ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 200 g intended to be used in the package of 20 x 200 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CITRAMOX 1000 mg/g POWDER FOR USE IN DRINKING WATER FOR CHICKENS, TURKEYS, DUCKS AND PIGS
Amoxicillin trihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substance:
Amoxicillin trihydrate.....1000 mg
(equivalent to 871.2 mg Amoxicillin)

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
A white powder. Clear and colourless liquid when in solution.

4. PACKAGE SIZE

200g bag

5. TARGET SPECIES

Chickens, ducks, turkeys, pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal:

Chickens	1 day
Ducks	9 days
Turkeys	5 days
Pigs	2 days

Not authorised for use in laying birds producing eggs for human consumption and within 3 weeks before the onset of the laying period.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 3 months
Once opened, use by _____
Shelf life after dilution or reconstitution according to directions: 24 hours

11. SPECIAL STORAGE CONDITIONS

Keep the bags tightly closed.

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

Disposal: read the package leaflet.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Marketing authorisation holder:
Laboratorios Karizoo, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 - Caldes de Montbui (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31223/4006

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box containing 20 x 200 g-bags

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CITRAMOX 1000 mg/g POWDER FOR USE IN DRINKING WATER FOR CHICKENS, TURKEYS, DUCKS AND PIGS
Amoxicillin trihydrate

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substance:
Amoxicillin trihydrate.....1000 mg
(equivalent to 871.2 mg Amoxicillin)

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
A white powder. Clear and colourless liquid when in solution.

4. PACKAGE SIZE

20 x 200g bag

5. TARGET SPECIES

Chickens, ducks, turkeys, pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal:

Chickens	1 day
Ducks	9 days
Turkeys	5 days
Pigs	2 days

Not authorised for use in laying birds producing eggs for human consumption and within 3 weeks before the onset of the laying period.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 24 hours

11. SPECIAL STORAGE CONDITIONS

Keep the bags tightly closed.

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

Disposal: read the package leaflet.

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

For animal treatment only.
To be supplied only on veterinary prescription.

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

Marketing authorisation holder:
Laboratorios Karizoo, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 - Caldes de Montbui (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31223/4006

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
CITRAMOX 1000 mg/g powder for use in drinking water for chickens, turkeys, ducks and pigs

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

Marketing authorisation holder and manufacturer responsible for batch release:
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CITRAMOX 1000 mg/g POWDER FOR USE IN DRINKING WATER FOR CHICKENS, TURKEYS, DUCKS AND PIGS
Amoxicillin trihydrate

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

Each g contains:

Active substance:
Amoxicillin trihydrate.....1000 mg
(equivalent to 871.2 mg Amoxicillin)

A white powder. Clear and colourless liquid when in solution.

4. INDICATION(S)

Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.
Pigs: For the treatment of pasteurellosis.

5. CONTRAINDICATIONS

This product should not be administered to horses or to rabbits, guinea pigs, hamsters, gerbils or any other small herbivore.
Do not use in animals with known hypersensitivity to penicillins or other ß-lactam antibiotics.
Do not administer to animals with renal disease including anuria or oliguria.

6. ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious.

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, pigs.

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

In drinking water use.

Prepare the solution with fresh potable water immediately before use. Any medicated water which is not consumed within 24 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 of product per litre of drinking water):

x mg product per kg bodyweight per day	X	mean bodyweight (kg) of animals to be treated	
Mean daily water consumption (litres) per animal			= mg of product / litre of drinking water

Medicated water should be the only source of drinking water during the treatment period.

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 animals. In order to obtain the correct dosage the concentration of amoxicillin has to be adjusted taking into account water intake.

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

Ducks
Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 20 mg product/kg bodyweight/day) for 3 consecutive days.

Turkeys
Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 15-20 mg product/kg bodyweight/day) for 3 days or in severe cases for 5 days.

Pigs:
Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 20 mg product/kg bodyweight/day) daily for up to 5 days.

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.

Solubility in drinking water varies depending on temperature and water quality. Maximum solubility is approximately 1 g/l at 4ºC in soft water but increases to 2 g/l at 20ºC in hard water.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Meat and offal:

Chickens	1 day
Ducks	9 days
Turkeys	5 days
Pigs	2 days

Not authorised for use in laying birds producing eggs for human consumption and within 3 weeks before the onset of the laying period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the bags tightly closed.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 3 months
Shelf life after dilution or reconstitution according to directions: 24 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
Not effective against beta-lactamase producing organisms.
Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.
Pigs: The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead.
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 package 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 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 the active substance or who have been advised not to work with such preparations should avoid contact with the veterinary medicinal product.
Handle this product with great care to avoid exposure, taking all recommended precautions.
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.
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 ENl43.
Wear gloves during preparation and administration of medicated water.
Wash any exposed skin after handling the product or medicated water. Wash hands after use.

