SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Awazom 800 mg/g powder for use in drinking water for chickens, ducks and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Amoxicillin 697 mg (equivalent to 800 mg of amoxicillin trihydrate).

Excipients:

Qualitative composition of excipients and other constituents
Sodium carbonate monohydrate
Sodium citrate
Silica, colloidal anhydrous

White to pale yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Chicken (broiler, pullet, for reproduction), duck (broiler, for reproduction), turkey.

3.2 Indications for use for each target species

Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.

3.3 Contraindications

Do not use in horses, rabbits, hamsters, gerbils and guinea pigs or any other small herbivores.
Do not use in cases of hypersensitivity to penicillins or other β-lactam antibiotics or to any of the excipients.
Do not use in the presence of ß-lactamase-producing bacteria.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 cephalosprins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity 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 veterinary medicinal product.
Handle this veterinary medicinal product with care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.
During preparation and administration of the medicated drinking water, avoid skin and eye contact and inhalation of dust particles, as this veterinary medicinal product may be irritating.
Wear impervious gloves and an appropriate dust mask (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 EN143) when mixing and handling the veterinary medicinal product.
In the event of eye or skin contact , rinse the affected area with large amounts of clean water.
Do not smoke, eat or drink while handling the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens, ducks, turkeys:

Undetermined frequency (cannot be estimated from the available data):	Allergic reaction* Hypersensitivity reaction

*Occasionally serious allergic reaction may be observed.

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

Laboratory studies in rats have not produced any evidence of teratogenic effects.

3.8 Interaction with other medicinal products and other forms of interaction

Amoxicillin exerts its bactericidal action by inhibition of bacterial cell wall synthesis during multiplication. It is therefore in principle not compatible with bacteriostatic antibiotics (e.g. tetracyclines) which inhibit multiplication. Synergism occurs with ß-lactam antibiotics and aminoglycosides.

3.9 Administration routes and dosage

In drinking water use.

Chickens
The recommended dosage is 15 mg amoxicillin trihydrate (equivalent to 18.8 mg veterinary medicinal product) per kg body weight for 3 days or in severe cases for 5 days.

Ducks
Recommended dosage is 20 mg amoxicillin trihydrate (equivalent to 25 mg veterinary medicinal product) per kg body weight for 3 consecutive days.

Turkeys
Recommended dosage is 15-20 mg amoxicillin trihydrate (equivalent to 18.8 to 25 mg veterinary medicinal product) per kg body weight for 3 days or in severe cases for 5 days.

For the preparation of medicated water the body weight of the animals to be treated and their actual daily water consumption should be taken into account The intake of medicated water depends on the clinical condition of the animals and other factors, like age, species, breed and husbandry system (e.g. different temperature, different light regimes). In order to obtain the correct dosage, the concentration of amoxicillin may need to be adjusted accordingly.

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:

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

The use of suitably calibrated measuring equipment is recommended.

Preparation of medicated water should provide an amount to be consumed within the next 12 hours. Any unused medicated water should be discarded after 12 hours, and freshly medicated water for the next 12 hours should be prepared. Maximum solubility of the veterinary medicinal product in water between 5 °C and 20 °C is approximately 6 g/l. The complete dissolution of the powder should be ensured. Appearance of the veterinary medicinal product after dilution: colourless to pale yellowish solution. The proportioner setting should be changed accordingly. In target animal species, water uptake may vary due to various factors, including environmental temperature, age and type of feed.

Make sure the animals do not have access to non-medicated water during the period when the medicated water is given. When all medicated water has been consumed, turn on the normal water supply again. 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.

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

Not known.

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

Chickens (meat and offal): 1 day
Ducks (meat and offal): 9 days
Turkeys (meat and offal): 5 days

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA04

4.2 Pharmacodynamics

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, production 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. Observed resistance rates are variable.

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: 3 years.

Shelf-life after first opening the immediate packaging:
100 g bag: 1 month.
250 g, 500 g and 1000 g bags: 2 months.

Shelf life after dilution according to directions: 12 hours.

5.3 Special precautions for storage

Once opened, the medicinal product should be stored at temperatures below 25 °C.

Store in the original package in order to protect from moisture.
Once opened, keep the bags tightly closed by folding the cut edge of the bag over and securing with a clip.

5.4 Nature and composition of immediate packaging

Thermosealed bags of PET/Al/PE containing 100 g, 250 g, 500 g or 1000 g powder.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

7. MARKETING AUTHORISATION NUMBER

Vm 01656/3071

8. DATE OF FIRST AUTHORISATION

09 April 2019

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

December 2023

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).

Approved 09 April 2024