ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

Securitainer (250 g, 500 g, 1 kg) and bucket (1 kg, 2.5 kg, 5 kg)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxy Active, 697 mg/g, oral powder for pigs and chickens.

2. COMPOSITION

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

White to off-white oral powder.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs and chickens (broilers, pullets, chickens for reproduction).

5. INDICATIONS FOR USE

Indications for use

Pigs: Treatment of respiratory tract infections, gastro-intestinal tract infections, urogenital infections, secondary infections following viral infections and septicaemia caused by micro-organisms susceptible to amoxicillin.

Chickens: Treatment of respiratory tract infections and gastro-intestinal tract infections caused by micro-organisms susceptible to amoxicillin.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to penicillin or other substances of the beta-lactam group or to any of the excipients.
Do not use in the presence of ß-lactamase-producing bacteria.
Do not use in lagomorphs and rodents such as guinea pigs, hamsters or gerbils.
Do not use in animals with serious kidney malfunction including anuria and oliguria.
Do not use in ruminants or horses.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
Sick animals have an altered drinking behaviour and should be medicated parenterally where applicable.

Special precautions for 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 label 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.
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, you should seek medical advice 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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects.
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 ß-lactam antibiotics and aminoglycosides.

Overdose:
In case of overdosing no other effects are known than mentioned in section Adverse events.

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

8. ADVERSE EVENTS

Adverse events

Pigs and chickens:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions* Digestive tract disorder (vomiting, diarrhoea)

*the severity varying from skin rash to anaphylactic shock.

Reporting adverse events is important. It allows continuous safety monitoring of a 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.

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

Dosage for each species, routes and method of administration

In drinking water use in pigs and chickens.

Pigs:
The recommended dose is 11.2 mg amoxicillin per kg of body weight daily (corresponding to 16.1 mg of the veterinary medicinal product per 1 kg of body weight per day) given for 3 - 5 consecutive days.

Chickens:
The recommended dose is 20 mg amoxicillin per kg of body weight daily (corresponding to 28.7 mg of the veterinary medicinal product per 1 kg of body weight per day) given for 3 - 5 consecutive days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The use of suitably calibrated measuring equipment is recommended.

For the preparation of medicated water the body weight of the animals to be treated and their actual daily water consumption should be taken into account. Consumption may vary depending on factors like species, age, state of health, breed and husbandry system (e.g. different temperature, different light regimes). 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.
Preparation of medicated water should provide an amount to be consumed within the next 12 hours. Any unused medicated water should be discarded after 12 hours, and freshly medicated water for the next 12 hours should be prepared.
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:

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

The veterinary medicinal product should be added to the drinking water by thorough stirring until the veterinary medicinal product is completely dissolved. Maximum solubility of the veterinary medicinal product in water is approximately 6 g/litre. Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. In free range husbandry systems animals should be kept in the stable during treatment.
Where applicable the water supply system should be cleaned appropriately after the end of the medication period to avoid intake of sub-therapeutic amounts of the active substance.

11. WITHDRAWAL PERIODS

Withdrawal periods

Pigs: meat and offal: 2 days.
Chickens: meat and offal: 1 day.
Not for use in birds producing eggs for human consumption.
Do not use within 4 weeks of 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 the original container.
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 or pharmacist 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 28365/3001

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

September 2023

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 reactions:
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

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: 28 days
Shelf life after dissolution according to directions: 12 hours
Once opened, use by …

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Securitainer (100 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amoxy Active, 697 mg/g, oral powder.

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

100 g

4. TARGET SPECIES

Pigs and chickens (broilers, pullets, chickens for reproduction).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use and in-feed use in pigs.
In drinking water use in chickens.

7. WITHDRAWAL PERIODS

Withdrawal period:
Pigs: meat and offal: 2 days.
Chickens: meat and offal: 1 day.
Not for use in birds producing eggs for human consumption.
Do not use within 4 weeks of the start of the laying period.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.
Once diluted in the drinking water, use within 12 hours.
Once incorporated into the feed, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 ºC. Store in the original container.

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 28365/3001

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Amoxy Active, 697 mg/g, oral powder for pigs and chickens.

