SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxinsol 100% w/w Powder for Oral Solution

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.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, ducks, turkeys

4.2 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.

4.3 Contra-indications

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

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

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

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 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):

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

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.
Chickens
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
utive 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 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
Ducks (meat & offal):	9 days
Turkeys (meat & offal):	5 days

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

Shelf life of the veterinary medicinal product as packages 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.
Any medicated water which is not consumed within 12 hours should be discarded.

6.5 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

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4068

9. DATE OF FIRST AUTHORISATION

12 August 1996

10. DATE OF REVISION OF THE TEXT

May 2018

Approved: 02 May 2018

D Austin