PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {Securitainer and bucket}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each gram contains

Active substances:

Amoxicillin	697 mg
as amoxicillin trihydrate	800 mg

White to off-white powder.

3. PACKAGE SIZE

250 g, 500 g, 1 kg, 2.5 kg, 5 kg.

4. TARGET SPECIES

For chickens (broiler, pullet, breeder), turkeys, ducks (broiler, breeder).

5. INDICATIONS FOR USE

Indications for use

Treatment of infections caused by bacteria susceptible to amoxicillin.

6. CONTRAINDICATIONS

Contraindications

Do not use in the presence of ß-lactamase-producing bacteria.
Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.
Do not use in cases of hypersensitivity to the active substance or other substances from the beta-lactam group or to any of the excipients.
Do not use in ruminants or horses.

7. SPECIAL WARNINGS

Special warnings

Special precautions for safe use in the target species:
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the veterinary medicinal 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 veterinary medicinal 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 contact with the veterinary medicinal product.
Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin and eyes.
Do not smoke, eat or drink while handling the veterinary medicinal product.
During preparation and administration of the medicated drinking water, skin contact with the veterinary medicinal product and inhalation of dust particles should be avoided.
Personal protective equipment consisting of 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 should be worn when mixing and handling the veterinary medicinal 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, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Laying birds:
Laboratory studies in rats have not produced any evidence of a teratogenic effects due to the administration of amoxicillin.
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interactions 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 ß-lactam antibiotics and aminoglycosides.

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

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

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water or liquid feed containing biocidal products, feed additives or other substances used in drinking water.

8. ADVERSE EVENTS

Adverse events

Chickens, turkeys, ducks:

Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reactions Allergic reactions[1]

[1] May occasionally be serious.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use.

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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product/kg body weight/day) for 3 consecutive days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice 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.

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of amoxicillin may need to be adjusted accordingly.

The use of suitably calibrated measuring equipment is recommended.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{… mg veterinary medicinal product/kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{… mg veterinary medicinal product per litre of drinking water}$$

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.

Maximum solubility of the veterinary medicinal 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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Chickens:	meat and offal:	1 day.
Turkeys:	meat and offal:	5 days.
Ducks:	meat and offal:	9 days.

Not for use in birds producing eggs for human consumption.
Do not use within 4 weeks before the start of the laying period.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of sight and reach of children.
Store below 25 ºC. Store in a dry place. Store in the original container.
Keep the container tightly closed in order to protect from moisture.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 28365/4013

Pack sizes

- Securitainer: 100 g, 250 g, 500 g, 1 kg.
- Bucket: 1 kg, 2.5 kg, 5 kg.

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands
Tel: +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

18. OTHER INFORMATION

Other information

POM-V

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 1 month.
Shelf life after dissolution according to directions: 12 hours.
Once opened use by…

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Securitainer 100 g}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxy Active CTD 697 mg/g powder for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

100 g

4. TARGET SPECIES

For chickens (broiler, pullet, breeder), turkeys, ducks (broiler, breeder).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Chickens: meat and offal: 1 day.
Turkeys: meat and offal: 5 days.
Ducks: meat and offal: 9 days.
Not for use in birds producing eggs for human consumption.
Do not use within 4 weeks before the start of the laying period.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 1 month.
Once dissolved according to directions, use within 12 hours.
Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 ºC. Store in a dry place. Store in the original container.
Keep the container tightly closed in order to protect from moisture.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 28365/4013

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each gram contains:

Active substances:

Amoxicillin	697 mg
as amoxicillin trihydrate	800 mg

White to off-white powder.

3. Target species

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

4. Indications for use

Treatment of infections caused by bacteria susceptible to amoxicillin.

5. Contraindications

Do not use in the presence of ß-lactamase-producing bacteria.
Do not use in rabbits, guinea pigs, hamsters, gerbils or any other small herbivores.
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Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
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9. Advice on correct administration

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10. Withdrawal periods

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Turkeys: meat and offal: 5 days.
Ducks: meat and offal: 9 days.
Not for use in birds producing eggs for human consumption.
Do not use within 4 weeks before the start of the laying period.

11. Special storage precautions

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Shelf life after dissolution according to directions: 12 hours.

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13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 28365/4013

List of pack sizes:
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Marketing authorisation holder and contact details to report suspected adverse events:
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Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands
Tel: +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

17. Other information

POM-V

Gavin Hall
Approved: 17 December 2025