PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Individual Cardboard box for 100 ml and Cardboard box of 12 x 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Redymox 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
150 mg Amoxicillin (172 mg Amoxicillin trihydrate).

3. PACKAGE SIZE

100 ml
12 x 100 ml

4. TARGET SPECIES

Cattle, sheep, pigs, dogs, cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle, sheep and pigs : By intramuscular injection only.
Dogs and cats : By subcutaneous or intramuscular injection.

Shake bottle before use.
Use a dry syringe for extraction of suspension to avoid hydrolysis of amoxicillin.
The dosage rate is 7 mg/kg once 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.

If dose volume exceeds 20 ml in cattle or 10 ml in pigs, it should be divided and injected into two sites.

The stopper should not be punctured more than 40 times.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Meat and offal: 18 days.
Milk: 24 hours (1 day).

Sheep:
Meat and offal: 10 days.
Not authorised in sheep producing milk for human consumption.

Pigs:
Meat and offal: 16 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the container: 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”

Penicillin/cephalosporin may occasionally cause severe allergic reactions.
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 Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 05150/5006
Vm 05150/3006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {100 ml Type II glass or HDPE vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Redymox 150 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

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

Cattle
Meat and Offal: 18 days.
Milk: 24 hours (1 day).

Sheep
Meat and Offal: 10 days.
Not authorised in sheep producing milk for human consumption.

Pigs
Meat and Offal: 16 days.

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}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 1 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 caused by a wide range of Gram-positive and Gram-negative pathogenic bacteria including:
Actinobacillus equuli
Actinomyces bovis
Actinobacillus lignieresi
Bacillus anthracis
Erysipelothrix rhusiopathiae
Bordetella bronchiseptica
Escherichia coli
Clostridium species
Haemophilus species
Corynebacterium species
Pasteurella species
Fusiformis species
Proteus mirabilis
Moraxella species
Salmonella species
Staphylococci
Streptococci
Not effective against beta-lactamase producing organisms.

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 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.

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:
Care should be taken to avoid accidental self-injection. In the 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. Do not handle this veterinary medicinal 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 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 local representatives using the contact details at the end of this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes and method of administration

Cattle, sheep and pigs : By intramuscular injection only.
Dogs and cats : By subcutaneous or intramuscular injection.

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

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

If dose volume exceeds 20 ml in cattle or 10 ml in pigs, it should be divided and injected into two sites.

The stopper should not be punctured more than 40 times.

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

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: 18 days.
Milk: 24 hours (1 day).

Sheep
Meat and offal: 10 days.
Not authorised in sheep producing milk for human consumption.

Pigs
Meat and offal: 16 days.

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 05150/5006
Vm 05150/3006

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

100 ml High density polyethylene vial sealed with nitrile bung and aluminium overseal.

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 and contact details to report suspected adverse reactions:
Univet Limited
Tullyvin
Cootehill
County Cavan
H16 T183
Ireland
353 49-5553203

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

17. Other information

POM-V	Veterinary medicinal product subject to prescription

High levels of Amoxicillin are found in kidney, urine, liver and bile.
Also important is the rapid bactericidal action after absorption due to its wide distribution.
In common with other penicillins an absence of toxicity is apparent even at high dose levels. Animals with functional rumens should only be treated parenterally.

Gavin Hall

Approved: 01 October 2025