SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CITRAMOX 1000 mg/g POWDER FOR USE IN DRINKING WATER FOR CHICKENS, TURKEYS, DUCKS AND PIGS [IE, ES, NL, UK, PL, PT, HU, RO, CZ, SK, EL]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

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

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, ducks, turkeys, pigs.

4.2 Indications for use, specifying the target species

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

4.3 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 ß-lactam antibiotics or to any of the excipients.
Do not administer to animals with renal disease including anuria or oliguria.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. 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.

ii. 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 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 ENl43.
Wear gloves during preparation and administration of medicated water.
Wash any exposed skin after handling the product or medicated water. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 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.

4.8 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.

4.9 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):

x mg product per kg bodyweight per day	X	mean bodyweight (kg) of animals to be treated	
Mean daily water consumption (litres) per animal			= 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.

<u>Chickens</u>
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 4ºC in soft water but increases to 2 g/l at 20ºC 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.

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

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

4.11 Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibiotic, penicillins.
ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

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.
Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.
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)).

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

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

6.3 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

6.4 Special precautions for storage

Keep the bags tightly closed.

6.5 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.

6.6 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.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Karizoo, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – Caldes De Montbui (Barcelona)
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 31223/4006

9. DATE OF FIRST AUTHORISATION

27 June 2016

10. DATE OF REVISION OF THE TEXT

June 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

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


27 June 2016