SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

TETROXY L.A.
200mg/ml Oxytetracyline Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Oxytetracycline (as Oxytetracycline Dihydrate)	200 mg/ml .

Excipient(s)

Polyvinylpyrrolidone (K - 17)	Co-solvent	
N-Methyl Pyrrolidone	Co-solvent	370.0 mg/ml

For full list of excipients refer to 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.

4.3 Contraindications

Not recommended for cats, dogs, horses and donkeys.

4.4 Special warnings for each target species

Prolonged use of anti-infectives may result in super infection by non-susceptible organisms. Photodermatitis may occasionally occur after treatment under strong exposure to sunlight.

4.5 Special precautions for use

Special precautions for use in animals

Following withdrawal of the first dose, use the product within 28 days.
Not recommended in cases of renal impairment (see also 4.4 above). Discard unused material.

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

Take care to avoid accidental self injection. In case of contact with eyes or skin, wash immediately with plenty of water as irritation may occur. Wash hands after use.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

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 discoloration.

The safety of the veterinary medicinal product has not been established in cattle, sheep and pigs during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

Do not dilute. It is unwise to administer bacteriostatic and bactericidal antibiotics concurrently.

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 10kg bodyweight which is equivalent to 20mg Oxytetracycline per kg.

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

Cattle and Sheep - 10 ml
Pigs 5 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., this is a single dose treatment.

4.10 Overdose

Not applicable.

4.11 Withdrawal Periods

Cattle (meat & offal): 39 days
Pigs (meat & offal): 40 days
Sheep (meat & offal): 28 days
Do not use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

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

The product is long acting and is intended to be administered as a single dose. Effective blood levels are maintained for up to 72 hours in cattle and 48 hours in pigs and sheep. 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.

Tetroxy L.A. is recommended for the treatment and control of diseases in cattle, sheep and pigs caused by or associated with organisms sensitive to Oxytetracycline.

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 concentration 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Oxide Heavy, N-Methyl Pyrrolidone, Pvidone K17, Sodium Formaldehyde Sulphoxylate as Sodium Formaldehyde Sulphoxylate Dihydrate, Ethanolamine, Hydrochloric Acid, Water for Injection

6.2 Incompatibilities

Tetroxy L.A. should not be brought into contact with calcium solutions. Do not dilute.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.
Discard unused material.

6.4 Special precautions for storage

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

6.5 Nature and contents of immediate packaging

100ml amber Type II glass vials, fitted with bromobutyl rubber stoppers and sealed with plain aluminium caps containing a clear yellow to amber sterile aqueous solution.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from use of such products, if appropriate

Any unused veterinary medicinal product or waste material s 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
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4028

9. DATE OF THE FIRST AUTHORISATION

12 November 1990

10. DATE OF REVISION OF THE TEXT

October 2023

Approved 25 January 2024