Pregnancy and lactation:
Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.
Use only according to the benefit-risk assessment of 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.

Overdose (symptoms, emergency procedures, antidotes):
No problems with overdosage have been reported. Treatment should be symptomatic and 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. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2021

15. OTHER INFORMATION

Package size:
200 g bag
500 g bag
1kg bag
20 x 200 g bag
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.

For animal treatment only.
To be supplied only on veterinary prescription.

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

Bags of 200 g, 500 g and 1 kg

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

Marketing authorisation holder and manufacturer responsible for batch release:
Laboratorios Karizoo, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 - Caldes de Montbui (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CITRAMOX 1000 mg/g POWDER FOR USE IN DRINKING WATER FOR CHICKENS, TURKEYS, DUCKS AND PIGS
Amoxicillin trihydrate

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

Each g contains:

Active substance:
Amoxicillin trihydrate.....1000 mg
(equivalent to 871.2 mg Amoxicillin)

4. PHARMACEUTICAL FORM

Powder for use in drinking water.
A white powder. Clear and colourless liquid when in solution.

5. PACKAGE SIZE

200 g bag
500 g bag
1kg bag

6. INDICATION(S)

Treatment of infections in chickens, turkeys and ducks caused by bacteria susceptible to amoxicillin.
Pigs: For the treatment of pasteurellosis.

7. CONTRAINDICATIONS

This product should not be administered to horses or to rabbits, guinea pigs, hamsters, gerbils or any other small herbivore.
Do not use in animals with known hypersensitivity to penicillins or other ß-lactam antibiotics.
Do not administer to animals with renal disease including anuria or oliguria.

8. ADVERSE REACTIONS

Penicillins and cephalosporins may cause hypersensitivity reactions which may occasionally be serious.

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, pigs.

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

In drinking water use.

Prepare the solution with fresh potable water immediately before use. Any medicated water which is not consumed within 24 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 of product per litre of drinking water):

x mg product per kg bodyweight per day	X	mean bodyweight (kg) of animals to be treated	= mg of product / litre of drinking water
Mean daily water consumption (litres) per animal			

Medicated water should be the only source of drinking water during the treatment period.

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 animals. In order to obtain the correct dosage the

concentration of amoxicillin has to be adjusted taking into account water intake.

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

Ducks
Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 20 mg product/kg bodyweight/day) for 3 consecutive days.

Turkeys
Recommended dosage is 15-20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 15-20 mg product/kg bodyweight/day) for 3 days or in severe cases for 5 days.

Pigs:
Recommended dosage is 20 mg amoxicillin trihydrate/kg bodyweight (corresponding to 20 mg product/kg bodyweight/day) daily for up to 5 days.

Solubility in drinking water varies depending on temperature and water quality. Maximum solubility is approximately 1 g/l at 4ºC in soft water but increases to 2 g/l at 20ºC in hard water.

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. ADVICE ON CORRECT ADMINISTRATION

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.

12. WITHDRAWAL PERIOD

Meat and offal:

Chickens	1 day
Ducks	9 days
Turkeys	5 days
Pigs	2 days

Not authorised for use in laying birds producing eggs for human consumption and within 3 weeks of onset of laying.

13. SPECIAL STORAGE PRECAUTIONS

Keep the bags tightly closed.

14. SPECIAL WARNING(S)

Special warnings for each target species
None

Special precautions for use in animals
Not effective against beta-lactamase producing organisms.
Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.
Pigs: The uptake of medication by animals may be altered as a consequence of illness. In case of insufficient water uptake, animals should be treated parenterally instead.
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 package 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 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 the active substance or who have been advised not to work with such preparations should avoid contact with the veterinary medicinal product.
Handle this product with great care to avoid exposure, taking all recommended precautions.
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.
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 ENl43.
Wear gloves during preparation and administration of medicated water.
Wash any exposed skin after handling the product or medicated water. Wash hands after use.

Pregnancy and lactation
Laboratory studies in rats have not produced any evidence of a teratogenic effect due to the administration of amoxicillin.
Use only according to the benefit-risk assessment of 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.

Overdose (symptoms, emergency procedures, antidotes), if necessary
No problems with overdosage have been reported. Treatment should be symptomatic and 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. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

16. DATE ON WHICH THE TEXT WAS LAST APPROVED

May 2021

17. OTHER INFORMATION

Pack sizes:
200 g bag
500 g bag
1kg bag
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.

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

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 {month/year}

Do not use this veterinary medicinal product after the expiry date which is stated on the bag after “EXP”. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 3 months
Once opened, use by...
Shelf life after dilution or reconstitution according to directions: 24 hours

21. MARKETING AUTHORISATION NUMBER(S)

Vm 31223/4006

22. MANUFACTURER’S BATCH NUMBER

Batch {number}

Approved: 18/05/21