ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE 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 for chickens, ducks and turkeys
Amoxicillin trihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

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

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

100 g

5. TARGET SPECIES

Chicken (broiler, pullet, breeder), duck (broiler, breeder), turkey.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Chickens (meat and offal): 1 day
Ducks (meat and offal): 9 days
Turkeys (meat and offal): 5 days
The product is not authorised for use in laying birds producing eggs for human consumption and within 3 weeks of onset of laying.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

10. EXPIRY DATE

EXP:

Shelf life after first opening the immediate packaging:1 month.

Once opened use by...

11. SPECIAL STORAGE CONDITIONS

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

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA UK Ltd
Thames House
Waterside Drive
Langley
Berkshire
SL3 6EZ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 47636/4000

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE 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 for chickens, ducks and turkeys
Amoxicillin trihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

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

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

250 g
500 g
1000 g

5. TARGET SPECIES

Chicken (broiler, pullet, breeder), duck (broiler, breeder), turkey.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Chickens (meat and offal): 1 day
Ducks (meat and offal): 9 days
Turkeys (meat and offal): 5 days
The product is not authorised for use in laying birds producing eggs for human consumption and within 3 weeks of onset of laying.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

10. EXPIRY DATE

EXP:

Shelf life after first opening the immediate packaging:2 months.

Once opened use by...

11. SPECIAL STORAGE CONDITIONS

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

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA UK Ltd
Thames House
Waterside Drive
Langley
Berkshire
SL3 6EZ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 47636/4000

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
KRKA UK Ltd
Thames House
Waterside Drive
Langley
Berkshire
SL3 6EZ
United Kingdom

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Amoxicillin trihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:

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

White to pale yellow powder.

4. INDICATION(S)

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 known 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. ADVERSE REACTIONS

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

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chicken (broiler, pullet, breeder), duck (broiler, breeder), turkey.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

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. Consumption may vary depending on factors like species, age, state of health, breed and husbandry system (e.g. different temperature, different light regimes). In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted accordingly.

The following formula may be used to calculate the required amount of veterinary medicinal product in mg per litre of drinking water:

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

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

The use of suitably calibrated weighing scales is recommended for measuring the calculated amount of the product.

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 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 product after dilution: colorless 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

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 PERIOD(S)

Chickens (meat and offal): 1 day
Ducks (meat and offal): 9 days
Turkeys (meat and offal): 5 days
The product is not authorised for use in laying birds producing eggs for human consumption and within 3 weeks of onset of laying.

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

12. SPECIAL WARNING(S)

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 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 product.
Handle this 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 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 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 product.
Wash hands after use.

Lay:
Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.

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 (symptoms, emergency procedures, antidotes):
Not known.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2021

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.

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

Approved: 07/07/21