negative bacteria on which the outer layer of the bacterial cell wall is composed of lipopolysaccharide and proteins.
There are three main mechanisms of resistance to beta-lactams: beta-lactamase production, altered expression and/or modification of penicillin binding proteins (PBP), and decreased penetration of the outer membrane. One of the most important is the inactivation of penicillin by beta-lactamase enzymes produced by certain bacteria. These enzymes are capable of cleaving the beta-lactam ring of penicillins, making them inactive. The beta-lactamase could be encoded in chromosomal or plasmidic genes.
The use of extended spectrum beta-lactam drugs (e.g. aminopenicillins) might lead to the selection of multi-resistant bacterial phenotypes (e.g. those producing extended spectrum beta-lactamases (ESBLs)).

4.3 Pharmacokinetics

Amoxicillin is well absorbed following oral administration and it is stable in the presence of gastric acids. Excretion of amoxicillin is mainly in the unchanged form via the kidneys to give high concentration in renal tissue and urine. Amoxicillin is well distributed in body fluids.
Studies in birds have indicated that amoxicillin is distributed and eliminated more rapidly than in mammals.

Biotransformation appeared a more important route of elimination in birds than in mammals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution or reconstitution according to directions: 24 hours.

5.3. Special precautions for storage

Keep the bags tightly closed.

5.4 Nature and composition of immediate packaging

Thermosealed bags made of polyester, aluminium and polyethylene complex. Pack sizes:

200 g bag
500 g bag
1 kg bag
20 x 200 g

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Karizoo S.A.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10786/005/002

8. DATE OF FIRST AUTHORISATION

15/07/2016

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

25/06/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).