# 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 interactions**

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 15$^{th}$ 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 particulars**

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 Major 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 derived from the use of such products**

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 Animal Health Limited
2, 3 & 4 Airton Close
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## 8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/044/001

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

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

## 10 DATE OF REVISION OF THE TEXT

June 2019