ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET/ALU/PE bag of 100 g, 200 g, 500 g, 1 kg, 5 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhemox Forte, 1000 mg/g Powder for use in Drinking Water for chickens, ducks, turkeys
amoxicillin trihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:
Active substance:

Amoxicillin trihydrate	1000 mg
(equivalent to amoxicillin	871.24 mg)

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

4. PACKAGE SIZE

100 g
200 g
500 g
1 kg
5 kg

5. TARGET SPECIES

Chickens, ducks, turkeys

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal:

Chickens:	1 day
Ducks:	9 days
Turkeys:	5 days

Not for use in birds producing or intended to produce eggs for human consumption.

Do not use within 3 weeks of the start of laying period.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
100 g, 200 g, 500 g:
Once opened, use within 3 months
Use by:

1 kg, 5 kg:
Once opened, use within 6 months
Use by:

Shelf life after dilution according to directions: 24 hours
Any medicated water which is not consumed within 24 hours should be discarded.

11. SPECIAL STORAGE CONDITIONS

Store in a dry place.
Keep the bag tightly closed after first opening in order to protect from moisture and light.
This veterinary medicinal product does not require any special temperature storage conditions.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
Veterinary prescription only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona), Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

Package Leaflet

Rhemox Forte, 1000 mg/g Powder for use in Drinking Water for chickens, ducks, turkeys

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona), Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhemox Forte, 1000 mg/g Powder for use in Drinking Water for chickens, ducks, turkeys
Amoxicillin trihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each g contains:

Active substance:

Amoxicillin trihydrate	1000 mg
(equivalent to amoxicillin	871.24 mg)

White to off-white powder.

4. INDICATION(S)

Treatment of infections in chickens, ducks and turkeys caused by bacteria susceptible to amoxicillin.

5. CONTRAINDICATIONS

Do not use in animals with hypersensitivity to penicillins and other ß-lactam antibiotics.
Do not use in ruminants and horses and lagomorphs and rodents such as rabbits, hamsters, gerbils and guinea pigs.
Do not administer to animals with renal disease including anuria or oliguria.

6. ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity reactions following administration in very rare occasions. Allergic reactions to these substances may occasionally be serious. If suspected adverse reactions do occur, treatment should be discontinued immediately.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Chickens, ducks, turkeys

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

In drinking water use.

Dosage:
Use the following formula in order to calculate the quantity of the product (mg) that should be incorporated in the drinking water tank:

$$\frac{Dose\ \begin{matrix}(mg\ product\ per\ kg \\ body\ weight\ per\ day)\end{matrix} * \begin{matrix}mean\ body\ weight\ (kg) \\ of\ animals\ to\ be\ treated\end{matrix}}{mean\ daily\ water\ consumption\ (litre)\ per\ animal\ per\ day} = \_\_ mg\ \begin{matrix}product\ per\ litre \\ drinking\ water\end{matrix}$$

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.

Suitably calibrated weighing equipment should be used for dispensing the calculated amount of the product.

Solubility in water varies depending on temperature and water quality as well as on time and intensity of stirring. Under worst case conditions (4 °C and soft water) maximum solubility is approximately 1.0 g/l but increases by raising temperature. At 20 °C and in hard water maximum solubility is increased to at least 2.1 g/l. Complete dissolution of the powder should be ensured.

For stock solutions and for use of a proportioner: Take care not to exceed 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 treated. Moderate increase of temperature and constant stirring can help to raise solubility.

Chickens
Recommended dosage is 15 mg amoxicillin trihydrate/kg bodyweight.
The total period of treatment should be for 3 consecutive days or in severe cases for 5 consecutive 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 consecutive days or in severe cases for 5 consecutive days.

Administration route:
The product is administered in the drinking water. Prepare the solution with fresh tap water immediately before use. Any unused medicated water should be discarded after 24 hours.
In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.
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.

9. ADVICE ON CORRECT ADMINISTRATION

Please refer to section “Dosage for each species, route(s) and method of administration”.

10. WITHDRAWAL PERIOD(S)

Meat and offal:

Chickens:	1 day
Ducks:	9 days
Turkeys:	5 days

Not for use in birds producing or intended to produce eggs for human consumption.
Do not use within 3 weeks of the start of laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a dry place.
Keep the bag tightly closed after first opening in order to protect from moisture and light.

This veterinary medicinal product does not require any special temperature storage conditions.

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:

100 g, 200 g, 500 g:	3 months
1 kg, 5 kg:	6 months

Shelf life after dilution or reconstitution according to directions: 24 hours
Any medicated water which is not consumed within 24 hours should be discarded.

12. 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 SPC 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 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.

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:

- Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non disposable respirator to European Standard EN140 with a filter to EN143.
- Wear impervious gloves during preparation and administration of medicated water.
- Wash any exposed skin after handling the product or medicated water.
- Wash hands after use.

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.
Pregnancy/Lactation/Lay:
Laboratory studies in rats have not produced any evidence of a teratogenic effect 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:
The product should not be administered with antibiotics that have a bacteriostatic mode of action, such as tetracyclines, macrolides, sulphonamides.
Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.

Overdose (symptoms, emergency procedures, antidotes):
No side effects with overdosage have been reported. 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2021

15. OTHER INFORMATION

Package size:
Bag of 100 g
Bag of 200 g
Bag of 500 g
Bag of 1 kg
Bag of 5 kg

Not all pack sizes may be marketed.

C. COMBINED LABEL AND PACKAGE LEAFLET

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

100 g, 200 g, 500 g, 1 kg, 5 kg PET/ALU/PE bag

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona), Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rhemox Forte, 1000 mg/g Powder for use in Drinking Water for chickens, ducks, turkeys
Amoxicillin trihydrate

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each g contains:
Active substance:
Amoxicillin trihydrate 1000 mg
(equivalent to amoxicillin 871.24 mg)

White to off-white powder.

4. PHARMACEUTICAL FORM

Powder for use in drinking water.

5. PACKAGE SIZE

100 g
200 g
500 g
1 kg
5 kg

6. INDICATION(S)

Treatment of infections in chickens, ducks and turkeys caused by bacteria susceptible to amoxicillin.

7. CONTRAINDICATIONS

Do not use in animals with hypersensitivity to penicillins and other ß-lactam antibiotics.
Do not use in ruminants and horses and lagomorphs and rodents such as rabbits, hamsters, gerbils and guinea pigs.
Do not administer to animals with renal disease including anuria or oliguria.

8. ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity reactions following administration in very rare occasions. Allergic reactions to these substances may occasionally be serious. If suspected adverse reactions do occur, treatment should be discontinued immediately.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

9. TARGET SPECIES

Chickens, ducks, turkeys

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

In drinking water use.

Dosage:
Use the following formula in order to calculate the quantity of the product (mg) that should be incorporated in the drinking water tank:

$$\frac{Dose \begin{matrix}(mg\ product\ per\ kg \\ body\ weight\ per\ day)\end{matrix} * \begin{matrix}mean\ body\ weight\ (kg) \\ of\ animals\ to\ be\ treated\end{matrix}}{mean\ daily\ water\ consumption\ (litre)\ per\ animal\ per\ day} = \_\_ mg \begin{matrix}product\ per\ litre \\ drinking\ water\end{matrix}$$

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.

Suitably calibrated weighing equipment should be used for dispensing the calculated amount of the product.

Solubility in water varies depending on temperature and water quality as well as on time and intensity of stirring. Under worst case conditions (4 °C and soft water) maximum solubility is approximately 1.0 g/l but increases by raising temperature. At 20 °C and in hard water maximum solubility is increased to at least 2.1 g/l. Complete dissolution of the powder should be ensured.

For stock solutions and for use of a proportioner: Take care not to exceed 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 treated. Moderate increase of temperature and constant stirring can help to raise solubility.

Chickens
Recommended dosage is 15 mg amoxicillin trihydrate/kg bodyweight.
The total period of treatment should be for 3 consecutive days or in severe cases for 5 consecutive 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 consecutive days or in severe cases for 5 consecutive days.

Administration route:
The product is administered in the drinking water. Prepare the solution with fresh tap water immediately before use. Any unused medicated water should be discarded after 24 hours.
In order to ensure consumption of the medicated water, animals should not have access to other water supplies whilst being treated.
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.

11. ADVICE ON CORRECT ADMINISTRATION

Please refer to section “Dosage for each species, route(s) and method of administration”.

12. WITHDRAWAL PERIOD(S)

Meat and offal:
Chickens: 1 day
Ducks: 9 days
Turkeys: 5 days
Not for use in birds producing or intended to produce eggs for human consumption.
Do not use within 3 weeks of the start of laying period.

13. SPECIAL STORAGE PRECAUTIONS

Store in a dry place.
Keep the bag tightly closed after first opening in order to protect from moisture and light.

This veterinary medicinal product does not require any special temperature storage conditions.

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.

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 SPC 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 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.

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:

- Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non disposable respirator to European Standard EN140 with a filter to EN143.

- Wear impervious gloves during preparation and administration of medicated water.
- Wash any exposed skin after handling the product or medicated water.
- Wash hands after use.

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.

Pregnancy/Lactation/Lay:
Laboratory studies in rats have not produced any evidence of a teratogenic effect 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:
The product should not be administered with antibiotics that have a bacteriostatic mode of action, such as tetracyclines, macrolides, sulphonamides.
Not to be used simultaneously with neomycin since it blocks the absorption of oral penicillins.

Overdose (symptoms, emergency procedures, antidotes):
No side effects with overdosage have been reported. 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 PRODUCT 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 LABEL WAS LAST APPROVED

March 2021

17. OTHER INFORMATION

Package sizes:
Bag of 100 g
Bag of 200 g
Bag of 500 g
Bag of 1 kg
Bag of 5 kg

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

<Address>

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. Veterinary prescription only.

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 {month/year}
100 g, 200 g, 500 g:
Once opened, use within 3 months
Use by:

1 kg, 5 kg:
Once opened, use within 6 months
Use by:

Shelf life after dilution according to directions: 24 hours
Any medicated water which is not consumed within 24 hours should be discarded.

21. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4001

22. MANUFACTURER'S BATCH NUMBER

Batch {number}

Approved 02 July 2021