[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxy Active CTD 697 mg/g powder for use in drinking water for chickens, turkeys and ducks (DE, HU, IT, NL, PL, RO, UK)

Amdocyl CTD 697 mg/g powder for use in drinking water for chickens, turkeys and ducks (FR, LT)

Aviamox 697 mg/g powder for use in drinking water for chickens, turkeys and ducks (ES)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:

Amoxicillin	697 mg
as amoxicillin trihydrate	800 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium carbonate
Sodium citrate

White to off-white powder.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

Treatment of infections caused by bacteria susceptible to amoxicillin.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet or immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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 ß-lactam antibiotics and aminoglycosides.

3.9 Administration routes and dosage

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/day) 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.

Prepare the solution with fresh potable 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01CA04

4.2 Pharmacodynamics

Amoxicillin is a time-dependent bactericidal antibiotic belonging to the semisynthetic penicillin group which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. It has a broad spectrum of activity against Gram positive and Gram negative bacteria, and owes its activity to the inhibition of the development of the peptidoglycan network structure in the bacterial cell wall.

There are three main mechanisms of resistance to beta-lactams: beta-lactamase production, altered expression and/or modification of penicillin binding proteins (PBP), and decreased penetration of the outer membrane. One of the most important is the inactivation of penicillin by beta-lactamase enzymes produced by certain bacteria. These enzymes are capable of cleaving the beta-lactam ring of penicillins, making them inactive. The beta-lactamase could be encoded in chromosomal or plasmidic genes.
Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.
The use of extended spectrum beta-lactam drugs (e.g. aminopenicillins) might lead to the selection of multi-resistant bacterial phenotypes (e.g. those producing extended spectrum beta-lactamases (ESBLs)).

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 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.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 1 month.
Shelf life after dissolution according to directions: 12 hours.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

- Securitainer: white cylindrical polypropylene container, covered with a low-density polyethylene closure.
The securitainer contains 100 g, 250 g, 500 g or 1 kg of veterinary medicinal product.
- Bucket: white polypropylene square container provided with a polypropylene closure.
The bucket contains 1 kg, 2.5 kg or 5 kg of veterinary medicinal product.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - 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 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 or its local representative using the contact details on this label, or via your national reporting system.

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:

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

average daily 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 the 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

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. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

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

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

Local representative and contact details to report suspected adverse events:
{Name}
<{Address}
{Country} - {Town} {Code}>
Tel: + {Telephone number}
<{E-mail}>

18. OTHER INFORMATION

<Other information

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}

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

15. BATCH NUMBER

Lot {number}

B. 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.
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.

6. 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.
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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 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.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, 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 or its local representative using the contact details at the end of this leaflet, or via your national reporting system.

8. 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.

9. 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.

10. 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.

11. Special storage precautions

Keep out of the 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.

Shelf life after first opening the immediate packaging: 1 month.
Shelf life after dissolution according to directions: 12 hours.

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

List of 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.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

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

Local representative and contact details to report suspected adverse events:
{Name}
<{Address}
{Country} - {Town} {Code}>
Tel: + {Telephone number}
<{E-mail}>

<17. Other information
