

ANNEX III
LABELLING AND PACKAGE LEAFLET

**<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>
COMBINED LABEL AND PACKAGE LEAFLET
Securitainer and bucket**

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer, NL

Manufacturer responsible for the batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer, NL

2. Name of the veterinary medicinal product

Amoxy Active CTD 697 mg/g powder for use in drinking water for chickens, turkeys and ducks

Amoxicillin as amoxicillin trihydrate

3. Statement of the active substance(s) and other ingredients

Amoxicillin	697 mg/g
as amoxicillin trihydrate	800 mg/g

4. Pharmaceutical form

Powder for use in drinking water

White to off-white powder

5. Package size

100 gram, 250 gram, 500 gram, 1 kg, 2.5 kg, 5 kg.

6. Indication(s)

Treatment of infections caused by bacteria susceptible to amoxicillin.

7. Contra-indications

Do not use in the presence of β -lactamase-producing bacteria.
Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.
Do not use in animals with known hypersensitivity to penicillins or other substances from the beta-lactam group or to any of the excipients.
Do not use in ruminants or horses.

8. Adverse reactions

Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious.

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Chickens (broiler, pullet, breeder), turkeys, ducks (broiler, breeder).

10. Dosage for each species, route(s) and method of administration

For use in drinking water.

Chickens:

The recommended dosage is 15 mg amoxicillin trihydrate (equivalent to 13.1 mg amoxicillin) per kg body weight per day (corresponding to 19 mg product/kg body weight/day) The total period of treatment should be for 3 days or in severe cases for 5 days.

Turkeys:

Recommended dosage is 15-20 mg amoxicillin trihydrate (equivalent to 13.1 – 17.4 mg amoxicillin) per kg body weight per day (corresponding to 19 – 25 mg product/kg body weight) for 3 days or in severe cases for 5 days.

Ducks:

Recommended dosage is 20 mg amoxicillin trihydrate (equivalent to 17.4 mg amoxicillin) per kg body weight per day (corresponding to 25 mg product/kg body weight/day) for 3 consecutive days.

11. Advise on correct administration

Prepare the solution with fresh tap water immediately before use. Any medicated water which is not consumed within 12 hours should be discarded and the medicated drinking water replenished. 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 required concentration of product (in milligrams per litre of drinking water):

$$\frac{\dots \text{mg product/ kg body weight/day} \quad \times \quad \text{mean body weight (kg) of animals to be treated}}{\text{mean daily water consumption (l) per animal}} = \dots \text{ mg product per litre of drinking water}$$

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The uptake of medicated water depends on the clinical condition of the animal. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted taking into account water intake.

After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

The calculated dose should be measured out with calibrated scales.

Maximum solubility of the product in water is approximately 3 g per litre.

For stock solutions and when using a proportioner, take care not to exceed the maximum solubility which can be achieved under the given conditions. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated.

12. Withdrawal period(s)

Withdrawal periods:

Chickens: meat and offal: 1 day.

Turkeys: meat and offal: 5 days.

Ducks: meat and offal: 9 days.

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

Do not use within 4 weeks before the onset of the laying period.

13. Special storage conditions

Store below 25 °C. Store in a dry place.

Store in tightly closed original container to protect from moist.

Do not use after the expiry date stated after exp.

14. Special warning(s)

Special warnings for each target species

None.

Special precautions for use in animals

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the product deviating from the instructions given in the product literature may increase the prevalence of bacteria resistant to the amoxicillin and may decrease the effectiveness of the treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Penicillins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact.

Hypersensitivity to penicillins may cause cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

People with known hypersensitivity to beta-lactam antibiotics should avoid handling the product.

Handle this product with great care to avoid exposure, taking all recommended precautions.

This product may cause skin and eye irritation. Avoid contact with skin and eyes.

Do not smoke, eat or drink while handling the product.

During preparation and administration of the medicated drinking water, skin contact with the product and inhalation of dust particles should be avoided. Wear gloves and either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator conforming to European Standard EN140 with a filter to EN 143 when mixing and handling the product. Wash hands after use

In case of contact with eyes or skin, wash immediately with water.

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.

Lay

Laboratory studies in rats have not produced any evidence of a teratogenic effects due to the administration of amoxicillin.

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

Do not combine with bacteriostatic antibiotics.

Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.

Synergism occurs with β -lactam antibiotics and aminoglycosides.

Overdose (symptoms, emergency procedures, antidotes)

No problems with overdosage have been reported. In case of overdosing the treatment should be symptomatic. No specific antidote is available.

Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

15. 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 product should be disposed of in accordance with local requirements.

16. Date on which the package leaflet was last approved

17. Other information

List of pack sizes:

- Securitainer: 100 g, 250 g, 500 g, 1 kg.

- Bucket: 1, 2.5, 5 kg.

Not all pack sizes may be marketed.

<h3>18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable</h3>
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For animal treatment only - to be supplied only on veterinary prescription

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

Exp << >>

Once opened, use by ...

Shelf life after first opening the container: 1 month

Shelf life after dilution according to directions: 12 hours.

21. Marketing authorisation number(s)

Vm 28365/4013

22. Manufacturer's batch number

Batch << >>

Approved: 14 February 2019

