1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Amoxicillin 150.0 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. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs

3.2 Indications for use for each target species

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

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

3.3 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.

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment
Not applicable

3.6 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 3.9). 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use (i.m.).
To ensure a correct dosage and to avoid underdosing, body weight should be determined as accurately as possible.

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Amoxicillin has a wide safety margin.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

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

Pigs:
Meat and offal: 16 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CA04

4.2 Pharmacodynamics

Amoxicillin is a broad-spectrum antibiotic of the aminopenicillin family with close structural relationship to ampicillin. Amoxicillin is a bactericide and is active against Gram-positive and Gram-negative bacteria. Amoxicillin is a semisynthetic penicillin and susceptible to the action of bacterial beta-lactamases. Amoxicillin is a time-dependent antibiotic.

The following Minimum Inhibitory Concentrations (MIC) have been determined for amoxicillin/ampicillin in European isolates (Germany, Spain, Sweden) between 2017 and 2020.

Bacteria Species	Origin	No of isolates	MIC of amoxicillin (µg/ml)		
			MIC range	MIC50	MIC90
P. multocida	Cattle	374	0.12-16	0.25	0.5
M. haemolytica	Cattle	100	0.03-128	0.12	0.5
P. multocida	Pigs	130	0.12-8	0.25	0.5

The antimicrobial mechanism of action consists of the inhibition of the biochemical process of bacterial wall synthesis, through a selective and irreversible blockade of several enzymes, in particular transpeptidases, endopeptidases and carboxypeptidases. The inadequate formation of the bacterial wall, in the susceptible species, produces an osmotic imbalance that especially affects bacteria in the growth phase (during which bacterial wall synthesis processes are especially important), which ultimately leads to the lysis of the bacterial cell.

There are three main mechanisms of resistance to beta-lactams: beta-lactamase production, altered expression and/or modification of penicillin binding proteins (PBP), and decreased penetration of the outer membrane. One of the most important is the inactivation of penicillin by beta-lactamase enzymes produced by certain bacteria. These enzymes are capable of cleaving the beta-lactam ring of penicillins, making them inactive. The beta-lactamase could be encoded in chromosomal or plasmidic genes.
Acquired resistances are frequent for Gram-negative bacteria which produce different types of beta-lactamases that remain in the periplasmic space. Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins (ampicillin).
The use of extended spectrum beta-lactam drugs (e.g. aminopenicillins) might lead to the selection of multi-resistant bacterial phenotypes (e.g. those producing extended spectrum beta-lactamases (ESBLs)).

4.3 Pharmacokinetics

In cattle C_{max} (4.54 µg/ml) is reached 2.0 hours after intramuscular administration. The terminal half-life time is 9.9 hours.
In pigs C_{max} (4.97 µg/ml) is reached 2.0 hours after intramuscular administration. The terminal half-life time is 3.2 hours.

Amoxicillin is mainly distributed to the extra-cellular compartment. Its distribution into tissues is facilitated by its low degree of plasma protein binding (17%). Concentrations in pulmonary, pleural and bronchial tissues are similar to plasma concentrations. Amoxicillin diffuses into pleural and synovial fluid and into lymphatic tissue.

Amoxicillin is biotransformed in the liver by hydrolysis of the beta-lactam ring leading to inactive penicilloic acid (20%).
Amoxicillin is mainly excreted in active form via the kidneys, and secondarily by the biliary route and through milk.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Do not store above 30°C.

5.4 Nature and composition of immediate packaging

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Kela nv

7. MARKETING AUTHORISATION NUMBER(S)

VPA10981/016/001

8. DATE OF FIRST AUTHORISATION

25/08/2023

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

28/09/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)..