



**Veterinary  
Medicines  
Directorate**

**United Kingdom  
Veterinary Medicines Directorate  
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**NATIONAL PROCEDURE**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY  
MEDICINAL PRODUCT**

**Redymox 150 mg/ml Suspension for injection for Cattle, Sheep, Pigs, Dogs  
and Cats**

**Date Created: December 2025**

## MODULE 1

### PRODUCT SUMMARY

Name, strength and pharmaceutical form	Redymox 150 mg/ml Suspension for injection for Cattle, Sheep, Pigs, Dogs and Cats, Suspension for injection
Applicant	Univet Limited, Tullyvin, Cootehill, County Cavan, H16 T183, Ireland
Active substance	Amoxicillin Trihydrate
ATC Vetcode	QJ01CA04
Target species	Cats Cattle Dogs Pigs Sheep
Indication for use	For the treatment of infections caused by a wide range of Gram-positive and Gram-negative pathogenic bacteria including:  <i>Actinobacillus equuli</i> <i>Actinomyces bovis</i> <i>Actinobacillus lignieresii</i> <i>Bacillus anthracis</i> <i>Erysipelothrix rhusiopathiae</i> <i>Bordetella bronchiseptica</i> <i>Escherichia coli</i> <i>Clostridium species</i> <i>Haemophilus species</i> <i>Corynebacterium species</i> <i>Pasteurella species</i> <i>Fusiformis species</i> <i>Proteus mirabilis</i> <i>Moraxella species</i> <i>Salmonella species</i> <i>Staphylococci</i> <i>Streptococci</i>

	<b>Not effective against beta-lactamase producing organisms.</b>
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## **MODULE 2**

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

[www.gov.uk/check-animal-medicine-licensed](http://www.gov.uk/check-animal-medicine-licensed)

## MODULE 3

### PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	01/10/2025

#### I. SCIENTIFIC OVERVIEW

The product was submitted for a generic application for authorisations in Great Britain (GB) and Northern Ireland (NI), in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.

The reference product for GB and NI is Betamox 150 mg/ml Suspension for Injection (Vm 02000/4071), marketed by Norbrook Laboratories Limited, which has been authorised in the UK since 30 June 1986. The applicant claimed exemption from the requirement to conduct bioequivalence studies under the principles of section 7.1.d) of EMA/CVMP/016/2000-Rev.4 which was accepted.

The dosage is 7 mg/kg once daily for up to 5 days in all species. This is by the intramuscular or subcutaneous route in dogs and cats and by intramuscular injection only in cattle, sheep and pigs.

The distribution category in GB and NI is POM-V, the same as the reference product.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC<sup>1</sup>. The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy<sup>2</sup> of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

<sup>1</sup> SPC – Summary of Product Characteristics.

<sup>2</sup> Efficacy – The production of a desired or intended result.

## **I. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS**

### ***II.A. Composition***

The product contains amoxicillin (as amoxicillin trihydrate) and the excipients aluminium distearate and propylene glycol dicaprylocaprate.

The container/closure system consists of either a 100ml type II glass vial sealed with a nitrile rubber bung and aluminium overseal or 100ml high density polyethylene (HDPE) vial sealed with a nitrile bung and aluminium overseal. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative is justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant regulatory guidelines.

### ***II.B. Description of the Manufacturing Method***

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

### ***II.C. Control of Starting Materials***

The active substance is amoxicillin (as trihydrate), an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

#### ***II.C.4. Substances of Biological Origin***

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

### ***II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process***

Not applicable.

### ***II.E. Control Tests on the Finished Product***

The finished product specification controls the relevant parameters for the pharmaceutical form.

The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the production sites have been provided demonstrating compliance with the specification. Control tests on the finished product are those appropriate for the pharmaceutical form.

### ***II.F. Stability***

Stability data on the active substance has been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

### ***G. Other Information***

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

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

Do not store above 25°C.

Protect from light.

## **III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACOTOXICOLOGICAL)**

### ***III.A Safety Documentation***

#### ***Pharmacological Studies***

Bibliographical data has been provided which show that amoxicillin (as trihydrate) acts as a broad-spectrum antibiotic of the  $\beta$ -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  $\beta$ -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)).

The applicant has also provided bibliographical data which show that amoxicillin is mainly distributed to the extra-cellular compartment. It's 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  $\beta$ -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.

### **Toxicological Studies**

Due to the legal basis of the application, no new pharmacological or toxicological studies were submitted.

### **User Safety**

A user risk assessment was provided in compliance with the relevant guideline which shows that there is no risk to the user when the veterinary medicinal product is used as directed.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- 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.
- Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- 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.

### **Environmental Safety**

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

#### **Phase I:**

The applicant has worked through the VICH Phase I decision tree until Question 17, where the  $PEC_{\text{soil initial}}$  has been calculated.

The initial predicted environmental concentration (PEC) in soil is greater than 100 µg/kg in cattle (>2 years), weaner pigs and fattening pigs and a Phase II ERA was required.

#### **Phase II Tier A:**

A Phase II tier A data set was provided according to the requirements of the VICH GL 38 and the CVMP guideline in support of the VICH guidelines including studies on physico-chemical properties, environmental fate and effects. It was demonstrated that amoxicillin is not stable in manure or soil, therefore Phase II assessment was carried out on penicilloic acid of amoxicillin (APA), the primary degradation product.

