PACKAGE LEAFLET
Biocillin 1000 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 and manufacturer responsible for batch release
bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

Distributor

[To be completed nationally]

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biocillin 1000 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 g contains:

Active substance:

Amoxicillin trihydrate 1000 mg
(equivalent to 871 mg Amoxicillin)
White, crystalline powder

4. INDICATION(S)

Biocillin is an antibiotic agent for treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.

5. 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.

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}".

7. TARGET SPECIES

Chickens, ducks, turkeys

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

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.

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

<u>Turkeys</u>
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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 14 days
Shelf life after dilution or reconstitution according to directions: 12 hours

Keep out of the sight and reach of children.
Keep the container tightly closed in order to protect from light and moisture.

Store in a dry place

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 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

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.

Overdose (symptoms, emergency procedures, antidotes), if necessary
No problems with overdose have been reported. Treatment should be symptomatic and no specific antidote is available.

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.

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

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.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION

Pack sizes:250 g, 500 g, 1 kg, 2.5 kg, 5 kg

Not all pack sizes may be marketed.