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

Amatib 800 mg/g oral powder for pigs and chickens

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

Oral powder.

4. PACKAGE SIZE

100 g

5. TARGET SPECIES

Pigs.

Chickens (broilers, pullets, breeders).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Pigs: in drinking water / in-feed use.
Chickens: In drinking water use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Pigs (meat and offal): 2 days.

Chickens (meat and offal): 1 day.

Not authorised for use in laying birds producing eggs for human consumption.

Do not use within 3 weeks of onset of lay.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

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

Once opened use by...

Shelf life after dilution according to directions: 12 hours.

Shelf life after incorporation into meal: use immediately.

11. SPECIAL STORAGE CONDITIONS

Once opened, do not store above 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, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/5070

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

Amatib 800 mg/g oral powder for pigs and chickens

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

Oral powder.

4. PACKAGE SIZE

250 g

500 g

1000 g

5. TARGET SPECIES

Pigs.

Chickens (broilers, pullets, breeders).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

In drinking water use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Pigs (meat and offal): 2 days.

Chickens (meat and offal): 1 day.

Not authorised for use in laying birds producing eggs for human consumption.

Do not use within 3 weeks of onset of lay.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the immediate packaging:

2 months.

Once opened use by...

Shelf life after dilution according to directions: 12 hours.

11. SPECIAL STORAGE CONDITIONS

Once opened, do not store above 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, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/5070

17. MANUFACTURER'S BATCH NUMBER

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Amatib 800 mg/g oral powder for pigs and chickens

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, 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

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amatib 800 mg/g oral powder for pigs and chickens

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.

Appearance of the product after dilution: Colorless to pale yellowish solution.

4. INDICATION(S)

Pigs:

Treatment of respiratory tract infections, gastro-intestinal tract infections, meningitis, arthritis and secondary infections caused by micro-organisms susceptible to amoxicillin.

Chickens:

Treatment of respiratory tract infections and gastro-intestinal tract infections (other than salmonella infections) caused by micro-organisms susceptible to amoxicillin.

5. CONTRAINDICATIONS

Do not use in cases of (known) hypersensitivity to penicillin, other substances of the beta-lactam group or to any of the excipients

Do not use in animals with serious kidney disease including anuria or oliguria.

Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.

Do not use in ruminants or horses.

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.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs.

Chickens (broilers, pullets, breeders).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.
In drinking water use and in-feed use in pigs.
In drinking water use in chickens.

Chickens:

The recommended dosage is 16 mg amoxicillin trihydrate per kg body weight per day (corresponding to 14 mg amoxicillin/kg body weight, or 20 mg of the product/kg body weight) administered in the drinking water, for 3-5 days.

Pigs:

The recommended dosage is 16 mg amoxicillin trihydrate per kg body weight per day (corresponding to 14 mg amoxicillin/kg body weight, or 20 mg of the product/kg body weight), for 3-5 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.

Bolus dosage: It is recommended to administer the product once daily via the drinking water for a limited period of time. Restrict access to the drinking water system for approx. two hours (shorter time in warm weather) until the time of medication. Scatter the calculated daily quantity of powder on the surface of 5-10 litres water. Mix thoroughly until the powder has dissolved. Mix this solution by stirring into the volume of drinking water that will be consumed within about 2 hours. Maximum solubility of the product in water is approximately 8 g/L at room temperature (approximately 20 °C). The maximum solubility can be considerably reduced at lower temperatures. The complete dissolution of the powder should be ensured.

Continuous treatment: 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. The maximum concentration of the pre-diluted medicated water is approximately 8 g/L at room temperature (approximately 20 °C). The maximum solubility can be considerably reduced at lower temperatures. The complete dissolution of the powder should be ensured. 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.

In-feed use in pigs: The product may also be offered via the feed at the recommended daily dose. This way of administration is only intended for the treatment of individual pigs on farms where only a small number of pigs are to receive the treatment. Only the pack size of 100 g is suitable for the in-feed use.

Larger groups should be treated with medicated drinking water.

Before each administration the powder should be thoroughly mixed into a small amount of food and should be given directly to the animal before the main ration.

Care should be taken to ensure complete consumption of all medicated feed prior to providing the remainder of the daily feed ration.

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.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted accordingly.

When used in feed for the treatment of individual pigs, the product should be mixed with a sufficient quantity of feed to ensure consumption of the entire dose prior to providing the remainder of the daily feed ration.

10. WITHDRAWAL PERIOD

Pigs (meat and offal): 2 days.

Chickens (meat and offal): 1 day.

Not authorised for use in laying birds producing eggs for human consumption.

Do not use within 3 weeks of onset of lay.

11. SPECIAL STORAGE PRECAUTIONS

The unopened medicinal product does not require any special temperature storage conditions.

Once opened, do not store above 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.

Shelf-life after first opening the immediate packaging:

100 g pack: 1 month.

250 g, 500 g and 1000 g packs: 2 months.

Shelf life after dilution according to directions: 12 hours.

Shelf life after incorporation into meal: use immediately.

Keep out of sight and reach of children.

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.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Sick animals may have reduced water and/or feed intake and consequently, may require parenterally administered medication instead.

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 package leaflet may increase the prevalence of bacteria resistant to the amoxicillin and may decrease the effectiveness of the treatment.

Pregnancy, lactation or lay:

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or lay. Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

Use only according to the benefit/risk assessment by the responsible veterinarian.

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.

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 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.

Avoid skin and eye contact as this product may be irritating.

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 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 EN 143) when mixing and handling the product. Wash hands after use.

In the event of eye or skin contact, rinse the affected area with large amounts of clean water.

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.

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

April 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.

Local representative:

KRKA UK Ltd

United Kingdom

Tel: 02071 646 156

pharmacovigilance.uk@krka.biz

Approved 04 June 2021