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 AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Oxytetracycline 200.0 mg (equivalent to 216.0 mg oxytetracycline dihydrate)

Excipients:

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

3. PACKAGE SIZE

50 ml, 100 ml and 250 ml

4. TARGET SPECIES

Cattle and pigs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use (deep).

7. 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 container: 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.

14. MARKETING AUTHORISATION NUMBERS

Vm 16849/5009

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Pregnant women should take extra care when handling this veterinary medicinal product. See full user warnings for details.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V (Veterinary medicinal product subject to prescription)

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 AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Oxytetracycline 200.0 mg (equivalent to 216.0 mg oxytetracycline dihydrate)

Excipients:

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

3. TARGET SPECIES

Cattle and pigs**.**

4. ROUTES OF ADMINISTRATION

Intramuscular use (deep).
Read the package leaflet before use.

5. 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 container: 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.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
POM-V (Veterinary medicinal product subject to prescription))

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclosol LA 200 mg/ml solution for injection.

2. COMPOSITION

Each ml contains:

Active substance:
Oxytetracycline 200.0 mg (equivalent to 216.0 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 (Actinomyces) 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 precautions for safe us 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 resistan**ce.**
Because oxytetracycline can retard foetal 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:
People with 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 veterinary medicinal product is not recommended in 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 reactions [b]
Undetermined frequency (cannot be estimated from the available data)	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 Transient swelling and/or yellow staining (and local necrosis) will occur following intramuscular administration. 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.

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hepatic toxicosis, Haematologic effects
Undetermined frequency (cannot be estimated from the available data)	Photosensitivity [a], Injection site reactions [b], Decreased milk production [c]

a When exposed to intensive sunlight, particularly treated animals with poor skin pigmentation.
b Transient swelling and/or yellow staining (and local necrosis) will occur following intramuscular administration. Swelling will be visible for several days after injection.
c 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 vents to the marketing authorisation holder or 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.
Shelf life after first opening the container: 14 days.
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.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Medicines should not be disposed of via waste water.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 16849/5009

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

Find more information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands.

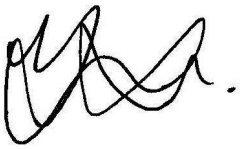
Local representative and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
SY4 4AS
United Kingdom
Tel: +44 (0)1939 211200

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

17. OTHER INFORMATION

POM-V (Veterinary medicinal product subject to prescription)



Approved: 03 April 2024