

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) REGULATIONS 2007

(S.I. No. 144 of 2007)

VPA: **10126/009/001**
Case No: 7003593

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 144 of 2007) hereby grants to:

Bimeda Chemicals

Broomhill Road, Tallaght, Dublin 24., 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:

Bimoxyl LA 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.

The authorisation,unless revoked, shall continue in force from **10/09/2007** until **01/10/2007**.

Signed on behalf of the Irish Medicines Board

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

Bimoxyl LA Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Each ml contains 150 mg Amoxicillin
(as Amoxicillin Trihydrate Ph. Eur.)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep, pigs and dogs.

4.2 Indications for use, specifying the target species

Cattle: For the control and treatment of respiratory and other infections caused by amoxycillin susceptible Gram-positive and Gram-negative bacteria only.

Sheep, Pigs and Dogs: For the treatment of infectious diseases in pigs, sheep and dogs, caused by or associated with organisms sensitive to amoxycillin.

4.3 Contraindications

Not suitable for intravenous or intrathecal administration.

Not to be administered to small herbivores.

Not for use in ewes producing milk for human consumption or food processing.

Do not use in known cases of hypersensitivity to penicillin or the active ingredient.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals

None known.

Special precautions to be taken by the person administering the product to animals

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.

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 require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

As with all penicillins, Bimoxyl LA may cause hypersensitivity (allergy) and should not be used when an animal is known to be allergic to penicillins.

Occasional local reaction of a transient nature may occur at the site of injection.

4.7 Use during pregnancy, lactation or lay

As with all other antibiotics, Bimoxyl LA should be used with caution during pregnancy and lactation. There is no evidence that the use of amoxycillin presents any particular hazard either to the dam or to the foetus.

4.8 Interaction with other medicinal products and other forms of interaction

Bimoxyl LA is unlikely to interact significantly with any other drugs commonly administered to animals.

4.9 Amounts to be administered and administration route

Cattle, Sheep and Pigs: By intramuscular route only.

Dogs: by subcutaneous injection.

The injection site should be massaged after injection.

The recommended dosage rate is 15 mg amoxycillin per kg bodyweight.

This is equivalent to 1 ml/10 kg. One repeat administration may be given after 48 hours.

The maximum injection volume at any one site is:

Cattle : 20 ml

Sheep : 4 ml

Pigs : 5 ml

Dogs : 2.5 ml

Larger dose volumes should be divided and given into separate sites.

Use a dry, sterile needle and syringe for extraction of suspension to avoid hydrolysis of amoxycillin.

Swab the septum before removing each dose.

Shake well before use.

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

The safety of amoxycillin is typical of that of other penicillins in that intrinsic toxicity is very low, except in animals with specific allergy to the Beta-lactams, and this seems rare. Tolerance studies at twice the normal recommended dose in the named target species have been carried out with no adverse effects being observed.

4.11 Withdrawal Period(s)

Foodstuffs for human consumption must not be taken during the treatment period.

Cattle - Meat 18 days.
 - Milk 72 hours.

Sheep - Meat 21 days.
Not to be used in sheep producing milk for human consumption.

Pigs - Meat 11 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Amoxycillin is a broad spectrum antibiotic of the penicillin group which in turn is a member of the beta-lactam group

The mode of action of beta-lactams involves interference with cell wall synthesis. These drugs are therefore more effective when the cell wall is growing. At high dose levels the penicillins have additional bactericidal effects within the bacterial cell and may affect dormant bacteria.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate
Imwitor 988
Fractionated Coconut Oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
2 years.
Following withdrawal of the first dose, use the product within 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.

6.5 Nature and composition of immediate packaging

100 ml clear glass (Type I or II) multidose type vials sealed with a bromobutyl rubber stopper and capped with aluminium overseal, containing an oily suspension of amoxicillin trihydrate.

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

Bimeda Chemicals Limited,
Broomhill Road,
Tallaght,
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/9/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002

10 DATE OF REVISION OF THE TEXT

30th November 2006

25th April 2007

10th September 2007