

**IRISH MEDICINES BOARD ACT 1995**

**ANIMAL REMEDIES REGULATIONS, 2005**

**(S.I. No. 734 of 2005)**

VPA: **10019/043/001**  
Case No: 7002014

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

**Pfizer Healthcare Ireland**

**Trading as Pfizer Animal Health, Ringaskiddy, Co. Cork, Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**Clamoxyl L.A. Injection**

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clamoxyl LA Injection

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

##### Active Substance

Amoxicillin (as amoxicillin trihydrate) 150.0 mg

##### Excipients

Base to 1.0 ml

#### 3 PHARMACEUTICAL FORM

Suspension for injection.

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Cattle, sheep, dogs and cats.

##### 4.2 Indications for use, specifying the target species

Clamoxyl is a broad-spectrum semi-synthetic penicillin which is bactericidal *in vitro* against a wide range of Gram-positive and Gram-negative bacteria including the following:

Gram-negative: *Actinobacillus lingnieresii*; *Actinobacillus equili*; *Bordetella bronchiseptica*, *Escherichia coli* non beta-lactamase producing strains; *Fusobacterium spp.*; *Haemophilus spp.*; *Moraxella spp.*; *Pasteurella spp.*; *Proteus mirabilis* non beta-lactamase producing strains; *Salmonella spp.*

Gram-positive: *Actinomyces bovis*; *Bacillus anthracis*; *Clostridium spp*; *Corynebacterium spp.*; *Erysipelothrix rhusiopathiae*; Streptococci; Staphylococci non beta-lactamase producing strains.

Clamoxyl L.A. Injection is suitable for the control of infections caused by susceptible organisms in cattle, sheep, dogs and cats where prolonged activity from a single injection is required. It may also be used to control secondary bacterial invasion in conditions where bacteria are not a primary cause of disease.

##### 4.3 Contraindications

In common with all other penicillins, amoxicillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters or gerbils. Caution is advised in its use in any other very small herbivores. Do not administer by the intravenous route. Do not use in sheep producing milk for human consumption. Do not use in animals with known sensitivity to the active ingredient.

#### **4.4 Special warnings for each target species**

None known.

#### **4.5 Special precautions for use**

##### **Special precaution(s) for use in animals**

Shake well before use.

The product does not contain an antimicrobial preservative.

Swab the spectrum before removing each dose.

Since amoxicillin hydrolyses rapidly in the presence of water, it is important that a dry sterile needle and syringe is used when withdrawing the suspension for use to avoid contaminating the remaining suspension with drops of water.

##### **Special precautions to be taken by the person administering the veterinary medicinal product to animals**

Operator warning: 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 reaction 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 a 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 may require urgent medical attention.

#### **4.6 Adverse reactions (frequency and seriousness)**

Use of the product may occasionally result in local tissue reaction.

#### **4.7 Use during pregnancy, lactation or lay**

Clamoxyl L.A. Injection may be used during pregnancy and lactation.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

## 4.9 Amounts to be administered and administration route

Clamoxyl L.A. Injection is intended for use via the intramuscular or subcutaneous routes.

*Dosage rate:* the recommended dosage rate is 15 mg/kg which is equivalent to 1.0 ml/10 kg bodyweight. The dose may be repeated after 48 hours.

*Dosing guide:* the following table gives examples of doses for the different species.

Animal	Specimen Weight (kg)	Dose (ml)
Cattle	450	45.0
Store Cattle	200	20.0
Calf	50	5.0
Sheep	65	6.5
Lamb	10	1.0
Dog - large	35	3.5
medium	20	2.0
small	10	1.0
Cat	5	0.5

Shake the vial well before use to suspend the active material. Inject by the subcutaneous or intramuscular route, then massage the injection site. (For ease of administration in dogs and cats, needles no finer than 20 gauge should be used). When used in cattle if the volume to be given is greater than 20 ml it should be divided and injected into two separate sites.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Amoxicillin is of a very low order of acute toxicity and is well tolerated by the parenteral route. Occasional injection site reactions may occur with the recommended dose, but no other adverse side-effects are to be expected from accidental overdosing.

## 4.11 Withdrawal Period(s)

Milk from treated cows must not be taken for human consumption until 96 hours (i.e. at the 9<sup>th</sup> milking for cows milked twice daily) after the last treatment.

Cattle must not be slaughtered for human consumption until 21 days after the last treatment.

Sheep must not be slaughtered for human consumption until 35 days after the last treatment.

Do not use in sheep producing milk for human consumption.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The following features of Clamoxyl L.A. Injection warrant special mention:

1. After absorption, amoxicillin is widely distributed throughout body tissues, with especially high levels in the kidneys, urine, liver and bile.
2. Amoxicillin is very rapidly bactericidal. At a concentration of 10 µg/ml *Escherichia coli* is completely lysed in only 1 hour, *in vitro*.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

#### Base Composition

Aluminium Stearate  
Fractionated Coconut Oil BP

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Unopened: 2 years  
In Use: 28 days.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and composition of immediate packaging**

Clamoxyl L.A. Injection is a sterile off-white non aqueous suspension containing 150mg/ml amoxicillin as amoxicillin trihydrate. It is presented in clear, colourless Type III glass vials of 100 ml capacity and fitted with rubber plugs and aluminium seals. The product is available in 6 x 100ml presentations.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

## **7 MARKETING AUTHORISATION HOLDER**

Pfizer Healthcare Ireland  
Trading as Pfizer Animal Health  
Ringaskiddy  
County Cork  
Ireland

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10019/43/1

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

1<sup>st</sup> October 2002