1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance:

Amoxicillin	150 mg
(equivalent to amoxicillin trihydrate	172 mg)

Excipient(s):

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

A white to off-white oily suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, pigs, dogs, cats.

3.2 Indications for use, specifying the target species

For the treatment of infections caused by a wide range of Gram-positive and Gram-negative pathogenic bacteria including:

Bacillus anthracis
Bacillus cereus
Bordetella bronchiseptica
Clostridium spp.
Corynebacterium spp.
Erysipelothrix rhusiopathiae
Escherichia coli
Fusiformis spp.
Haemophilus spp.
Pasteurella spp.
Proteus mirabilis
Salmonella spp.
Non-penicillinase producing Staphylococci
Non-penicillinase producing Streptococci.

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

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 bacteria at farm level, or at local/regional level.

Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to 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

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances can occasionally be serious.

People with known hypersensitivity to amoxicillin trihydrate should avoid contact with the veterinary medicinal product. Administer the veterinary medicinal product with caution.

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

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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

In case of accidental self-administration/ self-injection ingestion/ spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable.

3.6 Adverse events

Cattle, sheep, pigs, dogs, cats:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic-type reaction[1]
Very rare (<1 animal/ 10,000 animals treated, including isolated reports):	Injection site irritation

[1]May occur following use of amoxicillin containing products.

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 route and dosage

Administration is by the intramuscular or subcutaneous route.
Shake the vial vigorously to achieve full resuspension before use.
This product does not contain an antimicrobial preservative.
Use a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin.
To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

The dosage rate is 7 mg/kg daily for up to 5 days in all species.
Massage the injection site.

Animal	Weight (kg)	Dosage volume (ml)
Cattle	450 kg	20.0 ml
Sheep	65 kg	3.0 ml
Pigs	150 kg	7.0 ml
Dogs	20 kg	1.0 ml
Cats	5 kg	0.25 ml

(Guide-dose volume is approximately equivalent to 0.25 ml per 5 kg daily).
Normal aseptic precautions should be observed.

The cap should not be punctured more than 20 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: 18 days.
Milk: 48 hours.

Sheep
Meat and offal: 7 days.
Do not use in sheep producing milk for human consumption.

Pigs
Meat and offal: 14 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet 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 (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.

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: 18 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25ºC.

5.4 Nature and composition of immediate packaging

100 ml clear, colourless Type II glass vial, closed with nitrile rubber bung and aluminium overseal.
100 ml HDPE vial sealed with nitrile bung and aluminium overseal.

Pack Sizes
100 ml vial in a cardboard box.
12 x 100 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

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10990/054/001

8. DATE OF FIRST AUTHORISATION

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

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