ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX/50 ml; 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclosol LA 200 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance
Oxytetracycline (as dihydrate) 200.0 mg (equivalent to 216 mg Oxytetracycline dihydrate)

3. PACKAGE SIZE

50 ml; 100 ml and 250 ml

4. TARGET SPECIES

Cattle and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle : meat and offal: 35 days
milk: 8 days
Pigs : meat and offal: 28 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 14 days.
Once broached, use by: __/__/__.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Keep the container in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V. (or logo)

14. MARKETING AUTHORISATION NUMBERS

Vm 16849/3009

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL/50 ml; 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclosol LA 200 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance
Oxytetracycline (as dihydrate) 200.0 mg (equivalent to 216 mg Oxytetracycline dihydrate)

3. TARGET SPECIES

Cattle and pigs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle : meat and offal: 35 days
milk: 8 days
Pigs : meat and offal: 28 days

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the immediate packaging : 14 days.
Once broached, use by: __/__/__.

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Keep the container in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V. (Dechra logo)

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:
Active substance
Oxytetracycline (as dihydrate) 200.0 mg (Equivalent to 216 mg Oxytetracycline dihydrate)

Excipients:

Sodium formaldehyde sulphoxylate dihydrate	5.0 mg
Povidone K17	50.0 mg
N-methyl 2 pyrrolidone	380.0 mg

A clear yellow to reddish-brown aqueous solution.

3. Target species

Cattle and pigs.

4. Indications for use

Cattle: For the treatment of respiratory infections caused by oxytetracycline susceptible organisms such as *Arcanobacterium pyogenes* and *Haemophilus somnus.*
Pigs: For the treatment of respiratory infections caused by oxytetracycline susceptible organisms such as *Pasteurella multocida.*

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Do not use in animals with an impaired liver and/or kidney function.

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
For the 250 mL pack, the use of a multidose syringe is recommended. To refill the syringe, the use of a draw off needle is recommended to avoid excessive broaching of the stopper.
It is recommended to use the veterinary medicinal product in the early stages of disease and to evaluate the response to treatment within 72 hours.

Resistance against oxytetracycline may vary. Use of the veterinary medicinal product should be based on susceptibility testing and taking into account official and local antimicrobial policies.

Inappropriate use of the veterinary medicinal product 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.

Because oxytetracycline can retard skeletal development and may cause discoloration and enamel hypoplasia of foetal teeth, the veterinary medicinal product should be used cautiously in the last half of pregnancy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Persons with a known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product. The direct or indirect contact of the user via skin or mucosa should be avoided because of the risk of sensitisation. Wash hands after use. In case of contact with eyes or skin, wash immediately with water as irritation may occur.
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.

Other precautions:
Not applicable.

Pregnancy and lactation:
The placenta is readily passed by oxytetracycline and concentration in the foetal blood may reach those of the maternal circulation, although concentration is usually somewhat lower. The use is not recommended during the last 2-3 weeks of pregnancy.
The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy until 3 weeks before expected partus, 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.
Tetracyclines are deposited in deciduous and permanent teeth causing discoloration, enamel hypoplasia, and reduced mineralisation. Tetracyclines can retard foetal skeletal development. Oxytetracycline is excreted in the milk; concentrations are generally low.

Interaction with other medicinal products and other forms of interaction:
Oxytetracycline should not be administered simultaneously with penicillins or cephalosporins.

Overdose:
After intramuscular administration of the antibiotic in lethal dosages, central nervous system symptoms as excitation and convulsions, followed by depression, generalized

muscular paralysis and respiratory arrest, preceding death were observed (death usually occurs through respiratory failure). Long-term treatment may result in gastrointestinal disturbances and changes of gut flora (supra-infections). High dosages or chronic administration of oxytetracycline may delay bone growth and healing in young animals. Chronic overdose may lead to drug accumulation and nephrotoxicity. There are no known antidotes to oxytetracycline toxicity.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction including anaphylaxis [a], Hepatic toxicosis, Haematologic effects
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling, injection site reaction (yellow discolouration), injection site necrosis [b]
Undetermined frequency (cannot be estimated from the available data)	Photosensitivity [c], Decreased milk production [d]

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hepatic toxicosis, Haematologic effects
Undetermined frequency (cannot be estimated from the available data)	Injection site swelling, injection site reaction (yellow discoloration), injection site necrosis [b,] Photosensitivity [c], Decreased milk production [d]

[a] Which may be fatal. In case of a serious anaphylactic reaction in cattle the administration of
epinephrine, antihistamines and corticosteroids should be considered.
[b] Swelling will be visible for several days after injection.
[c] When exposed to intensive sunlight, particularly treated animals with poor skin pigmentation.

[d] Small drop in lactating animals for up to 3 days following injection.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Administration route: intramuscular use (deep).
It is strongly recommended to divide the intramuscular dosages over two or more injection sites - maximum 15 ml per injection site in cattle over 150 kg body weight and 7 ml in pigs and calves. Injection sites should be alternated.

- Pigs
  20 mg oxytetracycline per kg bodyweight, if necessary repeat after 72 hours
- Cattle **not** producing milk for human consumption
  20 mg oxytetracycline per kg bodyweight, if necessary repeat after 72 hours
- Cattle producing milk for human consumption
  20 mg oxytetracycline per kg bodyweight as a single injection only

9. Advice on correct administration

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

10. Withdrawal periods

Cattle	: meat and offal	: 35 days
	milk	: 8 days
Pigs	: meat and offal	: 28 days

11. Special storage precautions

Keep out of the sight and reach of children.
Do not freeze. Keep the container in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 14 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 16849/3009

Pack sizes:
Amber coloured, glass type II vials containing 50/100/250 ml solution for injection in an outer cardboard box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

November 2023

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands.
Tel: +31 348 563434

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Approved: 03 April 2024