

Consumer leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. Name of the veterinary medicine, form and strength

AMOXYGAL VETERINARY, powder for dissolution in drinking water

2. Active ingredient and quantity in a single dose

Amoxicillin trihydrate 100% w/w

3. What is the medicine intended for

For the treatment of bacterial infections sensitive to amoxicillin in broilers.

Therapeutic group: antibiotic belonging to the semisynthetic penicillin group.

4. Contra-indications

Do not administer the product to rabbits, hamsters, gerbils and guinea pigs.
Do not treat animals with known sensitivity to penicillin or beta-lactams.

5. Side effects

No side effects were reported for the product.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link:

<https://sideeffects.health.gov.il/>

6. Target animals: Broilers.

Not for use in laying birds producing eggs for human consumption.

7. Dosage and administration

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

$$\frac{\text{Number of birds x average live weight (kg)}}{66 \text{ (for dosage of 15 mg/kg)}}$$

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.

The recommended dosage is 15 mg amoxicillin trihydrate per kg bodyweight.
The total period of treatment should be for 3 consecutive days or in severe cases for 5 consecutive days.

8. How to use the product

The product is administered in the drinking water. Prepare the solution with fresh tap water immediately before use. Once opened, use the contents of the package immediately. 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.

9. Withdrawal period

Broilers for slaughter for meat - 1 day

Not for use in laying birds producing eggs for human consumption

10. Warnings

- Special warnings regarding the safety for the person administering the veterinary medicinal product to animals

Avoid inhalation of the powder.

Wash hands after use.

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.

- 1) Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
- 2) Handle this product with great care to avoid exposure, taking all recommended precautions.
- 3) 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.

- Use during laying period

Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.

- Overdose

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

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place outside the reach of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after its expiration date (exp. date) as it appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions: Store below 25°C.

12. Instructions for disposing of the product / remaining product at the end of its use

Any veterinary medical product that was unused or any substance remaining after using the veterinary medical product must be disposed of as toxic waste; do not throw into the sewage system.

- Any medicated water which is not consumed within 12 hours should be discarded.

13. Additional information

- This medicine does not contain other ingredients in addition to the active ingredient.
- What does the medicine look like and what is the content of the package – Plastic bottle or laminate bag containing white to almost white powder.
- Package sizes: 250 or 500 gram.

Manufacturer and License holder: BIOVAC LTD., HAILAN STR. 30, North Industrial Zone, OR-AKIVA 3060000

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Registration number of this medicine in the Ministry of Health State Medicine Registry: 083-95-92412-00