2. Composition

Each g contains:

Active substance:

Amoxicillin	697 mg
as amoxicilline trihydrate	800 mg

White to off-white oral powder.

3. Target species

Pigs and chickens (broilers, pullets, chickens for reproduction).

4. Indications for use

Pigs: Treatment of respiratory tract infections, gastro-intestinal tract infections, urogenital infections, secondary infections following viral infections and septicaemia caused by micro-organisms susceptible to amoxicillin.

Chickens: Treatment of respiratory tract infections and gastro-intestinal tract infections caused by micro-organisms susceptible to amoxicillin.

5. Contraindications

Do not use in cases of hypersensitivity to penicillin or other substances of the beta-lactam group or to any of the excipients.
Do not use in the presence of ß-lactamase-producing bacteria.
Do not use in lagomorphs and rodents such as guinea pigs, hamsters or gerbils.
Do not use in animals with serious kidney malfunction including anuria and oliguria.
Do not use in ruminants or horses.

6. Special warnings

Special warnings:
Sick animals have an altered drinking behaviour and should be medicated parenterally where applicable.

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) epidemological information about susceptibility of the target bacteria. Use of the veterinary medicinal product deviating from the instructions given in the leaflet 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.
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Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
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.
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If you develop symptoms following exposure, such as a skin rash, you should seek medical advice 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.

Pregnancy and lactation:
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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 ß-lactam antibiotics and aminoglycosides.

Overdose:
In case of overdosing no other effects are known than mentioned in section Adverse events.

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

7. Adverse events

Pigs and chickens:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions* Digestive tract disorder (vomiting, diarrhoea)

*the severity varying from skin rash to anaphylactic shock.

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 using the contact details at the end of this leaflet, or via your national reporting system.

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

In drinking water use and in-feed use in pigs.
In drinking water use in chickens.

Pigs:
The recommended dose is 11.2 mg amoxicillin per kg of body weight daily (corresponding to 16.1 mg of the veterinary medicinal product per 1 kg of body weight per day) given for 3 - 5 consecutive days.

Chickens:
The recommended dose is 20 mg amoxicillin per kg of body weight daily (corresponding to 28.7 mg of the veterinary medicinal product per 1 kg of body weight per day) given for 3 - 5 consecutive days.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing. The use of suitably calibrated measuring equipment is recommended.

In drinking water use:
For the preparation of medicated water the body weight of the animals to be treated and their actual daily water consumption should be taken into account. Consumption may vary depending on factors like species, age, state of health, breed and husbandry system (e.g. different temperature, different light regimes). 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.
Preparation of medicated water should provide an amount to be consumed within the next 12 hours. Any unused medicated water should be discarded after 12 hours, and freshly medicated water for the next 12 hours should be prepared.

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:

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The veterinary medicinal product should be added to the drinking water by thorough stirring until the veterinary medicinal product is completely dissolved. Maximum solubility of the veterinary medicinal product in water is approximately 6 g/litre. Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. In free range husbandry systems animals should be kept in the stable during treatment.
Where applicable the water supply system should be cleaned appropriately after the end of the medication period to avoid intake of sub-therapeutic amounts of the active substance.

In-feed use:
The veterinary medicinal product may also be offered via the feed at the recommended daily dose. This way of administration is only intended for the treatment of individual pigs on farms where only a small number of pigs are to receive the treatment. Only the pack size of 100 g is suitable for the in-feed use.
Larger groups should be treated with medicated drinking water.
Before each administration the powder should be thoroughly mixed into a small amount of food and should be given directly to the animal before the main ration. Care should be taken that the intended dose will be completely ingested.

10. Withdrawal periods

Pigs: meat and offal: 2 days.
Chickens: meat and offal: 1 day.
Not for use in birds producing eggs for human consumption.
Do not use within 4 weeks of 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 the original container.
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 of the immediate packaging: 28 days.
Shelf life after dissolution according to directions: 12 hours.
Shelf life after incorporation into meal: use immediately.

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 or pharmacist 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

Vm 28365/3001

- 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

September 2023

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 reactions:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
Tel: +31-162-582000
pharmacovigilance@dopharma.com

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

<17. Other information>

Approved 10 January 2024