

**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](mailto: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  
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E-mail: [karizoo@karizoo.com](mailto: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](mailto: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](mailto: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°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 colostrum 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**

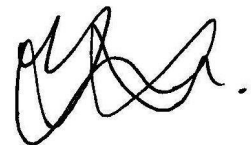
**15. OTHER INFORMATION**

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.

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 12 February 2021