SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocillin 1000 mg/g Powder for use in drinking water for chickens, ducks and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Amoxicillin trihydrate 1000 mg
(equivalent to 871 mg Amoxicillin)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
White, crystalline powder.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, ducks, turkeys

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use this product to treat infections caused by bacteria producing the enzyme beta lactamase.

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

Do not use in cases of hypersensitivity to amoxicillin trihydrate, penicillins or other ß-lactam antibiotics.

4.4 Special warnings for each target species

None.

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 bacterial resistance to amoxicillin and may decrease its effectiveness.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion and skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

- People with known hypersensitivity to amoxicillin trihydrate, penicillins or other ß-lactam antibiotics should avoid contact with the veterinary medicinal product.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- If you develop symptoms following exposure such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
- Avoid inhalation of dust.
- Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to ENl43.
- Wear impervious gloves during preparation and administration of medicated water.
- Wash any exposed skin after handling the product or medicated water

4.6 Adverse reactions (frequency and seriousness)

In very rare cases penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

The product should not be administered with antibiotics that inhibit the multiplication of bacteria (bacteriostatic effect) such as tetracyclines, macrolides and sulphonamides.

4.9 Amounts to be administered and administration route

To be administered in drinking water.

Prepare the solution with fresh tap water immediately before use.

Any unused medicated water should be discarded after 12 hours.

In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.

The use of suitably calibrated weighing equipment to accurately measure the required amount of product is recommended.

The following formula may be used to calculate the amount of product (in grams) required per litre drinking water:

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The intake of medicated water depends on the clinical condition of the birds. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted taking into account water intake.

Solubility in water varies depending on temperature and water quality as well as on time and intensity of stirring. Under worst case conditions (4°C and soft water) maximum solubility is approximately 1 g/l but increases by raising temperature. At 21.5°C and in hard water maximum solubility is increased to at least 1.5 g/l.

The dosage differs between species:

<u>Chickens</u>
The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight (equivalent to 15 mg product/kg/bwt) per day.

The total period of treatment should be for 3 consecutive days or in severe cases for 5 consecutive days.

Ducks
Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight (equivalent to 20 mg product/kg/bwt) per day for 3 consecutive days.

Turkeys
Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight (equivalent to 15-20 mg product/kg/bwt) per day for 3 consecutive days or in severe cases for 5 consecutive days.

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

No problems with overdose have been reported. Treatment should be symptomatic and no specific antidote is available.

4.11 Withdrawal period(s)

Chickens (meat & offal):	1 day
Ducks (meat & offal):	9 days
Turkeys (meat & offal):	5 days

Not authorised for use in birds producing eggs for human consumption and within 3 weeks of the start of the laying period.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:	Beta-Lactam antibacterials Penicillins
ATCvet code:	QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a time-dependent bactericidal antibiotic belonging to the semisynthetic penicillin group which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. It has a broad spectrum of activity against Gram positive and Gram negative bacteria, and owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

There are three main mechanisms of resistance to beta-lactams: beta-lactamase production, production of penicillin binding proteins (PBP), and decreased penetration of the outer membrane. One of the most important is the inactivation of penicillin by beta-lactamase enzymes produced by certain bacteria. These enzymes are capable of cleaving the beta-lactam ring of penicillins, making them inactive. The beta-lactamase could be encoded in chromosomal or plasmidic genes.
Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.

5.2 Pharmacokinetic particulars

Amoxicillin is well absorbed following oral administration and it is stable in the presence of gastric acids. Excretion of amoxicillin is mainly in the unchanged form via the kidneys to give high concentration in renal tissue and urine. Amoxicillin is well distributed in body fluids.

Studies in birds have indicated that amoxicillin is distributed and eliminated more rapidly than in mammals. Biotransformation appeared a more important route of elimination in birds than in mammals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

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:	14 days
Shelf life after dilution or reconstitution according to directions:	12 hours

6.4 Special precautions for storage

Keep the container tightly closed in order to protect from light and moisture.
Store in a dry place

6.5 Nature and composition of immediate packaging

250 g, 500 g, 1 kg in fold-up carton with inner layer (paper/PE/Alu/PE)
2.5 kg, 5 kg in kard-o-seal-bag (PE/paper/PE/Alu/PE)

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

Bela-Pharm GmbH & Co. KG
Lohner Strasse 19
49377 Vechta
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 41816/4001

9. DATE OF FIRST AUTHORISATION

22 June 2016

10. DATE OF REVISION OF THE TEXT

September 2021

Approved 17 September 2021