SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AMOXYGAL VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Amoxicillin trihydrate 100% w/w

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for oral solution. A white powder to almost white.

4. CLINICAL PARTICULARS

4.1 Target species

Broilers

4.2 Indications for use, specifying the target species

For the treatment in bacterial infections sensitive to amoxicillin in broilers.Not effective against beta-lactamase producing organisms.

Use of the product should be based on susceptibility testing and it should take into account official and local antimicrobial policies.

4.3 Contra-indications

Amoxinsol 100 should not be administered to rabbits, hamsters, gerbils and guinea pigs.

Hyperseneitivity to the active substance.

4.4 Special warnings for each target species

Do not use in animals known to be hypersensitive to the active ingredient

4.5 Special precautions for use

i. Special precautions for use in animals

None

ii. Special precautions to be taken by the person administering the veterinary

medicinal product to animals

Avoid inhalation of dust.
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.

4.6 Adverse reactions (frequency and seriousness)

None reported

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

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.

4.8 Interaction with other medicinal products and other forms of interaction

None reported

4.9 Amounts to be administered and administration route

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

Number of birds x average live weight (kg)
66 (for 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.

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

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

4.11 Withdrawal period(s)

Chickens (meat & offal): 1 day
Not for use in laying birds producing eggs for human consumption

5. PHARMACOLOGICAL PROPERTIES

Summary presentation of the active ingredient: Amoxicillin is a bactericidal antibiotic belonging to the semisynthetic penicillin group. It owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

Pharmacodynamic properties: Amoxicillin is a semisynthetic penicillin with a broad spectrum of activity against Gram positive and Gram negative bacteria.

Pharmacokinetic properties: 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 Incompatibilities

None known

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4. Special precautions for storage

Store below 25˚C.
Any medicated water which is not consumed within 12 hours should be discarded.

6.5 Nature and composition of immediate packaging

Plastic bottle 250 g, 500 g.
Laminate Bag 250 g, 500 g.
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 products should be disposed of in accordance with local requirements.

7. Manufacturer and License holder: BIOVAC LTD., HAILAN STR. 6, POB 300, OR-AKIVA 30600, ISRAEL

Registration number: 083-95-92412-00

This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in 11/2018