SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMOXY ACTIVE CTD 697 mg/g powder for use in drinking water for chickens, turkeys and ducks

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Amoxicillin	697 mg
as amoxicillin trihydrate	800 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMAPEUTICAL FORM

Powder for use in drinking water.
White to off-white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (broiler, pullet, breeder), turkeys, ducks (broiler, breeder).

4.2 Indications for use, specifying the target species

Chickens, turkeys and ducks: treatment of infections caused by bacteria susceptible to amoxicillin.

4.3 Contraindications

Do not use in the presence of ß-lactamase-producing bacteria.
Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.
Do not use in animals with known hypersensitivity to penicillins or other substances from the beta-lactam group or to any of the excipients.
Do not use in ruminants or horses.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 product literature 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 may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may cause cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity to beta-lactam antibiotics should avoid handling the product.
Handle this product with great care to avoid exposure, taking all recommended precautions.
This product may cause skin and eye irritation. Avoid contact with skin and eyes.
Do not smoke, eat or drink while handling the product.
During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. Wear gloves and either 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 when mixing and handling the product.
Wash hands after use.
In case of contact with eyes or skin, wash immediately with water.
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.

4.6 Adverse reactions (frequency and seriousness)

Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of a teratogenic effects due to the administration of amoxicillin.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not combine with bacteriostatic antibiotics.
Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.
Synergism occurs with ß-lactam antibiotics and aminoglycosides.

4.9 Amounts to be administered and administration route

For use in drinking water.

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):

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

To ensure a correct dosage, body weight 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.

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.

Chickens:
The recommended dosage is 15 mg amoxicillin trihydrate (equivalent to13.1 mg amoxicillin) per kg body weight per day (corresponding to 19 mg product/ kg body weight/day).
The total period of treatment should be for 3 days or in severe cases for 5 days.

Turkeys:
Recommended dosage is 15-20 mg amoxicillin trihydrate (equivalent to 13.1 – 17.4 mg amoxicillin) per kg body weight per day (corresponding to 19 – 25 mg product/kg body weight/day) for 3 days or in severe cases for 5 days.

Ducks:
Recommended dosage is 20 mg amoxicillin trihydrate (equivalent to 17.4 mg amoxicillin) per kg body weight per day (corresponding to 25 mg product /kg body weight/day) for 3 consecutive days.

The calculated dose should be measured out with calibrated scales.
Maximum solubility of the product in water is approximately 3 g per litre.
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. In case of overdosing the treatment should be symptomatic. No specific antidote is available.

4.11 Withdrawal period(s)

Chickens: meat and offal: 1 day.
Turkeys: meat and offal: 5 days.
Ducks: meat and offal: 9 days.
Not authorised for use in birds producing eggs for human consumption.
Do not use within 4 weeks before the onset of the laying period.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Beta-lactam antibacterials***,*** Penicillins

ATCvet-code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a time-dependent bactericidal antibiotic belonging to the semisynthetic penicillin group which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. It has a broad spectrum of activity against Gram positive and Gram negative bacteria, and owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

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

Sodium carbonate
Sodium citrate

6.2 Major 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: 3 years.
Shelf life after first opening of the immediate packaging: 1 month.
Shelf life after reconstitution in drinking water: 12 hours.

6.4 Special precautions for storage

Store below 25 ºC. Store in a dry place.
Store in tightly closed original container to protect from moisture.

6.5 Nature and composition of immediate packaging

- Securitainer: white cylindrical polypropylene container, covered with a low-density polyethylene closure.

The securitainer contains 100 g, 250 g, 500 g or 1 kg of product.
- Bucket: white polypropylene square container provided with a polypropylene closure.

The bucket contains 1, 2.5 or 5 kg of product.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 28365/4013

9. DATE OF THE FIRST AUTHORISATION

14 February 2019

10. DATE OF REVISION OF THE TEXT

February 2019

PROHIBITION OF SALE, SUPPLY AND/OR USE

On veterinary prescription only.

Approved: 14 February 2019