

Bovines • Swines

Terraflan® LA

Veterinary Use

Broad-spectrum antimicrobial agent, associated with analgesic, antipyretic and anti-inflammatory in long-acting vehicle

Terraflan LA is a long-acting antimicrobial based on oxytetracycline (hydrochloride), associated with piroxicam (anti-inflammatory, analgesic and antipyretic). **Terraflan LA** is indicated for the treatment of infections caused by microorganisms sensitive to oxytetracycline in bovines and pigs.

COMPOSITION:

Each 100 mL contains:	
Oxytetracycline (hydrochloride).....	20g
Piroxicam.....	300mg
Expicent(s).....	100ml

ATTENTION: COMPLY WITH THE FOLLOWING WITHDRAWAL PERIODS.**BOVINE AND SWINE**

SLAUGHTER: THE SLAUGHTER OF ANIMALS TREATED MUST ONLY BE MADE 45 DAYS AFTER THE LAST APPLICATION.

MILK: THIS PRODUCT SHOULD NOT BE APPLIED IN MILK-PRODUCING COWS FOR HUMAN CONSUMPTION.

THE USE OF THE PRODUCT UNDER CONDITIONS OTHER THAN THOSE INDICATED IN THIS LEAFLET MAY CAUSE RESIDUES OF THE PRODUCT TO EXCEED THE APPROVED LIMITS, RENDERING THE FOOD OF ANIMAL ORIGINS UNFIT FOR HUMAN CONSUMPTION.

INDICATIONS:

Terraflan LA is indicated for the treatment and effective control of infections caused by gram positive and gram negative bacteria, rickettsias, mycoplasmas, protozoa and chlamydia in bovines and pigs, such as:

BOVINE: Pneumonia and respiratory infections (*Pasteurella multocida*, *Haemophilus* spp.); Enteritis (*Escherichia coli*, *Salmonella* spp); Actinobacilose (*Actinobacillus* spp); Anaplasmosis (*Anaplasma* spp); Keratoconjunctivitis (*Moraxella bovis*); Symptomatic Caruncle (*Clostridium chauvoei*); Malignant edema (*Clostridium septicum*); Enterotoxemia (*Clostridium perfringens*); Listeriosis (*Listeria* spp); Nephritis, Abscess, Pyoderma, Cystitis (*Streptococcus* spp, *Staphylococcus* spp, *Corynebacterium* spp); Brucellosis (*Brucella* spp); Mastitis (*Enterobacter aerogenes*, *Streptococcus* spp, *Staphylococcus aureus*, *Corynebacterium pyogenes*); Onfaloplebitis (*Streptococcus* spp, *Staphylococcus* spp); Foot-Root (*Fusobacterium necrophorum*); Tetanus (*Clostridium tetani*).

SWINES: Enteritis (*Escherichia coli*, *Salmonella* spp); Enzootic pneumonia (*Mycoplasma hyopneumoniae*); Swine pleuropneumonia (*Haemophilus pleuropneumoniae*); Enterotoxemias (*Clostridium* spp); Infectious polyarthritis (*Haemophilus parasuis*); Erysipelas (*Erysipelotrix rhusiopathiae*); Leptospirosis (*Leptospira* spp); Atrophic rhinitis (*Bordetella bronchiseptica*); MMA Syndrome (*Staphylococcus* spp, *Streptococcus* spp, *Corynebacterium* spp); Nephritis, Metritis, Cystitis, Abscess (*Staphylococcus* spp, *Streptococcus* spp, *Corynebacterium pyogenes*).

DOSAGE: Terraflan LA is ready for use.

BOVINE AND SWINES: The recommended dose is 1mL/10 kg of body weight, intramuscularly, corresponding to a concentration of 20mg / kg of oxytetracycline (hydrochloride) and 0.3mg / kg of piroxicam. A single application is usually sufficient for effective treatment. However, the treatment should last for at least 48 hours after the disappearance of the symptoms or at the discretion of the Veterinarian.

