

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10126/010/001**

Case No: 7004803

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 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:

Tetroxy LA 200 mg/ml Solution for 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 previously revoked, shall continue in force from **30/09/2008**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Tetroxy LA
200 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Oxytetracycline Ph. Eur. 200.0 mg/ml

Excipients

Povidone (K-17) 25.0 mg/ml

N-Methylpyrrolidone 370.0 mg/ml

Sodium formaldehyde sulfoxylate 2.7 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep and Pigs

4.2 Indications for use, specifying the target species

Tetroxy L.A. is indicated in the treatment and control of diseases caused by or associated with organisms sensitive to Oxytetracycline in cattle, sheep and pigs. These include *Pasteurella spp.*, *Salmonella spp.*, *Escherichia coli* and *Listeria spp.*

4.3 Contraindications

Do not use in cats, dogs, horses and donkeys.

Do not use in sheep intended to be milked for human consumption.

4.4 Special warnings for each target species

Prolonged use of anti-infectives may result in super infection by non-susceptible organisms.

4.5 Special precautions for use

Special precautions for use in animals

Use of the 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.

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

Wash hands after use.

Avoid contact with the eyes.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

The use of Tetroxy L.A. during the period of tooth development including late pregnancy, may lead to tooth discoloration.

4.8 Interaction with other medicinal products and other forms of interaction

Tetroxy L.A. should not be diluted with solutions of calcium salts as this causes precipitation.

4.9 Amounts to be administered and administration route

Tetroxy L.A. is administered by deep intramuscular injection at the rate of 1 ml per 10 kg bodyweight which is equivalent to 20 mg Oxytetracycline per kg bodyweight.

It is recommended that the following amounts of Tetroxy L.A. at one site should not be exceeded:

Cattle, Sheep and Pigs	10 ml
Pigs under 10 kg maximum dose of	1 ml

Effective blood levels are maintained for up to 72 hours in cattle and 48 hours in pigs and sheep.

Because of the sustained blood levels attained at the above dosage rates with Tetroxy L.A., one treatment is usually sufficient.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

Not relevant

4.11 Withdrawal Period(s)

Meat withdrawal time:

Cattle and sheep for human consumption should not be slaughtered within 28 days of treatment.
Pigs for human consumption should not be slaughtered within 21 days of treatment.

Milk withdrawal time:

Milk intended for human consumption or the manufacture of cheese and yoghurt may not be drawn from treated animals for 7 days after treatment. Milk may only be taken from the 15th milking with a twice daily milking programme. Do not use in sheep intended to be milked for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Tetracyclines
 ATCvet code: QJ01AA06

5.1 Pharmacodynamic properties

Tetroxy L.A. is a multidose injection product containing Oxytetracycline Dihydrate Ph. Eur equivalent to 200 mg Oxytetracycline per ml as a magnesium complex.

Oxytetracycline is a broad spectrum antibiotic of the tetracycline group. The drug was discovered in the 1950's. It is derived from a soil mould, *Actinomyces rimosus*. Oxytetracycline is bacteriostatic at therapeutic concentrations but may be bactericidal at higher concentrations.

The mode of action of Oxytetracycline and other tetracyclines involves interference with protein and RNA synthesis in the growing and reproducing bacterial cell.

5.2 Pharmacokinetic properties

The product is long acting and is intended to be administered as a single dose which will maintain therapeutic blood levels for up to three days.

Long acting antibiotic preparations are not only convenient but may also provide more constant blood and tissue drug concentrations by avoiding the peaks and troughs associated with conventional administration. Another important advantage is avoidance of the stress and irritation to the animals of repeated injection.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Heavy Magnesium Oxide
 Sodium formaldehyde sulfoxylate
 Monoethanolamine
 Hydrochloric Acid
 Povidone K17
 N-Methyl pyrrolidone
 Water for Injection

6.2 Incompatibilities

Tetroxy L.A. should not be brought into contact with calcium solutions as this causes precipitation.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

100 ml amber Type II glass vials, fitted with bromobutyl rubber stoppers and sealed with plain aluminium caps.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bimeda Chemicals Ltd.,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/010/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT