1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oxytetracycline 200 mg/ml L.A. solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Oxytetracycline 200 mg
As Oxytetracycline hydrochloride

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium formaldehyde sulfoxylate	5 mg
N-Methylpyrrolidone	0.50 ml
Magnesium chloride	
Povidone	
Ethanolamine	
Water for injections	

A clear, pale yellow to brown solution

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

Treatment of prophylaxis of susceptible bacterial infections.

Some specific indications are: respiratory infections such as pasteurellosis, bronchopneumonia, bovine respiratory disease complex.

3.3 Contraindications

Do not use in animals with severe renal insufficiency.
Do not use in cases of hypersensitivity to the active substance.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Warm the solution to body temperature before use.

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:
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.
In order to prevent any possible reaction, direct contact with the drug must be avoided.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]
Undetermined frequency (cannot be estimated from the available data)	Discoloured teeth[2]

1 Transient

2 During the period of tooth development, including late pregnancy

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. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in cattle during pregnancy, lactation or in animals intended for breeding.

Pregnancy and lactation:
Since oxytetracycline seems to be responsible for foetal malformations in laboratory animals, excessive treatment of pregnant animals must be avoided.
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.

3.8 Interaction with other medicinal products and other forms of interaction

In order to avoid possible interactions, do not mix Oxytetracycline 20% L.A. with other drugs in the same syringe.
Enzyme inducers such as phenobarbital and phenylbutazone increase the metabolism of tetracyclines and also shorten their plasma half-lives.

3.9 Administration routes and dosage

For deep intramuscular injection. Dosage: 20 mg/kg b.w. (1 ml per 10 kg bodyweight) with a maximum of 20 ml per injection site.
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)

When used intramuscularly in cattle at the recommended dosage, this veterinary medicinal product has a very low toxicity, and toxic reactions are not expected.

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

Meat and offal: 28 days.
Milk: 10 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01AA06

4.2 Pharmacodynamics

Oxytetracycline is a broad-spectrum antibiotic with a bacteriostatic action. It is active against gram-positive and gram-negative bacteria, spirochetes and actinomycetes. Resistant are *Proteus vulgaris* and *Pseudomonas aeruginosa*.

4.3 Pharmacokinetics

One injection of this long-acting preparation assures a therapeutic blood level for 3 days in cattle.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Store in a refrigerator (2°C – 8°C).
Protect from light.

5.4 Nature and composition of immediate packaging

Brown glass vial 100 ml, type II, with a bromobutyl rubber closure, sealed with an aluminium cap, containing 100 ml of the veterinary medicinal product.

The vials are packed in a polystyrene box, 12 vials of 100 ml per box, with 12 package leaflets.

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

Kela nv

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10981/005/001

8. DATE OF FIRST AUTHORISATION

30th September 2008

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

20/12/2023

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).