PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(Individual carton box for 50 ml, 100 ml and 250 ml vial; cardboard box of 12 x 50 ml, 12 x 100 ml and 6 x 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trymox LA 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
150 mg Amoxicillin equivalent to 172 mg amoxicillin trihydrate.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cattle, sheep, pigs, dogs, cats.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Cattle, sheep and pigs - intramuscular use.

Dogs and cats - subcutaneous or intramuscular use.

To be shortened or omitted for multilingual packs in case of space restriction

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.

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. Use a dry sterile needle and syringe.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

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.

7. WITHDRAWAL PERIODS

Withdrawal period:

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.

8. EXPIRY DATE

Exp {mm/yyyy}

Once broached use within 28 days.

Once opened, use by _____

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Protect from light.

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

Univet Limited

14. MARKETING AUTHORISATION NUMBERS

Vm.: 05150/5003

15. BATCH NUMBER

<Lot> {number}

16. SPECIAL WARNING(S), IF NECESSARY

User warnings
Penicillins may occasionally cause severe allergic reactions.
See package leaflet for user warnings.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {250 ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trymox LA 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE

Each ml contains:

150 mg Amoxicillin equivalent to 172 mg amoxicillin trihydrate.

3. TARGET SPECIES

Cattle, sheep, pigs, dogs, cats.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {50 ml/100 ml vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trymox LA

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

150 mg/ml Amoxicillin (172 mg/ml Amoxicillin trihydrate)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trymox LA 150 mg/ml suspension for injection for cattle, sheep, pigs, dogs and cats

2. COMPOSITION

Each ml contains:

Active substance:

Amoxicillin	150 mg
(equivalent to amoxicillin trihydrate	172 mg)

A white to off-white oily suspension

3. TARGET SPECIES

Cattle, sheep, pigs, dogs, cats.

4. INDICATIONS FOR USE

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

5. 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.

6. SPECIAL WARNINGS

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.

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 package leaflet 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.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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.

Overdose:
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.

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, 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 (hives)) [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 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:
Website:https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Cattle, sheep and pigs - intramuscular use.

Dogs and cats - subcutaneous or intramuscular use.

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.

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

9. ADVICE ON CORRECT ADMINISTRATION

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. Use a dry sterile needle and syringe.
To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.
As with other injectable preparations normal aseptic precautions should be observed.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.
The stopper should not be punctured more than 40 times.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and 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

Vm 05150/5003

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

Univet Limited
Tullyvin
Cootehill
Co.Cavan
Ireland
Tel No.: +353 49 5553203

Local representatives and contact details to report suspected adverse reactions:

FORTE Healthcare Ltd Block 3, Unit 9,
CityNorth Business Campus,
Stamullen,
Co. Meath.
K32 D990,
Ireland
Tel No.: +353 1 841 7666

e-mail: pharmacovigilance@fortehealthcare.com

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION

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)).

Gavin Hall
Approved: 25 November 2024