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 200 mg
as Oxytetracycline Dihydrate

Excipients
Sodium formaldehyde-sulphoxylate dehydrate 2.2 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear yellow to amber solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep, Pigs, Red Deer

4.2 Indications for use, specifying the target species

Cattle: For the treatment and control of pasteurellosis and pneumonia caused by oxytetracycline-sensitive organisms. May also be of value for the treatment of foul-in-the-foot.

Pigs: For the treatment of pneumonia caused by *Pasteurella* spp. and the control of atrophic rhinitis.

Sheep: For the control of enzootic abortion and pneumonia caused by oxytetracycline-sensitive organisms.Aid in the treatment of infectious ovine keratoconjunctivitis (pink-eye) and, in lambs, of tick-borne fever. May also be of value in the treatment of tick-pyaemia in lambs.

Red-deer: Aid in the control of yersiniosis.

4.3 Contraindications

Not for use in ewes producing milk for human consumption. Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

Not for use in ewes producing milk for human consumption.

Not to be injected subcutaneously except in piglets under 10 kg bodyweight.

Bacterial resistance may exist or develop after prolonged use of oxytetracycline.

4.5 Special precautions for use

Special precaution(s) for use in animals

Do not dilute.
Not to be injected subcutaneously except in piglets under 10 kg bodyweight.

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

Avoid skin contact to minimise the risk of sensitisation and contact of dermatitis.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Local reactions at the injection site may occur.
In very rare cases, hypersensitivity (allergic) reactions to treatment may occur in cattle, which may require appropriate symptomatic treatment.
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

None known.

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). In cattle and pigs not more than 10 ml and in sheep and deer 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, which may be given subcutaneously. For atrophic rhinitis a 0.5 ml dose is recommended at 3 days of age followed by a 1 ml dose at 12 and 21 days of age.

In young lambs for the treatment of tick pyaemia and as an aid in the treatment of tick-borne fever, a 2 ml dose is recommended per lamb.

For slow intravenous injection in cattle, which achieves low volume injection but no long-acting effect, a dose of 10 mg/kg body weight is recommended.
This may be followed by a single intramuscular injection of TERRAMYCIN LA 24 hours later at the 20 mg/kg bodyweight dose.
Alternatively treatment may be continued with daily doses of TERRAMYCIN Q -50 or TERRAMYCIN Q-100 by intramuscular injection at a dosage of 10 mg/kg bodyweight.

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 period(s)

Animals must not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after the following periods from the last treatment:-

Cattle, pigs and sheep: 21 days
Red deer: 30 days

Milk for human consumption must not be taken during treatment. Milk from treated cows may be taken for human consumption only after the following periods from the last treatment:-

Intramuscular Administration :

7 days (i.e. at the 15th milking in animals milked twice daily).

Intravenous Administration :

72 hours, (i.e. at the 7th milking in animals milked twice daily).

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracyclines
ATCvet Code: QJ01AA06

5.1 Pharmacodynamic properties

Mode of Action
Oxytetracycline is a member of the tetracycline group of antibiotics and is produced by fermentation of *Streptomyces rimosus*.
It possesses broad spectrum antimicrobial activity against a wide range of gram +ve and gram -ve bacteria, certain mycoplasmas, protozoa, rickettsiae and *Chlamydia*.
Oxytetracycline is bacteriostatic and acts by inhibiting protein synthesis within the cells of susceptible microorganisms.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium formaldehyde-sulphoxylate dihydrate
2-Pyrrolidone
Povidone
Magnesium Oxide
Monoethanolamine
Hydrochloric Acid Water for Injection

6.2 Major incompatibilities

None known

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

6.4 Special precautions for storage

Do not store above 25°C.
The solution may darken on exposure to air but the potency of the Terramycin remains unchanged.

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 centre tear off aluminium crimp seal and grey flick-off cap - containing a sterile, clear yellow to amber solution.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/077/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1988
Date of last renewal: 30th September 2008

10 DATE OF REVISION OF THE TEXT

November 2017