ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelamoxil LA 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Amoxicillin (as trihydrate) 150 mg/ml

3. PACKAGE SIZE

100 ml
250 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

IM

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Meat and offal: 18 days
Milk: 72 hours

Pigs:
Meat and offal: 20 days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C

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

Kela nv

14. MARKETING AUTHORISATION NUMBERS

Vm 06126/3001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Glass vial or PET vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelamoxil LA 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:
Amoxicillin (as trihydrate) 150 mg/ml

3. TARGET SPECIES

Cattle and   pigs

4. ROUTES OF ADMINISTRATION

IM

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Meat and offal: 18 days
Milk: 72 hours

Pigs:
Meat and offal: 20 days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Kela nv

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Kelamoxil LA 150 mg/ml suspension for injection for cattle and pigs

2. Composition

Each ml contains:
Active substance:
Amoxicillin 150 mg
(equivalent to 172.2 mg of amoxicillin trihydrate)

Excipients:

Qualitative composition of excipients and other constituents
Silica, colloidal anhydrous
Sorbitan oleate
Propylene glycol dicaprylocaprate

Suspension for injection.
White to grey-white oily suspension.

3. Target species

Cattle and pigs

4. Indications for use

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

In pigs:
Treatment of respiratory infections caused by *Pasteurella multocida*

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 case of infection with beta-lactamase-producing bacteria.
Do not administer to Equidae, because amoxicillin – like all aminopenicillins – may adversely affect the bacterial flora of the caecum.
Do not use in rabbits, hares, hamsters, guinea pigs or other small herbivores.

6. Special warnings

Special warnings:
This veterinary medicinal product is not effective against beta-lactamase producing organisms.
Cross-resistance has been shown between amoxicillin and other beta-lactam antibiotics. Use of the veterinary medicinal product should be carefully considered when susceptibility testing has shown resistance to beta-lactam antibiotics, because its effectiveness may be reduced.

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
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.
Do not administer intravenously.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillins and cephalosporins 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 veterinary medicinal product with great care to avoid exposure.
Wear gloves and wash hands after use of the veterinary medicinal product.
In case of contact with the skin or eyes, wash immediately with 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 veterinary 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.
As there is evidence of *in vitro* antagonism between beta-lactam antibiotics and bacteriostatic antibiotics (e.g. erythromycin and other macrolides, tetracyclines, sulfonamides, etc.), concomitant use is generally not recommended. Synergism with other beta-lactam antibiotics and aminoglycosides occurs.

Overdose:
Amoxicillin has a wide safety margin.

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

7. Adverse events

Cattle and pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site irritation[1]
Undetermined frequency (cannot be estimated from the available data)	Allergic reaction[2]

1) *The frequency may be decreased by reducing the volume of injection per injection site (see Advice on correct administration). The irritation is always of low intensity and recedes spontaneously and quickly.*
2) *Reactions, varying in severity from a light skin reaction such as urticaria to anaphylactic shock. In the case of allergic reactions, treatment should be discontinued and a symptomatic treatment should be initiated.*

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use.

Dosage: 15 mg amoxicillin per kg bodyweight; corresponding to 1 ml of the veterinary medicinal product / 10 kg BW.
Administration should be repeated once after 48 hours.

9. Advice on correct administration

To ensure a correct dosage and to avoid underdosing, body weight should be determined as accurately as possible.
Shake the vial vigorously to achieve full resuspension before use.
Do not administer more than 20 ml of the veterinary medicinal product per injection site in cattle.
Do not administer more than 6 ml of the veterinary medicinal product per injection site in pigs.
A separate injection site should be used for each administration.
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

10. Withdrawal periods

Cattle:
Meat and offal: 18 days
Milk: 72 hours

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 carton 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 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

Clear type II glass vial of 100 ml or 250 ml closed with type I laminated chlorobutyl rubber stopper and aluminium cap in a carton box.
Clear PET vial of 100 ml or 250 ml closed with type I laminated chlorobutyl rubber stopper and aluminium cap in a carton box.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Kela nv
Sint Lenaartseweg 48
2320 Hoogstraten
Belgium
Mobile : + 32 492 13 34 68
E-mail: Pharmacovigilance.vet@kela.health

17. Other information

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