

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE - SACHET**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Amoxinsol 100% w/w powder for oral solution

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Amoxicilin Trihydrate

**3. PHARMACEUTICAL FORM**

Powder

**4. PACKAGE SIZE**

Sachet of 200g

Sachet of 75g

**5. TARGET SPECIES**

Chickens, Ducks, Turkeys

**6. INDICATION(S)**

Antibiotic.

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

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.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

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

$$\frac{\text{Number of birds} \times \text{average live weight (kg)}}{50 \text{ (for 20 mg/kg) or } 66 \text{ (for 15 mg/kg)}}$$

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.

#### Chickens

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

#### Ducks

Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight for 3 consecutive days.

#### Turkeys

Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight for 3 days or in severe cases for 5 consecutive days.

### **8. WITHDRAWAL**

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

Not for use in laying birds producing eggs for human consumption

### **9. SPECIAL WARNING(S), IF NECESSARY**

See package leaflet for further information and before using the product.  
Do not administer to rabbits, hamsters, gerbils and guinea pigs or other small rodents.  
Avoid inhalation of dust. Wash hands after use. Penicillin's may occasionally cause severe allergic reactions. See package insert for further information.  
Spillages should be washed away with copious amounts of water.  
To be supplied only on veterinary prescription.

### **10. EXPIRY DATE**

Expiry date:

### **11. SPECIAL STORAGE CONDITIONS**

Any medicated water which is not consumed within 12 hours should be discarded.  
Store in a dry place.  
Do not store above 25°C.

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]**

For animal treatment only.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr. Alderton  
Towcester  
Northamptonshire  
NN12 7LS

**16. MARKETING AUTHORISATION NUMBER**

Vm 08007/4068

**17. MANUFACTURER’S BATCH NUMBER**

Batch No.:

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – LABEL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Amoxinsol 100% w/w powder for oral solution

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Amoxicillin Trihydrate

**3. PHARMACEUTICAL FORM**

Powder

**4. PACKAGE SIZE**

10 x 200g  
25 x 75g

**5. TARGET SPECIES**

Chickens, ducks and turkeys

**6. INDICATIONS**

Antibiotic.

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

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.

**7. METHOD AND ROUTE OF ADMINISTRATION**

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

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$$\frac{\text{Number of birds} \times \text{average live weight (kg)}}{50 \text{ (for 20 mg/kg) or } 66 \text{ (for 15 mg/kg)}}$$

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.

#### Chickens

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

#### Ducks

Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight for 3 consecutive days.

#### Turkeys

Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight for 3 days or in severe cases for 5 consecutive days.

### **8. SPECIAL WARNINGS, IF NECESSARY**

See package leaflet for further information and before using the product. Do not administer to rabbits, hamsters, gerbils and guinea pigs or other small rodents. Avoid inhalation of dust. Wash hands after use. Penicillin's may occasionally cause severe allergic reactions. See package insert for further information. Spillages should be washed away with copious amounts of water. To be supplied only on veterinary prescription.

### **9. EXPIRY DATE**

Expiry date:

### **10. SPECIAL STORAGE CONDITIONS**

Any medicated water which is not consumed within 12 hours should be discarded. Store in a dry place. Do not store above 25°C.

### **11. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Any medicated water which is not consumed within 12 hours should be discarded.

### **12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For animal treatment only.

**13. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”**

Keep out of reach and sight of children.

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NN12 7LS

**15. MARKETING AUTHORISATION NUMBER**

Vm 08007/4068

**16. MANUFACTURER’S BATCH NUMBER**

Batch No.:

**PACKAGE LEAFLET FOR:**

**NAME OF THE VETERINARY MEDICINAL PRODUCT**

Amoxinsol 100% w/w powder for oral solution

**QUALITATIVE AND QUANTITATIVE COMPOSITION**

Amoxicillin trihydrate 100% w/w

**PHARMACEUTICAL FORM**

Powder for oral solution. A white powder.

**4CLINICAL PARTICULARS**

**Target species**

Chickens, ducks, turkeys

**Indications for use, specifying the target species**

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

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.

**Contra-indications**

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

**Special warnings for each target species**

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

**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**

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.
- 1) Handle this product with great care to avoid exposure, taking all recommended precautions.
- 2) 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 EN140 with a filter to EN143.

Wear gloves during preparation and administration of medicated water.

Wash any exposed skin after handling the product or medicated water.

Wash hands after use.

### **Adverse reactions (frequency and seriousness)**

None reported

### **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.

### **Interaction with other medicinal products and other forms of interaction**

None reported

### **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 one sachet 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.

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### Chickens

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### Ducks

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### Turkeys

Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight for 3 days or in severe cases for 5 consecutive days.

### **Overdose (symptoms, emergency procedures, antidotes), if necessary**

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

### **Withdrawal period(s)**

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

Not for use in laying birds producing eggs for human consumption

### **PHARMACOLOGICAL PROPERTIES**

ATC VetCode:QJ01CA04

Pharmacotherapeutic Group: antibacterials for systemic use.

Summary presentation of the active ingredient: Amoxicillin is a bactericidal antibiotic belonging to the semi-synthetic 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 semi-synthetic 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.

### **PHARMACEUTICAL PARTICULARS**

#### **List of excipients**

None

### **Incompatibilities**

None known

### **Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale 18 months.  
Shelf life after dilution or reconstitution according to directions 12 hours.

### **Special precautions for storage**

Do not store above 25°C.  
Store in a dry place.  
Any medicated water which is not consumed within 12 hours should be discarded.

### **Nature and composition of immediate packaging**

75g in foil/polythene sachets, 25 sachets per box  
200g in foil/polythene sachets, 10 sachets per box  
Not all pack sizes may be marketed

### **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.

### **MARKETING AUTHORISATION HOLDER**

Vetoquinol UK Limited  
Steadings Barn  
Pury Hill Business Park  
Nr. Alderton  
Towcester  
Northamptonshire  
NN12 7LS

### **Manufacturer and site of batch release:**

Vetoquinol Biowet Sp.z.o.o  
140 Zwirowa Street  
Gorzow Wlkp., Poland

### **MARKETING AUTHORISATION NUMBER**

Vm 08007/4068

**POM-V**

To be supplied only on veterinary prescription.  
KEEP OUT OF REACH OF CHILDREN.  
FOR ANIMAL TREATMENT ONLY.

**DATE OF REVISION OF THE TEXT**

May 2018

Approved: 02 May 2018

A handwritten signature in black ink, appearing to read "D. Austin", with a horizontal line extending to the right.