

**Part II**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

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

Amoxinsol 50 % w/w powder for oral solution

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Amoxicillin trihydrate 50% w/w (equivalent to Amoxicillin 45.7% w/w)  
Anhydrous citric acid 50% w/w

**For a full list of excipients, see section 6.1**

**3. PHARMACEUTICAL FORM**

Powder for oral solution. A white powder.

**4. CLINICAL PARTICULARS**

**4.1 Target species**

Chickens, ducks, turkeys, pigs.

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

Chickens: For the treatment of pasteurellosis and colibacillosis.

Turkeys: For the treatment of pasteurellosis.

Ducks: For the treatment of infections caused by *Streptococcus bovis*, *Pasteurella anatipestifer* and *Escherichia coli*.

Pigs: For the treatment of salmonellosis and pasteurellosis caused by isolates sensitive to amoxicillin.

**4.3 Contra-indications**

Amoxinsol 50 should not be administered to rabbits, hamsters, gerbils and guinea pigs. Do not use in animals with known hypersensitivity to the active substance.

**4.4 Special warnings for each target species**

None

**4.5 Special precautions for use**

**(i) Special precautions for use in animals**

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

**(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 or 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 known.

**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.

Use only according to the benefit/risk assessment of the responsible veterinarian.

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

None known.

**4.9 Amounts to be administered and administration route**

Amoxinsol 50 is administered in drinking water

Prepare the solution with fresh tap water.

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

In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst on treatment.

**Chickens**

Dissolve the contents of one sachet (150g of the product) in 450 litres (100 gallons) of water immediately before use. This will provide medication for 5000kg bodyweight of birds for 1 day (15mg amoxicillin trihydrate per kilogram bodyweight). Alternatively, 750 g or 2.5 kg

packs may be measured using the 100 ml scoop provided. This scoop when levelled will deliver 67 g of product, three scoopfuls therefore delivering 200 g.

As a guide, 1 sachet of Amoxinsol 50 will treat the following number of birds.

<b>Broilers</b>	
<b>Age in weeks</b>	<b>No. of Birds</b>
1	30,000
2	13,500
3	7,500
4	5,000
6	3,000
8	2,000

Amoxinsol 50 medicated drinking water should be provided on alternate days. The total period of treatment should be for 3 days (2 days of medication) or in severe cases for 5 days (3 days of medication).

#### **Ducks**

Administer in the drinking water to give 20mg amoxicillin/kg bodyweight. Medication should be provided on alternate days for 3 days, i.e. 2 days of medication. Because of the variable water intake of ducks, depending on temperature, light and feeding regime, exact recommendation of dilution of the product cannot be given. In each case the quantities of Amoxinsol 50 to be used must be calculated taking into account the water intake and total bodyweight of the birds involved. Dissolve the contents of one sachet (150g of the product) in the requisite quantity of water immediately before use. Alternatively, 750 g or 2.5 kg packs may be measured using the 100 ml scoop provided. This scoop when levelled will deliver 67 g of product, three scoopfuls therefore delivering 200 g.

#### **Turkeys**

Administer in the drinking water to give 15-20mg/kg bodyweight. Medication to be provided on alternate days for 5 days (medication on days 1, 3 and 5). Dosage should be calculated taking into account normal water intake and total bodyweight of birds. Dissolve the contents of one sachet (150g of the product) in the requisite quantity of water immediately before use. Alternatively, 750 g or 2.5 kg packs may be measured using the 100 ml scoop provided. This scoop when levelled will deliver 67 g of product, three scoopfuls therefore delivering 200 g.

#### **Pigs**

Administer in the drinking water to give 20mg/kg bodyweight daily. The dose should be divided and administered at approximately 12 hourly intervals for up to 5 days. Dissolve the contents of one sachet (150g of the product) in the requisite quantity of water immediately before use. Alternatively, 750 g or 2.5 kg packs may be measured using the 100 ml scoop provided. This scoop when levelled will deliver 67 g of product, three scoopfuls therefore delivering 200 g.

#### **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)**

Meat:	Chickens	1 day
	Ducks	9 days
	Turkeys	5 days
	Pigs	2 days

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

### **5. PHARMACOLOGICAL PROPERTIES**

**ATC vet code: QJ01CA04**

Pharmacotherapeutic Group: antibacterials for systemic use.

**5.1** Pharmacodynamic properties: Amoxicillin is a bacterial semisynthetic penicillin with a broad spectrum of activity against Gram positive and Gram negative bacteria. IT owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

**5.2** 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**

Citric Acid Anhydrous

#### **6.2 Incompatibilities**

None known.

#### **6.3 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.

#### **6.4 Special precautions for storage**

Do not store above 25°C. Store in a dry place.

**6.5 Nature and composition of immediate packaging**

150g in foil/polyethylene sachets, 20 sachets packed in a box.

750g in a polyethylene bag sealed with a bag tie in a polypropylene container with polyethylene lid and 100ml measuring scoop.

2.5kg in a polyethylene bag sealed with a bag tie in a polypropylene container with polyethylene lid and 100ml measuring scoop.

**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. MARKETING AUTHORISATION HOLDER**

Vétoquinol UK Limited  
Vetoquinol House  
Great Slade  
Buckingham Industrial Park  
Buckingham  
MK18 1PA  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER(S)**

UK : Vm 08007/4019  
IE: VPA 10966/10/1

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

UK 27/7/1990 - 27/07/2005  
IRELAND 11/7/2000 - 11/7/2005

**10. DATE OF REVISION OF THE TEXT**

July 2009