SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TERRAMYCIN/LA 200 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Oxytetracycline (as dihydrate) ……200 mg

Excipient:
Sodium Formaldehyde Sulfoxylate…….2.20 mg

For the full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Light to dark yellowish brown solution. It may have a green tint.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

Cattle: for the treatment and control of pasteurellosis and pneumonia caused by oxytetracycline-sensitive organisms, and as an aid in the treatment of infectious bovine keratoconjunctivitis due to sensitive strains of *Moraxella bovis*. May also be of value for foul-in-the-foot.

Pigs: for the treatment of pneumonia caused by *Pasteurella*.

Sheep: for the control of enzootic abortion and pneumonia caused by oxytetracycline-sensitive organisms. The product may be an aid in the treatment of foot rot, acute severe mastitis, infectious ovine keratonconjunctivitis (pink-eye).

4.3 Contraindications

Not recommended for dogs, cats and horses.
Use with caution in animals with hepatic or renal impairment.

4.4 Special warnings for each target species

Not to be injected subcutaneously.
Bacterial resistance may exist or develop after prolonged use of tetracyclines.

4.5 Special precautions for use

i) Special precautions for use in animals

It is recommended in cattle that not more than 10ml, and in sheep and pigs not more than 5 ml, be injected at any one intramuscular site (see also 4.9).

Do not dilute.

The period of time between first and last dose withdrawal from a multi-dose vial should not be longer than 28 days. Discard unused material. Contamination of broached vials during use should be avoided.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Local reactions at the injection site may occur.

The use of tetracyclines during the period of tooth development including late pregnancy, may lead to tooth discolouration.

4.7 Use during pregnancy, lactation or lay

Suitable for use in pregnant and lactating animals but not in ewes producing milk for human consumption.

4.8 Interaction with other medicinal products and other forms of interaction

Do not combine with bactericidal antimicrobial products or with infusion fluids.

Concomitant vaccination is not recommended because of possible immuno-suppressive activity of tetracyclines.

4.9 Amounts to be administered and administration route

For long acting effect the solution is given by deep intramuscular injection at a rate of 20 mg oxytetracycline base per kg bodyweight (i.e. 1 ml Terramycin LA solution per 10 kg bodyweight once). In cattle not more than 10 ml and in sheep and pigs not more than 5 ml to be given at any one site.
In pigs weighing less than 10 kg a 1 ml dose should be used.

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

Oxytetracycline has a wide margin of safety in the target species and overdosing is unlikely to produce toxic symptoms.

4.11 Withdrawal periods

Meat
Cattle: 36 days
Pigs: 36 days
Sheep: 24 days

Milk
Cattle:
Milk for human consumption must not be taken during treatment.
Milk from cows may only be taken for human consumption after 7 days from the last treatment.
Not for use in ewes producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Oxytetracycline is a member of the tetracycline group of antibiotics and is produced by fermentation of *Streptomyces rimosus*.

It is indicated for the treatment of bacterial infections caused by, or associated with, oxytetracycline-sensitive organisms.

Oxytetracycline possesses broad spectrum antimicrobial activity against a wide range of Gram-positive and Gram-negative bacterial strains. Certain *Mycoplasma* species and rickettsiae, protozoa ad the chlamydiae are sensitive to oxytetracycline.

Oxytetracycline is bacteriostatic and acts by inhibiting protein synthesis within the cell.

From its intramuscular injection site part of the drug is rapidly absorbed into the blood stream and distributed widely throughout the tissues.

The remainder of the drug is released more slowly from the depot at the injection site thus giving rise to a prolonged action lasting 3-5 days after a single injection.

High peak blood levels are reached within 4 hours and the drug depletion profile maintains therapeutic levels for 3-5 days.

Oxytetracycline is concentrated in respiratory and ocular tissues.

ATCVet Code: QJ01AA06

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

2-Pyrrolidone
Povidone K17
Sodium Formaldehyde Sulphoxylate Dihydrate
Magnesium Oxide Heavy
Monoethanolamine
Hydrochloric Acid
Water for Injections

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 first dose, use the product within 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
The formulation will freeze at -2°C but, on thawing, reverts completely to its original condition.

6.5 Nature and composition of immediate packaging

Multi dose Type II amber coloured glass vials of 100 ml capacity stoppered with a red butyl rubber bung and capped with a grey colour-coded flick-off cap on top of an aluminium crimp seal.

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

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4151

9. DATE OF THE FIRST AUTHORISATION

27 July 1990

10. DATE OF REVISION OF THE TEXT

March 2021

Approved: 16/03/21

D Austin