1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclosol LA 200 mg/ml solution for injection for cattle and pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Oxytetracycline (as dihydrate) 200 mg

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 sulphoxylate dihydrate	5.0 mg
Povidone K17	50.0 mg
N-methyl pyrrolidone	380.0 mg
Magnesium oxide, light	
Ethanolamine	
Water for injections	

A clear yellow to reddish-brown solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of infections caused by oxytetracycline sensitive microorganisms.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Do not use in animals with serious liver and/or kidney disturbances.
Do not use by intravenous route.

3.4 Special warnings

In case of a serious anaphylactic reaction the administration of epinephrine, antihistamines and/or corticosteroids should be considered.

3.5 Special precautions for use

Special precautions for safe use in the target species:

It is strongly recommended to divide the intramuscular dosages over two or more injection sites (see posology).
Use of the veterinary medicinal 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.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to oxytetracycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to oxytetracycline should avoid contact with the veterinary medicinal product.
Avoid skin contact with the solution.

Laboratory studies in rabbits and rats conducted 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:
Not applicable.

3.6 Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction (including anaphylaxis [a])
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site irritation [b]
Undetermined frequency (cannot be estimated from the available data):	Dental discolouration [c]

Pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site irritation [b] Dental discolouration [c]

[a] Which may be fatal.
[b] In some animals this may persist for about four days.
[c] Occurs in the offspring of treated animals when the veterinary medicinal product is used during 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

Pregnancy, lactation and fertility:
The placenta is readily passed by oxytetracycline and concentration in the foetal blood may reach those of the maternal circulation. Oxytetracycline is also excreted in the milk. Tetracyclines are deposited in deciduous and permanent teeth may cause discoloration, enamel hypoplasia, and reduced mineralisation in the young when used during pregnancy.

The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats conducted 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

Oxytetracycline should not be administered simultaneously with penicillins, cephalosporins, polyvalent cations or neuromuscular blocking agents.

3.9 Administration routes and dosage

Administration route: intramuscular use (deep).
The general dose is 20 mg oxytetracycline per kg body weight, i.e. 1 ml per 10 kg body weight.
Avoid more than 15 ml per injection site in cows.
If necessary, treatment should be repeated after 72 hours.

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

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

Tetracyclines are generally well tolerated after acute overdoses. Long-term treatment may result in gastrointestinal disturbances and changes of gut flora (supra-infections). Chronic overdose may lead to drug accumulation and nephrotoxicity. When used according to the recommendations none of these adverse effects will occur.

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	: 30 days.
	milk	: 12 days.
Pigs :	meat and offal	: 30 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01AA06

4.2 Pharmacodynamics

Tetracyclines are antibiotics with a broad spectrum of antimicrobial activity, sharing the same basic structure of polycyclic naphthacenecarboxamide

In vitro, oxytetracycline is primarily bacteriostatic. Oxytetracycline exerts its action by inhibiting the protein synthesis of the bacterial cell. Especially cell-division and the formation of the cell wall are impaired.

4.3 Pharmacokinetics

Absorption of oxytetracycline following intramuscular injection of the veterinary medicinal product in pigs is relatively fast. In pigs maximum concentrations are measured within 2 to 4 hours; the C_{max} is approximately 4 micrograms per millilitre. In cattle absorption is somewhat slower; the C_{max} is measured after 6 to 7 hours; the C_{max} is approximately 5 to 6 micrograms per millilitre. Plasma concentrations of 0.5 micrograms per millilitre or more are maintained for approximately 60-72 hours in cattle and pigs. Concentrations of 0.1 micrograms per millilitre are maintained for approximately 5 days. Studies indicate that bioavailability of the veterinary medicinal product is as high as 100%. High concentrations of oxytetracycline are detectable in kidney, liver, and urine, but oxytetracycline is widely distributed in the body, including lungs and muscle. Oxytetracycline apparently is not metabolized in vivo and is eliminated unchanged primarily, via glomerular filtration. The withdrawal time depends on residues present at the injection site.

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: 36 months
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The solution is presented in 50, 100 and 250 ml amber Type II glass vials with bromobutyl stoppers and aluminium caps.
Not all pack sizes may be marketed.

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

Eurovet Animal Health B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10989/026/001

8. DATE OF FIRST AUTHORISATION

01 October 1988

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

01 December 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).