ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Thermosealed bags of PET/Al/PE containing 100 g powder}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Awazom 800 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Amoxicillin 697 mg (equivalent to 800 mg of amoxicillin trihydrate)

3. PACKAGE SIZE

100 g

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 1 month.
Once diluted use within 12 hours.

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d, Novo mesto

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3071

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Thermosealed bags of PET/Al/PE containing 250 g, 500 g or 1000 g powder}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Awazom 800 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Amoxicillin 697 mg (equivalent to 800 mg of amoxicillin trihydrate)

3. PACKAGE SIZE

250 g
500 g
1000 g

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 2 months.
Once diluted use within 12 hours.

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d, Novo mesto

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3071

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each gram contains:

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

White to pale yellow powder.

3. Target species

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

4. Indications for use

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

5. 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.

6. Special warnings

Special warnings:
None.

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.

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

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.

Overdose:
Not known.

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

7. 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. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:.

8. Dosage for each species, routes and method of administration

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.

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.

9. Advice on correct administration

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.

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.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the bag after Exp. The expiry date refers to the last day of that month.

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.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01656/3071

100 g, 250 g, 500 g or 1000 g.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

December 2023

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
KRKA, d.d, Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Approved 09 April 2024