PIGLETS: In piglets of 2 to 10 kg of body weight, it is recommended to apply 1.0 ml. In piglets weighing less than 2 kg of body weight, apply 0.5 ml. Note: Do not apply Terraflan LA the same day as applying iron to piglets. The maximum recommended volume at the same application site should be according to the table below:

Bovines and pigs.....	10,0mL
Piglets up to 1 day old.....	0,2mL
Piglets 2 to 7 days old.....	0,3mL
Piglets from 8 to 14 days of age.....	0,4mL
Piglets 15 to 21 days old.....	0,5mL
Piglets over 21 days old.....	1,0mL

PRECAUTIONS AND RECOMMENDATIONS FOR USE:

• **Keep the product in a safe place out of the reach of children and domestic animals.**

- Do not apply intravenously and subcutaneously.
- Use sterile and moisture-free syringes and needles to withdraw the product from the bottle.
- Do not store or apply with food, hygiene products and household utensils.
- Wash hands thoroughly with soap and water whenever the product comes into contact.
- Dispose of empty containers safely and avoid contamination of the environment.
- In case of accidental human contamination, seek medical attention by withdrawing the product packaging.

CONTRAINDICATIONS:

- Do not administer to equines, dogs and cats;
- Do not use in animals with a history of sensitivity to tetracyclines, piroxicam or any other pyrazolonic derivative, or in animals that have hepatic changes.

SIDE EFFECTS: Oxytetracyclines have no mutagenic and carcinogenic effects. However, they presented toxic effects to fetuses, which could lead to bone and dental malformations. Rare cases of neutropenia and anemia have been reported with the use of oxytetracyclines, in accordance to international literature this may occur with the use of oxytetracyclines:

- Allergic and anaphylactic reactions may occur in sensitive animals.
- Photosensitivity and chelating when used with Ca, Fe, Co and Al.
- Bone changes.

Note: Occasionally a discrete and transient reaction may occur at the point of application. However, such a reaction disappears without treatment.

DRUG INTERACTIONS:

- Do not administer in combination with benzylpenicillins and cephalosporins;
- Concomitant use of tetracyclines with methoxyflurane may result in fatal renal toxicity.
- May suffer or cause increased adverse reactions with cyclosporine, dipyrindamole, lithium, methotrexate, probenecid and salicylate.

PHARMACOKINETICS: Oxytetracycline is rapidly absorbed at the point of application and is distributed throughout the bloodstream of animals to all tissues, with higher concentrations in the liver and kidneys. The maximum absorption of oxytetracycline occurs in less than 24 hours, being detected at therapeutic levels for a period of 72 to 96 hours (AUC), in values above the minimum inhibitory concentration (MIC). Oxytetracycline is eliminated by urine and faeces. Piroxicam is rapidly absorbed from the point of application. It is distributed throughout the body of the animal. Being detected in therapeutic concentration for up to 50 hours after administration, its elimination is performed through urine, faeces and conjugation with glucuronic acid.

PHARMACODYNAMICS: Oxytetracycline is an antibiotic of the tetracycline family, bacteriostatic and exerts antimicrobial action by inhibiting protein synthesis, being active against a wide range of gram-positive and gram-negative organisms. Piroxicam is a non-hormonal anti-inflammatory agent (NSAID) that acts by inhibiting the synthesis and release of prostaglandins through a reversible inhibition of cyclooxygenase (cox 1 and 2) enzymes.

STORAGE: The product should be stored in its original packaging in an airy place, protected from light and heat, at room temperature ranging from 15 to 30°C. Once pierced the rubber stopper, use the contents within 28 days.

PRESENTATION: Amber glass vial of 50mL.

WARNING: This medicine is not for human use.

MANUFACTURER AND OWNER: CLARION BIOCÊNCIAS LTDA.

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Licensed at the Ministry of Agriculture under No. 7.438 on 08/18/2000.

Item number / Date of manufacture / Expiration date:

See bottle label.

SALE UNDER PRESCRIPTION AND APPLICATION UNDER THE VETERINARIAN'S ORIENTATION.

BRAZILIAN INDUSTRY

