

D3 Proposed Package Leaflet

Limoxin 200mg/ml LA Solution for Injection

Contains per ml:

Oxytetracycline (as dihydrate)200mg

Controlled Medicine
Keep out of reach of children
Jauhi dari kanak-kanak
MAL registration number

Product description:

Limoxin 200mg/ml LA Solution for Injection is a clear, yellow to amber coloured solution for intramuscular use.

Pharmacodynamics:

Oxytetracycline is a member of the tetracycline group of antibiotics and is produced by fermentation of *Streptomyces rimosus*.

It is indicated for the treatment of bacterial infections caused by, or associated with, oxytetracycline-sensitive organisms.

Oxytetracycline possesses broad spectrum antimicrobial activity against a wide range of Gram-positive and Gram-negative bacterial strains. Certain *Mycoplasma* species and rickettsiae, protozoa and the chlamydiae are sensitive to oxytetracycline.

Oxytetracycline is bacteriostatic and acts by inhibiting protein synthesis within the cell.

Pharmacokinetics:

From its intramuscular injection site part of the drug is rapidly absorbed into the blood stream and distributed widely throughout the tissues.

The remainder of the drug is released more slowly from the depot at the injection site thus giving rise to a prolonged action lasting 3-5 days after a single injection.

High peak blood levels are reached within 4 hours and the drug depletion profile maintains therapeutic levels for 3-5 days.

Oxytetracycline is concentrated in respiratory and ocular tissues.

Indication:

Cattle: for the treatment and control of pasteurellosis and pneumonia caused by oxytetracycline-sensitive organisms, and as an aid in the treatment of infectious bovine keratoconjunctivitis due to sensitive strains of *Moraxella bovis*. May also be of value for foul-in-the-foot.

Pigs: for the treatment of pneumonia caused by *Pasteurella*.

Sheep: for the control of enzootic abortion and pneumonia caused by oxytetracycline-sensitive organisms. The product may be an aid in the treatment of foot rot, acute severe mastitis, infectious ovine keratoconjunctivitis (pink-eye).

Recommended dose:

For long acting effect the solution is given by deep intramuscular injection at a rate of 20 mg oxytetracycline base per kg bodyweight (i.e. 1 ml Limoxin-200 LA per 10 kg bodyweight once).

In cattle not more than 10 ml and in sheep and pigs not more than 5 ml to be given at any one site.

In pigs weighing less than 10 kg a 1 ml dose should be used.

Contraindication:

Not recommended for dogs, cats and horses.

Use with caution in animals with hepatic or renal impairment.

Warning and Precautions:

Special warnings for each target species

Not to be injected subcutaneously.

Bacterial resistance may exist or develop after prolonged use of tetracyclines.

Special precautions for use

- i) Special precautions for use in animals
It is recommended in cattle that not more than 10ml, and in sheep and pigs not more than 5 ml, be injected at any one intramuscular site.
Do not dilute.
The period of time between first and last dose withdrawal from a multi-dose vial should not be longer than 28 days. Discard unused material.
Contamination of broached vials during use should be avoided.
- ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.

Interaction of other medicaments:

Do not combine with bactericidal antimicrobial products or with infusion fluids.

Concomitant vaccination is not recommended because of possible immuno-suppressive activity of tetracyclines.

Pregnancy and Lactation:

Suitable for use in pregnant and lactating animals but not in ewes producing milk for human consumption.

Side Effects:

Local reactions at the injection site may occur.

The use of tetracyclines during the period of tooth development including late pregnancy, may lead to tooth discolouration.

Symptoms and Treatment of Overdose:

Oxytetracycline has a wide margin of safety in the target species and overdosing is unlikely to produce toxic symptoms.

Withdrawal period:**Meat**

Cattle: 36 days

Pigs: 36 days

Sheep: 24 days

Milk

Cattle:

Milk for human consumption must not be taken during treatment.

Milk from cows may only be taken for human consumption after 7 days from the last treatment.

Not for use in ewes producing milk for human consumption.

Storage condition:

Do not store above 25°C. Do not store in the refrigerator. Do not freeze. Protect from direct sunlight.

Packaging:

Amber-coloured type II glass bottle of 100ml with a bromobutyl rubber stopper and aluminium cap.

Manufacturer:

Interchemie werken "De Adelaar" Eesti AS

Vanapere tee 14, Püünsi village, Viimsi municipality, Harju country, 74013 Estonia.

Marketing Authorization Holder:

Danberg (M) Sdn Bhd

Lot 1, Jalan Bursa 23/4, Seksyen 23, 40300 Shah Alam, Selangor, Malaysia.

Date of revision: 3 July 2019