1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trymox LA 150 mg/ml Suspension for Injection for Cattle, Sheep, Pigs, Dogs and Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

150 mg Amoxicillin equivalent to 172 mg amoxicillin trihydrate.

Excipients:

Qualitative composition of excipients and other constituents
Aluminium Distearate
Propylene Glycol Dicaprylocaprate

A white to off-white oily suspension.

3. CLINICAL PARTICULARS

3.1 Target species

Cattle, sheep, pigs, dogs, cats.

3.2 Indications for use for each target species

For the treatment of infections of the alimentary tract, respiratory tract, urogenital tract, skin and soft tissue caused by bacteria susceptible to amoxicillin.

3.3 Contraindications

Do not administer via the intravenous or intrathecal routes.

Do not administer to rabbits, hamsters, gerbils or guinea pigs.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The veterinary medicinal 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 veterinary medicinal product/amoxicillin should be carefully considered when antimicrobial susceptibility testing has shown resistance to penicillins 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 susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal 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.

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

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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.

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

2. Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.

3. If you develop symptoms following exposure such as skin rash, seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, sheep, pigs, dogs, cats:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site irritation[1]
Very rare (<1 animal/ 10,000 animals treated, including isolated reports):	Allergic reaction (e.g. anaphylactic shock and urticaria) [2,3]

[1]Typically of low intensity and recedes spontaneously and quickly. Frequency may be decreased by reducing the volume of injection per injection site.
[2] treatment should be discontinued and symptomatic treatment should be initiated.

[3] varying in severity.

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
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

It is not generally recommended to use bactericidal and bacteriostatic antibiotics at the same time.
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.

3.9 Administration routes and dosage

Cattle, sheep and pigs – intramuscular use.

Dogs and cats - subcutaneous or intramuscular use.

Shake the vial vigorously to achieve full resuspension before use.
This veterinary medicinal product does not contain an antimicrobial preservative.
Swab the septum before removing each dose.
To ensure the correct dosage, bodyweight should be determined as accurately as possible.

The recommended dosage rate is 15 mg per kg bodyweight, equivalent to 1 ml per 10 kg bodyweight to be repeated once after 48 hours.

Animal	Weight (kg)	Dosage volume (ml)
Cattle	450 kg	45.0 ml
Sheep	65 kg	6.5 ml
Pigs	150 kg	15.0 ml
Dogs	20 kg	2.0 ml
Cats	5 kg	0.5 ml

Dose volume is equivalent to 1 ml per 10 kg body weight. If dose volume exceeds 15 ml in cattle and 4 ml in sheep and pigs, it should be divided and injected into two or more sites.

The stopper should not be punctured more than 40 times.

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

The safety of amoxicillin is typical of that of other penicillins in that intrinsic toxicity is very low. Amoxicillin has a wide safety margin.
In case of overdose, treatment is symptomatic.

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: 39 days.
Milk: 108 hours (4.5 days).

Pigs:
Meat and offal: 42 days.

Sheep:
Meat and offal: 29 days.

Milk: Not authorised for use in sheep producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet code:

QJ01CA04

4.2 Pharmacodynamics

Amoxicillin is a broad-spectrum antibiotic of the β-lactam family belonging to the aminopenicillin group. This substance has time-dependent bactericidal activity and acts against Gram-positive and some Gram-negative microorganisms.
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.
Species considered to be susceptible to amoxicillin include Gram-positive bacteria: *Streptococcus* spp, and 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*.
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)).

4.3 Pharmacokinetics

Amoxicillin is mainly distributed to the extra-cellular compartment. Its distribution into tissues is facilitated by its low degree of plasma protein binding. Concentrations in pulmonary, pleural and bronchial tissues are similar to plasma concentrations. Amoxicillin diffuses into pleural and synovial fluid and into lymphatic tissue.
c tissue.
A small proportion of amoxicillin (around 20%) is biotransformed in the liver by hydrolysis of the ß-lactam ring leading to inactive penicilloic acid.
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 25ºC.
Protect from light.

5.4 Nature and composition of immediate packaging

50 ml, 100 ml and 250 ml clear, colourless Type II glass vial, closed with nitrile rubber bung and aluminium overseal.
100 ml and 250 ml clear polyethylene terephthalate vial sealed with nitrile bung and aluminium overseal.

Pack Sizes:
50 ml vial in a cardboard box.
100 ml vial in a cardboard box.
250 ml vial in a cardboard box.
12 x 50 ml vials in a cardboard/polystyrene box.
12 x 100 ml vials in a cardboard/polystyrene box.
6 x 250 ml vials in a cardboard/polystyrene box.

Not all pack sizes may be marketed.

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

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. These measures should help to protect the environment.

Medicines should not be disposed of via wastewater or household waste.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/051/001

8. DATE OF FIRST AUTHORISATION

12/04/2019

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

10/04/2024

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