Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxinsol 50 % w/w powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Amoxicillin trihydrate 50 % w/w (equivalent to Amoxicillin 43.6% w/w)

Excipients:
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, turkeys, ducks and pigs.

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.

Pigs: For the treatment of salmonellosis and pasteurellosis.

4.3 Contraindications

Amoxinsol 50 should not be administered to rabbits, hamsters, gerbils and guinea pigs, or to birds producing eggs intended for human consumption.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

Pigs: The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed/water, animals should be treated parenterally.

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

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.

- Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- 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 EN149 with a filter to ENI43.
- Wear gloves during preparation and administration of medicated water or liquid feed.
- Wash any exposed skin after handling the product or medicated water or feed.
- Wash hands after use.

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 interactions

None known.

4.9 Amounts to be administered and administration route

Chickens, turkeys and ducks

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):

$$\frac{\text{Number of birds x average live weight (kg)}}{25 \text{ (for 20 mg/kg) or } 33 \text{ (for 15 mg/kg)}}$$

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 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 days.

Pigs

For the medication of Pigs, Amoxinsol 50 may be administered via the drinking water or administered by addition to liquid feeds produced with commercial feed. It may not be used in dry feeds.

1. Administration via the drinking water

a. 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, 750g or 2.5kg packs may be measured using the 100ml scoop provided. This scoop when levelled will deliver 67g of product, three scoopfuls therefore delivering 200g.

b. For administration via the drinking water, the solution should be prepared with fresh potable water.
i. Any medicated water which is not consumed within 12 hours should be discarded.
ii. In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst on treatment

2. Administration in liquid feed

a. Administer in the liquid feed, to give 20mg amoxicillin trihydrate/kg bodyweight daily for up to 5 days. Medicated feed should be freshly prepared on at least 3 occasions per day over the treatment period. The daily dose should be calculated based on the number of animals and average weight and then divided by the number of feed lots prepared in the day.

b. Medicated liquid feed should be prepared with fresh potable water.

c. Dissolve the required amount of Amoxinsol 50 in water at a rate of 25g/L before addition to the feed. This may be done by dissolving the contents of one sachet (150g of the product) in approximately 6L of water immediately before use. Alternatively, 750g or 2.5kg packs may be measured using the 100 ml scoop provided. This scoop when levelled will deliver 67g of product which should be dissolved in approximately 2.5L of water immediately before use.

d. After adding the product to some or all of the water needed to make the liquid feed, ensure the product is fully dissolved. Dissolution of the product can take up to 10 minutes. This medicated water can then be mixed with the dry complete meal and if appropriate, the remaining water. The system used should ensure that the medicated water is evenly distributed into the feed. Once prepared the final medicated liquid feed should be fed to the pigs immediately.

e. The medicated liquid feed should not be fermented and should not be stored.

f. Stability of amoxicillin in all commercial feeds has not been established. In order to ensure that any loss of amoxicillin activity is minimized, the quantity of medicated liquid feed prepared should not exceed the amount of feed which will be consumed within 4 hours.

iii. Any medicated liquid feed which is not consumed within 4 hours should be discarded
iv. Although restricted access to other water supplies would help ensure medicated liquid feed is consumed, separate clean potable water should remain available at all times for welfare reasons.

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
Pigs (meat & offal): 2 days

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet 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 particulars

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 Major 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 in water according to directions 12 hours.
Shelf life after incorporation into liquid feed 4 hours.

6.4 Special precautions for storage

Do not store above 25^0C. 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 polypropylene or polyethylene lid and 100ml measuring scoop.
2.5kg in a polyethylene bag sealed with a bag tie in a polypropylene container with polypropylene or polyethylene lid and 100ml measuring scoop.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

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70200 Lure
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10521/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th July 1995
Date of last renewal: 10th July 2010

10 DATE OF REVISION OF THE TEXT

11 September 2026