ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (100/250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CITRAMOX L.A. 150 mg/ml suspension for injection for cattle and pigs (RMS)
Amoxicillin (as trihydrate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Amoxicillin 150.00 mg
(equivalent to 172.20 mg of amoxicillin trihydrate)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

1x100 ml
1x250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle:
Meat and offal: 18 days
Milk: 3 days
Pigs:
Meat and offal:20 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Penicillin and cephalosporin may occasionally cause severe allergic reactions. See package leaflet for full user warnings

10. EXPIRY DATE

EXP
Once broached use by 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

Dispose of waste material in accordance with local requirements.

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

Laboratorios Karizoo S.A.
Polígono Industrial La BordaMas Pujades, 11-12
08140 Caldes de Montbui
Barcelona
Spain
Tel: +34 93 865 41 48
Fax: +34 93 865 46 48
E-mail: karizoo@karizoo.com

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31223/4010

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle (100/250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CITRAMOX L.A. 150 mg/ml suspension for injection for cattle and pigs (RMS)
Amoxicillin (as trihydrate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Amoxicillin 150.00 mg
(equivalent to 172.20 mg of amoxicillin trihydrate)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle:
Meat and offal: 18 days
Milk: 3 days
Pigs:
Meat and offal: 20 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Penicillin and cephalosporin may occasionally cause severe allergic reactions. See package leaflet for full user warnings

10. EXPIRY DATE

EXP
Once broached use by 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

Dispose of waste material in accordance with local requirements.

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

Laboratorios Karizoo S.A.
Polígono Industrial La BordaMas Pujades, 11-12
08140 Caldes de Montbui
Barcelona
Spain
Tel: +34 93 865 41 48
Fax: +34 93 865 46 48
E-mail: karizoo@karizoo.com

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31223/4010

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

CITRAMOX L.A. 150 mg/ml suspension for injection for cattle and pigs (RMS)

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

Marketing authorisation holder:
Laboratorios Karizoo S.A.
Polígono Industrial La BordaMas Pujades, 11-12
08140 Caldes de Montbui
Barcelona
Spain
Tel: +34 93 865 41 48
Fax: +34 93 865 46 48
E-mail: karizoo@karizoo.com

Manufacturer responsible for batch release:
Vet-Agro Multi-Trade Company Sp. z o. o.
Gliniana 32, 20-616 Lublin
Poland
Tel. +48 81 44 52 300
Fax +48 81 44 52 320
E-mail: vet-agro@vet-agro.pl

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CITRAMOX L.A. 150 mg/ml suspension for injection for cattle and pigs (RMS)

Amoxicillin (as trihydrate)

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

Each ml contains:
Active substance:
Amoxicillin 150.00 mg
(equivalent to 172.20 mg of amoxicillin trihydrate)

White to almost white suspension.

4. INDICATION(S)

In cattle:
Treatment of respiratory infections caused by *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to amoxicillin.
In pigs:
Treatment of respiratory infections caused by *Pasteurella multocida* susceptible to amoxicillin.

5. CONTRAINDICATIONS

Do not use in cases of known hypersensitivity to penicillins, cephalosporins or to any of the excipients.
Do not use in cases of severe renal dysfunction with anuria and oliguria.
Do not use in rabbits, hares, hamsters, guinea pigs or other small herbivores.
Do not administer to Equidae, because amoxicillin – like all aminopenicillins – may adversely affect the bacterial flora of the caecum.
Do not administer intravenously.

6. ADVERSE REACTIONS

Hypersensitivity reactions, varying in severity from a light skin reaction such as urticaria to anaphylactic shock.
Although the penicillins are not considered hepatotoxic, elevated liver enzymes have been reported.

In cattle, local reactions and swelling at the injection site may occur, but always of low intensity and recedes spontaneously and quickly. In pigs small indurations at the injection site may be observed.

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

Cattle and pigs

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

Intramuscular use.
To ensure a correct dosage and to avoid underdosing, body weight should be determined as accurately as possible.
15 mg amoxicillin per kg bodyweight; corresponding to 1 ml of the veterinary medicinal product per 10 kg. Administration should be repeated once after 48 hours.
In cattle, do not administer more than 20 ml of the veterinary medicinal product per injection site.
In pigs, do not administer more than 6 ml of the veterinary medicinal product per injection site.
A separate injection site should be used for each administration.
Shake the vial vigorously to achieve full resuspension before use. As with other injectable preparations normal aseptic precautions should be observed.
For 100 ml vials: Do not broach the vial more than 15 times: if necessary, use automatic syringes.
For 250 ml vials: Do not broach the vial more than 20 times: if necessary, use automatic syringes.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 18 days
Milk: 3 days
Pigs:
Meat and offal: 20 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30^{o}C.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: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:

The product is not effective against beta-lactamase producing organisms. Complete cross-resistance has been shown between amoxicillin and other penicillins, in particular amino-penicillins. Use of the product/amoxicillin should be carefully considered when antimicrobial susceptibility testing has shown resistance to penicillins because its effectiveness may be reduced.

Special precautions for use in animals:

Use of the product should be based on identification and susceptibility testing of the target pathogen(s) isolated from the animal. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
Use of the product deviating from the instructions given in the package leaflet may increase the prevalence of bacteria resistant to amoxicillin and may decrease the effectiveness of treatment with other penicillins, due to the potential for cross-resistance.

The feeding of waste milk containing residues of amoxicillin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillin and cephalosporin may cause an allergic reaction following accidental injection, inhalation ingestion or absorption via the skin, which may be life threatening.
Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. People with known hypersensitivity to penicillins or cephalosporins, should avoid contact with the veterinary medicinal product.Handle the product with great care to avoid exposure.
Wear gloves and wash hands after use of the product.
If accidental exposure to the skin or eyes occur, wash immediately with plenty of water.
Do not smoke, eat or drink during use of the product.
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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects of amoxicillin. However, the tolerance of the medicinal product in cattle and pigs during pregnancy and lactation has not been investigated. In these cases, use only in accordance with the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not use with antibiotics, which inhibit bacterial protein synthesis, as these can antagonise the bactericidal action of penicillins.
Because there is evidence of in vitro antagonism between beta-lactam antibiotics and bacteriostatic antibiotics (e.g. chloramphenicol, erythromycin and other macrolides, tetracyclines, sulfonamides, etc.), use together has been generally not recommended, but actual clinical importance is not clear. There is also synergic action of penicillins with aminoglycosides.
Amoxicillin may decrease the renal excretion of methotrexate causing increased levels and potential toxic effects.
Probenecid competitively blocks the tubular secretion of most penicillins, thereby increasing serum levels and serum half-lives.

Overdose (symptoms, emergency procedures, antidotes):
Amoxicillin has a wide safety margin. In case of overdose, treatment is symptomatic. High doses or very prolonged use have been associated with neurotoxicity.

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

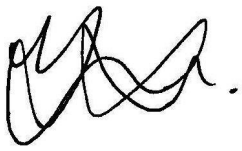
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size:
Cardboard box with 1 vial of 100 ml.
Cardboard box with 1 vial of 250 ml.

Not all pack sizes may be marketed.



Approved: 12 February 2021