### **Physico-chemical properties**

<b>Study type</b>	<b>Guideline</b>	<b>Result</b>
Water solubility	OECD 105	79.9 g/l
Dissociation constants in water pKa	OECD 112	pK <sub>a1</sub> = 8 pK <sub>a2</sub> = 10.1
UV-Visible Absorption Spectrum	OECD 101	pH<2: 230 nm, 272.4 nm Ph 7: 228.3 nm, 271.5 nm pH>10: 245 nm, 280.7 nm
Melting Point/Melting Range	OECD 102	No melting point before decomposition (at approx. 270°C)
Vapour Pressure	OECD 104	3.6 x 10 <sup>-16</sup> Pa
n-Octanol/Water Partition Coefficient logP <sub>ow</sub>	OECD 107	Log P <sub>ow</sub> = -2.2 (main component) Log P <sub>ow</sub> = 0.51 – 0.46 (minor components/impurities)

### **Environmental fate**

<b>Study type</b>	<b>Guideline</b>	<b>Result</b>
Soil Adsorption/Desorption	OECD 106	K <sub>oc</sub> <sup>ads</sup> = 66.7 l/kg
Aerobic and Anaerobic Transformation in Soil	OECD 307	1.6 days

### **Environmental effects**

<b>Study type</b>	<b>Guideline</b>	<b>Endpoint</b>	<b>Result</b>
Algae, Growth Inhibition Test/ <i>Species</i>	OECD 201	EC50	172 mg/l
<i>Daphnia</i> sp. immobilisation	OECD 202	EC50	>1000 mg/l
Fish, acute toxicity/ <i>Species</i>	OECD 203	LC50	≥1000 mg/l
Soil Microorganisms: Nitrogen Transformation Test (28 days)	OECD 216	% effect	>25% at 28 days
Terrestrial Plants, Growth Test/ <i>Species</i>	OECD 208	EC50	1152 mg/kg soil for emergence 1187 mg/kg soil for growth

Study type	Guideline	Endpoint	Result
Earthworm/Species subacute/reproduction	OECD 220/222	NOEC	≥2000 mg/kg soil

**Exposure assessment (Predicted exposure concentration)**

PEC values for soil, groundwater and surface water were calculated using the equations provided in the CVMP guidelines. The dose and duration of treatment were taken from the proposed SPC of the product. The following PEC values were calculated.

Target animal	PEC		
	Soil (µg/kg)	Groundwater (µg/l)	Surfacewater (µg/l)
Weaner pigs	152.05 µg/l	29.36 µg/l	9.79 µg/l

**Risk Characterisation (Risk Quotient)**

Using the assessment factors (AF) in VICH guidelines predicted no effect concentrations (PNEC) were calculated and compared with the PEC values for weaner pigs as follows.

**Weaner pigs**

Test organism	End point	AF	PNEC	PEC	RQ
Algae, Growth Inhibition	EC <sub>50</sub>	100	1.72 mg/l	0.00979 mg/l	0.006
<i>Daphnia</i> sp. immobilisation	EC <sub>50</sub>	1000	>1 mg/l	0.00979 mg/l	0.010
Fish, acute toxicity	LC <sub>50</sub>	1000	>1 mg/l	0.00979 mg/l	0.010
Soil Microorganisms:	<25% difference with control at day 28	-	-	-	-
Terrestrial Plants, Growth	EC <sub>50</sub>	100	11.52 mg/kg <sub>dwt</sub>	0.152 mg/l	0.013
Earthworm reproduction	NOEC	10	200 mg/kg <sub>dwt</sub>	0.152 mg/l	0.00076

As all RQ values were <1 the ERA ended at tier A. The product is not expected to pose a risk for the environment when used as recommended.

**III.B.2 Residues documentation  
Residue Studies**

No residue depletion studies were conducted because is for a generic marketing authorisation (MA) in both GB and NI. Betamox 150 mg/ml suspension for injection (Vm 02000/4071), which was authorised UK-wide, is the cited reference product.

### **MRLs**

Amoxicillin is listed in Table 1 of Regulation 37/2010 and MRLs have been established for edible tissues/milk/eggs/honey. The marker substance is amoxicillin.

MRLs are listed below:

	All food producing species
Muscle	50 µg/kg
Liver	50 µg/kg
Kidney	50 µg/kg
Fat / skin	50 µg/kg
Milk	4 µg/kg

The excipients in this veterinary medicine aluminium distearate and propylene glycol dicaprylocaprate, each have a 'no MRL required' status in GB and the EU for all food producing species.

### **Withdrawal Periods**

Based on the data provided, the withdrawal periods for the following species are as follows:

- Cattle; Meat and offal: 18 days and Milk: 24 hours
- Sheep; Meat and offal: 10 days. Not authorised in sheep producing milk for human consumption.
- Pigs; Meat and offal: 16 days

## **IV. CLINICAL DOCUMENTATION**

### **IV.I. Pre-Clinical Studies**

#### **Tolerance in the Target Species**

Tolerance studies were not required because of the legal basis of the application.

#### **Resistance**

The bibliography/information provided suggests that the applicant has presented an adequate description of the four main mechanisms of resistance to amoxicillin and has conducted a literature review to attempt to address the potential for development of resistance to the active substance.

Adequate warnings and precautions appear on the product literature.

### **IV.II. Clinical Documentation**

### ***Laboratory Trials***

No clinical data have been submitted. The applicant considers that clinical efficacy can be extrapolated from the reference products due to the similarity of formulations and the equivalent indications, target species and dosing recommendations. This was accepted.

## **V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT**

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics the benefit/risk profile of the product is favourable.

## **MODULE 4**

### **POST- AUTHORISATION ASSESSMENTS**

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

([www.gov.uk/check-animal-medicine-licensed](http://www.gov.uk/check-animal-medicine-licensed))

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

([www.gov.uk/check-animal-medicine-licensed](http://www.gov.uk/check-animal-medicine-licensed))