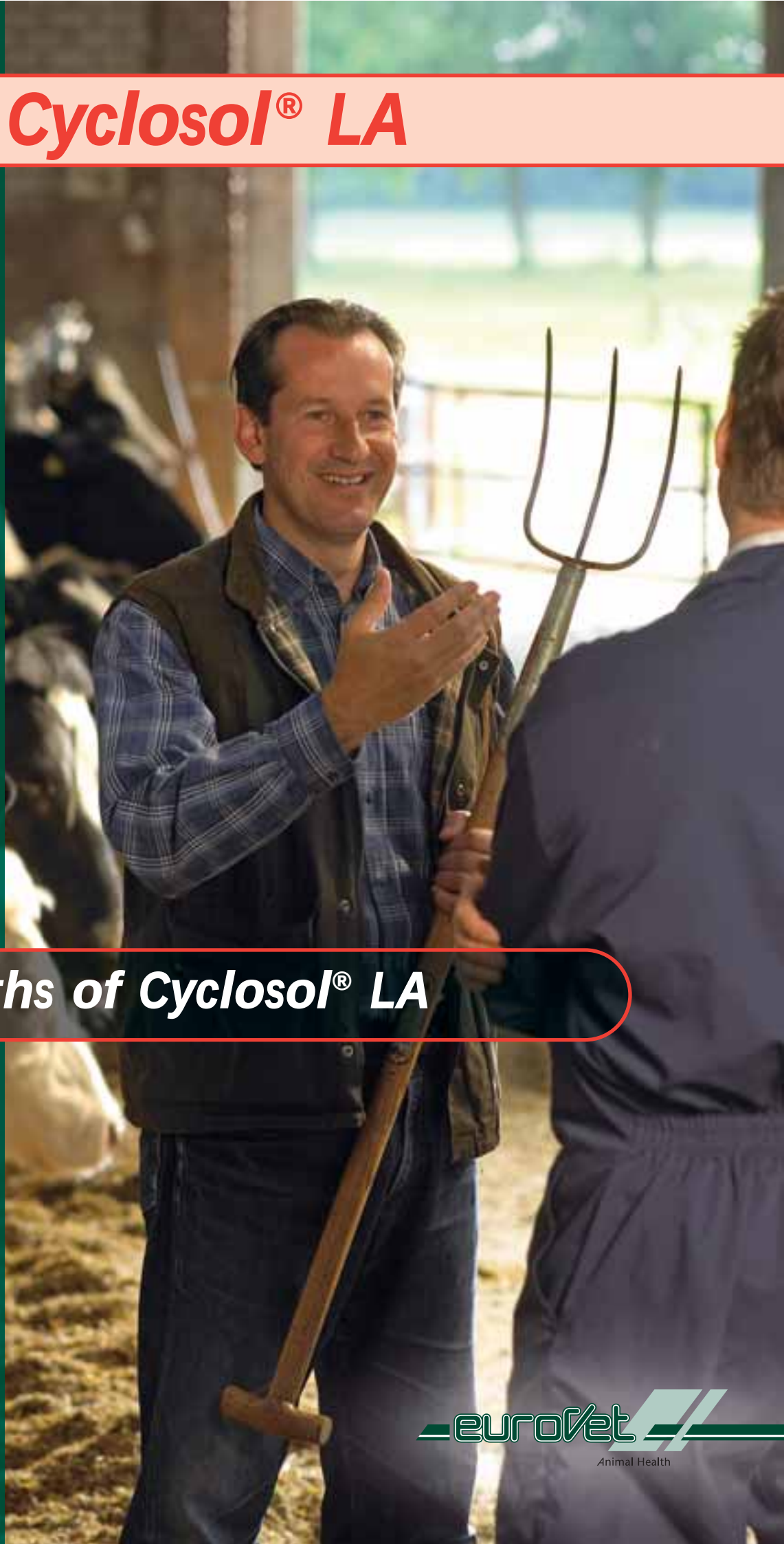
Cyclosol® LA



The strengths of Cyclosol® LA

Long-acting
Tissue friendly
Short withdrawal periods

eurovet
Animal Health

Cyclosol® LA

Introduction

Cyclosol® LA injection contains 216 mg oxytetracycline dihydrate per ml, equivalent to 200 mg of oxytetracycline.

Cyclosol® LA is indicated for the treatment of infections caused by bacteria, mycoplasmas, chlamydiae, rickettsias and protozoa susceptible to oxytetracycline in cattle, pigs, sheep and goats.

The recommended dose rates are:

- Cattle: 10 mg/kg (1 ml/20 kg); to be repeated after 48 hours.
- Cattle, calves and pigs: 20 mg/kg (1 ml/10 kg); if necessary, repeat after 72 hours.
- Sheep: 20 mg/kg (1 ml/10 kg); if necessary, repeat after 60 hours.

Cyclosol® LA is administered by deep intramuscular injection.
The maximum recommended volume per injection site is 15 ml in cattle weighing 150 kg or more and 7 ml in pigs, calves and sheep.

Formulated to be better

Cyclosol® LA is an aqueous solution of oxytetracycline in N-methyl-2-pyrrolidone/ PVP base.
This formulation combines a long duration of action with a remarkable tissue friendliness.

Long-acting in cattle, sheep and swine

Serum oxytetracycline concentrations are maintained above 0.5 µg/ml, the minimum inhibitory concentration for oxytetracycline for many pathogens[1], during

- 72 hours in cattle,
- 60 hours in sheep,
- and 60 to 72 hours in swine.

