SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amatib 800 mg/g oral powder for pigs and chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

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

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder.
White to pale yellow powder.
Appearance of the product after dilution: Colorless to pale yellowish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.
Chickens (broilers, pullets, breeders).

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

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 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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during 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.

4.8 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.

4.9 Amounts to be administered and administration route

For oral administration.
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.

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.

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.
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not known.

4.11 Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: beta-lactam antibacterials, penicillins, penicillins with extended spectrum
ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a semi-syntetic broad spectrum penicillin with bactericidal action against many Gram-positive and Gram-negative bacteria. It inhibits the development of the peptidoglycan network structure in the bacterial cell wall.
Amoxicillin is acid resistant, but it is not resistant to the action of beta-lactamases.

Bacterial resistance against β-lactam antibiotics including amoxicillin can be mediated via production of β-lactamases. Other resistance mechanisms are decreased penetration through the outer cell membrane (to access the cell wall enzymes), the resistance of the binding proteins to binding by the antibiotics, efflux pumps as part of either an acquired or intrinsic resistance phenotype. The resistance against amoxicillin may indicate resistance against other classes of β-lactam antibiotics, susceptible to β-lactamase.

5.2 Pharmacokinetic particulars

Amoxicillin is rapidly absorbed and maximum plasma concentrations are reached within 2 hours. Amoxicillin is widely distributed throughout the body and high concentrations are achieved in urine, bile, kidneys and liver. Amoxicillin is mainly eliminated via the kidneys in the active form.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium carbonate monohydrate
Sodium citrate
Silica, colloidal anhydrous

6.2 Major incompatibilities

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

6.3 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 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.

6.4 Special precautions for storage

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.

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 01656/5070

9. DATE OF FIRST AUTHORISATION

23 September 2015

10. DATE OF REVISION OF THE TEXT

June 2021

Approved 04 June 2021