Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Citramox 500 mg/g powder for use in drinking water for chickens, turkeys, ducks and pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Amoxicillin..... 436 mg
(as 500 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, turkeys, ducks and 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 rabbits, guinea pigs, hamsters, gerbils or any other small herbivore.
Do not use in known cases of hypersensitivity to penicillins or other ß-lactam antibiotics or to any of the excipients.
Do not use in animals with renal disease including anuria or oliguria.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

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 identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge susceptibility of the target bacteria at farm level, or at local/regional level.
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 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 or liquid feed
Wash any exposed skin after handling the product or medicated water or feed. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.
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 in lay within 3 weeks before the start of the laying period.

4.8 Interaction with other medicinal products and other forms of interactions

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

For oral administration. Prepare the solution with fresh potable water immediately before use. Any medicated water which is not consumed within 12 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):

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

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 animal. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted taking into account water intake.
The calculated dose should be measured out with calibrated scales.

Chickens
The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight per day (corresponding to 30 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/kg bodyweight per day (corresponding to 40 mg product/kg bodyweight/day) for 3 consecutive days.

Turkeys

Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight per day (corresponding to 30-40 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 40 mg product/kg·bodyweight) 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.

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 for use in birds producing or intended to produce eggs for human consumption.
Do not use within 3 weeks of the start of the laying period.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

Amoxicillin is a bactericidal antibiotic belonging to the group of semisynthetic penicillins with a broad spectrum of activity against Gram positive and Gram negative bacteria. It owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

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

Anhydrous citric acid.

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary 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: 21 months
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 12 hours

6.4 Special precautions for storage

Do not store above 30ºC.
Keep the bags tightly closed.

6.5 Nature and composition of immediate packaging

Thermosealed bags made of polyester, aluminium and polyethylene complex.

Pack sizes:
400g bag
1kg bag

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Laboratorios Karizoo S.A.
Pol. Ind. La Borda
Mas Pujades, 11-12
08140 Caldes de Montbui
Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10786/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 August 2014
Date of last renewal: 19 August 2019

10 DATE OF REVISION OF THE TEXT

August 2019

PROHIBITION OF SALE, SUPPLY AND/OR USE