1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimoxyvet LA 150 mg/ ml, Suspension for Injection for cattle, sheep and pigs – IE, IT, PT
Bimoxyl LA 150 mg/ml Suspension for Injection for cattle, sheep and pigs – AT, BE, FR, PL, RO, ES
Bimoxyl LA – DK
Bimoxyl Vet 150 mg/ml Suspension for Injection for cattle, sheep and pigs – FI

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Amoxicillin 150 mg
(equivalent to amoxicillin trihydrate 172 mg)

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
A cream to off-white oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

In cattle:
Treatment of respiratory and other infections caused by amoxicillin susceptible Gram-positive and Gram-negative bacteria.

In sheep and pigs:
Treatment of infectious diseases caused by or associated with amoxicillin susceptible bacteria.

4.3 Contraindications

Do not use in cases of hypersensitivity to amoxicillins, 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, hamsters, guinea pigs or gerbils or to any other small herbivores.
Do not administer to Equidae, because amoxicillin - like all aminopenicillins – may adversely affect the bacterial flora of the caecum.
Not suitable for intravenous or intrathecal administration.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals
Use of the 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 product should be in accordance with official, national and regional antimicrobial policies.

Use of the product deviating from the instructions given in the SPC 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
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product. 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.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Wash hands after use.

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.

4.6 Adverse reactions (frequency and seriousness)

Penicillins and cephalosporins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious .
Occasional local reaction of a transient nature may occur at the site of injection.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Beta-lactam antibiotics are known to interact with antibiotics with bacteriostatic action such as chloramphenicol, macrolides, sulfonamides and tetracyclines. There is also synergic action of penicillins with aminoglycosides.

4.9 Amounts to be administered and administration route

Intramuscular use
The recommended dosage rate is 15 mg amoxicillin per kg bodyweight.
This is equivalent to 1 ml/10 kg. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

The maximum injection volume at any one site is:
Cattle: 20 ml; Sheep: 4 ml; Pigs: 5 ml.
Larger dose volumes should be divided and given into separate sites.

One repeat administration should be given after 48 hours. Separate site(s) to the first injection(s) must be used.

Use a dry, sterile needle and syringe for extraction of suspension to avoid hydrolysis of amoxicillin.
Swab the septum before removing each dose.
Shake well before use.

The closure should not be pierced more than 30 times.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The safety of amoxicillin is typical of that of other penicillins in that intrinsic toxicity is very low, except in animals with specific allergy to the Beta-lactams, and this seems rare. Tolerance studies at twice the normal recommended dose in the named target species have been carried out with no adverse effects being observed.

4.11 Withdrawal period(s)

Cattle:	Meat and offal: 18 days.
	Milk: 72 hours.
Sheep:	Meat and offal: 21 days.
	Not authorised for use in sheep producing milk for human consumption.
Pigs:	Meat and offal: 21 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, penicillins with extended spectrum.
ATCvet code: QJ01CA04

5.1 Pharmacodynamic properties

Amoxicillin is a broad-spectrum antibiotic of the β-lactam family belonging to the aminopenicillin group. This substance has bactericidal activity and acts against Gram-positive and some Gram-negative microorganisms.

Mechanism of action
Amoxicillin is a time-dependent bactericidal antibiotic which acts by inhibiting the synthesis of bacterial cell walls during bacterial replication. The mechanism of antibacterial action of amoxicillin is the inhibition of the biochemical processes of bacterial cell wall synthesis by an irreversible and selective inhibition of various enzymes involved in these processes, mainly transpeptidases, endopeptidases and carboxypeptidases. Inadequate synthesis of the bacterial wall in susceptible species produces an osmotic imbalance that particularly affects the growth of bacteria (when the processes of bacterial wall synthesis are particularly important), eventually leading to lysis of the bacterial cell.

Antimicrobial spectrum of activity
Species considered to be susceptible to amoxicillin include:
- Gram-positive bacteria: *Streptococcus spp,*
- Gram-negative bacteria: *Pasteurellaceae and Enterobacteriaceae including strains of E. coli*

Bacteria normally resistant to amoxicillin are:
- Penicillinase-producing staphylococci
- Certain enterobacteriaceae such as *Klebsiella* spp., *Enterobacter* spp., *Proteus* spp.
- And other Gram-negative bacteria such as *Pseudomonas aeruginosa*.

Resistance mechanism
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 such as *E. coli* which produce different types of β-lactamases that remain in the periplasmic space. Cross-resistance is observed between amoxicillin and other penicillins, particularly with aminopenicillins.
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)).
No official clinical breakpoints have been established for amoxicillin in veterinary pathogens, however it has been proposed that veterinary bacterial pathogens can be categorised as 'susceptible' (MIC ≤ 1µg/ml), 'moderately susceptible' (MIC 2-4µg/ml) and 'resistant' (MIC > 4µg/ml).

5.2 Pharmacokinetic particulars

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 ß-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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Di-Tri Stearate
Glycerol Monocaprylate (type I)
Propylene Glycol Dicaprylocaprate

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Type I clear, glass vial sealed with a Type I bromobutyl rubber stopper and capped with aluminium overseal or clear Polyethylene terephthalate (PET) vials with a Type I chlorobutyl stopper and aluminium cap with plastic flip off seal.
Pack sizes:
Vial of 100ml
Vial of 250ml
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Maymó, S.A.
Vía Augusta, 302
08017 Barcelona

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE