

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Thermosealed bags of PET/Al/PE containing 100 g powder}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amatib 800 mg/g oral powder

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains:
Amoxicillin trihydrate 800 mg (corresponds to 697 mg of amoxicillin).

3. PACKAGE SIZE

100 g

4. TARGET SPECIES

Pigs and chickens (broilers, pullets, chickens for reproduction).



5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIODS

Withdrawal periods:
Pigs: meat and offal: 2 days.
Chickens: meat and offal: 1 day.
Not for use in birds producing eggs for human consumption. Do not use within 3 weeks before the start of the laying period.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 1 month.
Once dissolved, use within: 12 hours.
Once incorporated into meal, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Once opened, do not store above 25°C.
Store in the original package in order to protect from moisture.
Keep the bag tightly closed.

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 01656/5070

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

User warnings
Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for user warnings.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V (Veterinary medicinal product subject to prescription'.)
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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

Amatib 800 mg/g oral powder

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains:

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

3. PACKAGE SIZE

250 g

500 g

1000 g

4. TARGET SPECIES

Pigs and chickens (broilers, pullets, chickens for reproduction).



5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Pigs: meat and offal: 2 days.

Chickens: meat and offal: 1 day.

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 dissolved, use within 12 hours.

9. SPECIAL STORAGE PRECAUTIONS

Once opened, do not store above 25°C.

Store in the original package in order to protect from moisture.
Keep the bag tightly closed.

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 01656/5070

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

User warnings

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for user warnings.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V (Veterinary medicinal product subject to prescription'.)
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PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amatib 800 mg/g oral powder for pigs and chickens

2. COMPOSITION

Each gram contains:

Active substance:

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

White to pale yellow powder.

3. TARGET SPECIES

Pigs and chickens (broilers, pullets, chickens for reproduction).

4. INDICATIONS FOR USE

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 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 β -lactamase-producing bacteria.

6. SPECIAL WARNINGS

Special warnings:

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

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 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.

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

Do not smoke, eat or drink while handling the veterinary medicinal product.

During preparation and administration of the medicated drinking water, skin contact with the veterinary medicinal product and inhalation of dust particles should be avoided. Personal protective equipment consisting of 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 conforming to EN 143) should be worn when handling and mixing the veterinary medicinal 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 the package leaflet or label to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Pregnancy and lactation:

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

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

Laying birds:

The safety of the veterinary medicinal product has not been established during lay.

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 β -lactam antibiotics and aminoglycosides.

Major incompatibilities:

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

7. ADVERSE EVENTS

Pigs, chickens:

Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction*
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*Allergic reactions may occasionally be serious.

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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

[E-mail: adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

[Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine](https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine)

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For oral administration.

In drinking water use and in-feed use in pigs.

In drinking water use in chickens.

Appearance of the product after dissolution in water: Colourless to pale yellowish solution

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 veterinary medicinal 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 veterinary medicinal product/kg body weight), for 3-5 days.

In-water use:

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

The use of suitably calibrated measuring equipment is recommended.

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:

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

Bolus dosage: It is recommended to administer the veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

When used in feed for the treatment of individual pigs, the veterinary medicinal 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.

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 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

Pigs: Meat and offal: 2 days.

Chickens: Meat and offal: 1 day.
Not for use in birds producing eggs for human consumption. Do not use within 3 weeks before the start of the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of sight and reach of children.

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

Once opened, do not store above 25°C.

Store in the original package in order to protect from moisture.

Keep the bag tightly closed.

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 pack: 1 month.

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

Shelf life after dissolution according to directions: 12 hours.

Shelf life after incorporation into meal: use immediately.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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

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 01656/5070

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

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

Local representatives and contact details to report suspected adverse reactions:

KRKA UK Ltd

United Kingdom

Tel: 02071 646 156

info.uk@krka.biz

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

17. OTHER INFORMATION

POM-V ('Veterinary medicinal product subject to prescription.')

For animal treatment only.

Approved 18 June 2024
Gavin Hall