1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetroxy LA 200 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Oxytetracycline Ph. Eur 200.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Povidone (K-17)	25.0 mg
N-Methyl pyrrolidone	370.0 mg
Sodium formaldehyde sulfoxylate	2.7 mg
Heavy Magnesium Oxide	\
Monoethanolamine	\
Hydrochloric Acid	\
Water for Injection	\

A clear yellow to amber liquid with a characteristic odour.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in the treatment 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.

3.3 Contraindications

Do not use in cats, dogs, horses and donkeys.
Do not use in sheep intended to be milked for human consumption.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product to animals:
Wash hands after use.
Avoid contact with the eyes.
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.

Special precautions for the protection of the environment:
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

3.6 Adverse events

Cattle, sheep and pigs:

Undetermined frequency (cannot be estimated from the available data)	Injection site reaction.[1]

[1] Transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative, or the national competent authority via the national reporting system, www.hpra.ie See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay.

Pregnancy and lactation:
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.

The use of the veterinary medicinal product during the period of tooth development including late pregnancy, may lead to tooth discoloration.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product should not be diluted with solutions of calcium salts as this causes precipitation.

3.9 Administration routes and dosage

The veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal product, one treatment is usually sufficient.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 28 days.
Milk: 7 days. Milk may only be taken from the 15th milking with a twice daily milking programme.

Sheep:
Meat and offal: 28 days.
Milk: Not authorised for use in sheep intended to produce milk for human consumption.

Pigs:
Meat and offal: 21 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ01AA06

4.2 Pharmacodynamics

The veterinary medicinal product 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 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

The veterinary medicinal product should not be brought into contact with calcium solutions as this causes precipitation.

5.2 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.

5.3 Special precautions for storage

Do not store above 25ºC. Protect from light.

5.4 Nature and composition of immediate packaging

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

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products.

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited.

7. MARKETING AUTHORISATION NUMBER

VPA22033/044/001

8. DATE OF FIRST AUTHORISATION

01/10/1988

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

06/09/2024

10 CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).