

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

Amoxicillin trihydrate



Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different:

bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta / Germany

Name of the veterinary medicinal product:

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

Statement of the active substance(s) and other ingredient(s):

1.0 g powder contains:

Active substance:

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

Indications:

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

Contraindications:

Do not treat infections caused by bacteria producing the enzyme beta lactamase.
Do not administer to rabbits, hamsters, gerbils, guinea pigs or any other small herbivore.
Do not use in animals with known hypersensitivity to penicillins or other β -lactam antibiotics or to any of the excipients.

Adverse reactions:

Penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious.

Target species:

Chickens, ducks, turkeys.

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:

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

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing. The uptake 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:

· Chickens

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.

Advice on correct administration:

Not applicable.

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 onset of laying.

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.

Special warnings: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.

- Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. 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 EN143.
- 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 product must not be mixed with other veterinary medicinal products.

Special precautions for the disposal of unused product or waste materials, if any:

Remaining quantities shall be preferably given to pollutant collecting points. When wasted together with the general household waste, it has to be ensured that no misuse of the pharmaceutical is possible. Veterinary pharmaceuticals must not be wasted with waste water or sewage systems. Local regulations for the disposal of pharmaceuticals have to be observed.

Date of revision of the text:

22.04.2016

Other information:

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

Not all pack sizes may be marketed.

Marketing authorisation number: 402210.00.00 (Germany)

For animal treatment only.

Available on prescription only!