Tissue friendly

The tissue friendliness of Cyclosol® LA was demonstrated in two studies.[2]

Calves and pigs were given a single intramuscular injection with Cyclosol® LA at the recommended dose rate, and slaughtered at different time points for post-mortem examination of the injection site.
The injection site areas were photographed and an irritation index was determined based on the pathological findings and size of the injured area.

Irritation indexes

●	***No irritation or irritation repaired***	●	***Some irritation***
●	***Slight irritation***	●	***Severe irritation***

No or only mild tissue irritation 29 days after injection of calves with 20 mg/kg Cyclosol® LA

Days post injection	Post mortem irritation at injection site in calves after single intramuscular administration of Cyclosol LA (5 calves per day)				
	Calf 1	Calf 2	Calf 3	Calf 4	Calf 5
17 days	🔴	🟡	🟡	🟢	🟢
23 days	🟣	🟡	🟡	🟡	🟡
29 days	🟡	🟢	🟢	🟢	🟢
35 days	🟡	🟡	🟢	🟢	🟢

Injection site in a calf, 29 days after a single injection of Cyclosol® LA, at a dose rate of 20 mg/kg oxytetracycline per kg bodyweight, administered IM in the neck

No or only mild tissue irritation 25 days after injection of pigs with 20 mg/kg Cyclosol® LA

Days post injection	Post mortem irritation at injection site in pigs after single intramuscular administration of Cyclosol LA (5 pigs per day)				
	Pig 1	Pig 2	Pig 3	Pig 4	Pig 5
15 days	🔴	🟡	🟣	🟣	🔴
20 days	🟢	🟣	🟣	🔴	🟢
25 days	🟢	🟢	🟡	🟢	🟢
30 days	🟢	🟢	🟢	🟢	🟢

Injection site in a pig, 25 days after a single injection of Cyclosol® LA, at a dose rate of 20 mg/kg oxytetracycline per kg bodyweight, administered IM in the neck

References

1 U.S. Pharmacopeia Panel Report 2/23/96
2 Data on file, Eurovet

Shortened version of the insert

(for country specific details please consult your national registration)

Cyclosol LA, 200 mg/ml solution for injection

Qualitative and quantitative composition:
Each millilitre contains:
Active substance
Oxytetracycline (as dihydrate) 200.0 mg
(Equivalent to 216 mg Oxytetracycline dihydrate)

Target species:
Cattle and pigs

Indication 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*.

Contraindications:
Hypersensitivity to tetracyclines. The use of oxytetracycline in animals with an impaired liver and/or kidney function should be avoided.

Special precautions for use:
Special precautions for use in animals
It is strongly recommended to divide the intramuscular dosages over two or more injection sites (see posology).
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 Cyclosol LA in the early stages of disease and to evaluate the response to treatment within 72 hours.
Resistance against oxytetracycline may vary. Use of the product should be based on susceptibility testing and taking into account official and local antimicrobial policies.
Inappropriate use of the 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 fetal teeth, the 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 not handle this 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.

Undesirable effects (frequency and seriousness)
Hypersensitivity reactions (cattle), hepatotoxicity and haematologic effects have been reported, but are rare. In case of a serious anaphylactic reaction in cattle the administration of epinephrine, antihistamines and corticosteroids should be considered
Treated animals, particularly those with poor skin pigmentation, may develop photodermatitis when exposed to intensive sunlight. Following intramuscular administration a transient swelling and/or yellow staining (and local necrosis) will occur at the site of the injection. Swelling will be visible for several days after injection. Following injection a small drop in milk production may be observed in lactating animals for up to 3 days.
Interaction with other medicaments and other forms of interactions
Oxytetracycline should not be administered simultaneously with penicillins or cephalosporins.

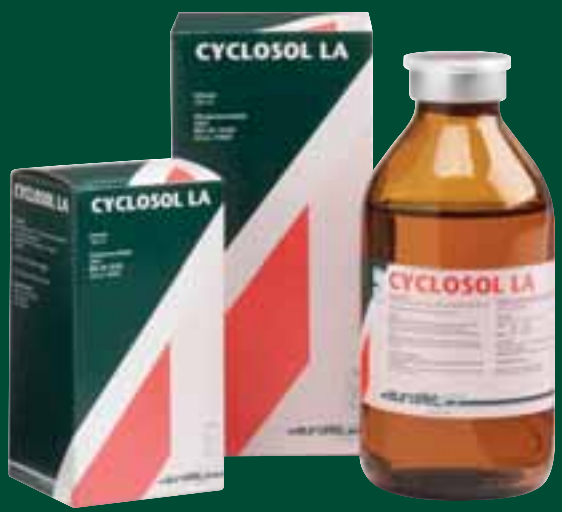
Amounts to be administered and administration route:
The product is indicated for (deep) intramuscular injection. It is strongly recommended to divide the intramuscular dosages over two or more injection sites - maximum 15 ml per injection site in cattle over 150 kg body weight and 7 ml in pigs and calves. 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

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

Shelf life:
Shelf-life of the veterinary medicinal product as packaged for sale: 30 months
Shelf-life after first opening the container: 14 days

Special precautions for storage:
Do not freeze. Keep container in the outer carton

Nature and composition of immediate packaging:
Amber coloured, glass type II vials containing 50/100/250 ml solution for injection. Not all pack sizes may be marketed.



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