SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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 white to off-white oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, Sheep, Pigs, Dogs, Cats

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not administer via the intravenous or intrathecal routes

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

Do not use in known cases of hypersensitivity to penicillins, cephalosporins or any of the excipients.

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 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 product is used.
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.

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 the case of accidental self-injection, seek medical advice immediately.

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

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

3. If you develop symptoms following exposure such as 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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, allergic reactions may occur, 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.
In rare cases local irritation may occur due to the injection of amoxicillin. The frequency of this adverse reaction may be decreased by reducing the volume of

injection per injection site. The irritation is typically of low intensity and recedes spontaneously and quickly

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

Cattle, sheep and pigs – By intramuscular injection only.

Dogs and cats - subcutaneous or intramuscular use.

Shake the vial vigorously to achieve full resuspension before use.

This 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 to avoid underdosing.

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.

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.

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. Amoxicillin has a wide safety margin.

In case of overdose, treatment is symptomatic.

4.11 Withdrawal period(s)

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.

5. PHARMACOLOGICAL PROPERTIES

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

ATC vet 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 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)).

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. Concentrations in pulmonary, pleural and bronchial tissues are similar to plasma concentrations.
Amoxicillin diffuses into pleural and synovial fluid and into lymphatic 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium distearate
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: 2 years
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light.

6.5 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
100 ml vial
250 ml vial

12 x 50 ml vials
12 x 100 ml vials
6 x 250 ml vials

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

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 05150/4008

9. DATE OF FIRST AUTHORISATION

03 April 2019

10. DATE OF REVISION OF THE TEXT

February 2021

Approved 15 February 2021