TENALINE® LA

Product information

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tenaline LA.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Oxytetracycline ..... 200.0 mg
Sodium hydroxymethyl sulfinate ..... 1.5 mg

Excipient QS 1 ml

For the full list of excipients, see section 6.1. List of excipients.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 | Target species

Cattle, sheep and pigs.

4.2 | Indications for use, specifying the target species

In cattle, sheep and swine:
Treatment of septicemia, respiratory infections digestive or genitourinary, interdigital paronychia due to oxytetracycline - sensitive germs.

4.3 | Contraindications

Do not use in case of known allergy to oxytetracycline or any other substance of the tetracycline group.

Do not use in case of known resistance to tetracyclines.

4.4 | Special warnings for each target species

None.

4.5 | Special precautions for use

i Special precautions for use in animals

None

ii Special precautions to be taken by the person administering the veterinary medicinal product to animals

Do not handle this product if you are allergic to tetracyclines.

In case of reaction after exposure to the product (rash for example), consult a doctor.

iii Other precautions

None.

4.6 | Side effects (frequency and severity)

Locally, intolerance reactions can be observed ranging from pain at the injection site to muscle necrosis lesions.

As with all tetracyclines, general adverse events were noted such as gastrointestinal disorders, less frequently allergic reactions and photosensitivity.

4.7 | Use during pregnancy, lactation or lay

Oxytetracycline showed no evidence of embryotoxicity or teratogenicity in laboratory animals.

In mammals, oxytetracycline passes the placental barrier, causing staining of teeth and slowing of fetal growth.

Tetracyclines are found in breast milk. Product safety has not been evaluated in pregnant or lactating animals. The use of the product in pregnant or lactating animals should be the subject of a risk-benefit assessment by the veterinarian.

4.8 | Interaction with other medicinal products and other forms of interaction

Divalents and trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines.

4.9 | Amounts to be administered and administration route

Intramuscular route for cattle, sheep and pigs (adults).
Subcutaneous route for piglets.

20 mg of oxytetracycline per kg bodyweight in a single injection, ie 1 ml of solution for injection per 10 kg bodyweight.
If clinical signs of disease persist 72 hours after the first administration, a second administration of 20 mg oxytetracycline per kg may be given.

4.10 | Overdose (symptoms, emergency procedures, antidotes), if necessary

See section “Undesirable effects”.

4.11 | Withdrawal period(s)

Meat and offal: 21 days.

Milk: 7 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibiotic, tetracyclines.
ATC-vet code: QJ01AA06.

5.1 | Pharmacodynamic properties

Oxytetracycline reversibly binds to the 30S ribosomal fraction receptors, leading to blocking of the aminoacyl-tRNA binding at the corresponding site of the ribosome-messenger RNA complex. This results in an inhibition of the protein synthesis and thus a stop of the growth of the bacterial culture. Oxytetracycline has a mainly bacteriostatic activity.

The bacteriostatic activity of oxytetracycline involves penetration of the substance into the bacterial cell. The penetration of oxytetracycline is exerted by both passive and active diffusion. The main mode of possible resistance is related to the possible presence of an R factor responsible for a decrease in the active transport of oxytetracycline.

Oxytetracycline is a broad-spectrum antibiotic. It is primarily active against gram-positive and negative microorganisms, aerobic and anaerobic, as well as against mycoplasma, chlamydia and Rickettsiae.

Acquired resistance to oxytetracycline has been reported. Such resistance is usually of plasmid origin. Cross resistance to other tetracyclines is possible. Continuous treatment with low doses of oxytetracycline may also result in increased resistance to other antibiotics.

5.2 | Pharmacokinetic particulars

After administration, oxytetracycline is rapidly absorbed and distributed throughout the body, with the highest concentrations found in the kidneys, liver, spleen and lungs. Oxytetracycline crosses the placental barrier.
The excipients of the specialty and the form of oxytetracycline used ensure a concentration of oxytetracycline in the plasma greater than 0.5 µg / ml for about 72 hours, following an intramuscular injection at the dose of 20 mg / kg.

Oxytetracycline binds to plasma proteins in a variable manner depending on the species (20-40%).

Oxytetracycline is eliminated unchanged, mainly by the urinary tract. It is also excreted by the bile duct but a large proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).

6. PHARMACEUTICAL PARTICULARS

6.1 | List of excipients

Sodium hydroxymethyl sulfinate
Heavy Magnesium Oxide (E530)
Dimethylacetamide
Monoethanolamine
Water for injections

6.2 | Major incompatibilities

Not known.

6.3 | Shelf life

3 years.
After opening: 28 days.

6.4 | Special precautions for storage

No special storage conditions.

6.5 | Nature and composition of immediate packaging

Type II colourless glass vials.

Multilayer polypropylene/ethylene vinyl alcohol (EVOH)/polypropylene vials.

Chlorobutyl stopper.

Aluminium and plastic capsule of “flipp off” type.

6.6 | Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste materials should be disposed of in accordance with national requirements.