OM-200 20% w/w Premix

For Animal Use Only

Name and Strength of Active Substance(s): 200g/kg Oxytetracycline (as Dihydrate)

Product Description: OM-200 20% w/w Premix is light yellow powder which contains oxytetracycline.

Pharmacodynamics:
Oxytetracycline is a bacteriostatic antibiotic that prevents the biosynthesis of bacterial proteins; this antibacterial action is the result of binding to the 30S subunit of ribosomes by chelating bonds with phosphate groups in messenger RNA. They thus prevent fixation of transfer RNA on messenger RNA (codon-anticodon interaction).
Oxytetracycline is a broad spectrum antibiotic. It is mainly active against Gram-positive and Gram-negative bacteria, as well as against mycoplasmas, chlamydia, leptospira and rickettsia.
Resistance can be natural or acquired and due to different mechanisms. Many tetracycline resistance genes are known and a large number of them are associated with mobile elements, whether in the form of plasmids, transposons or integrons. Three main mechanisms of resistance have been described: Three main mechanisms of resistance have been described: active antibiotic efflux, ribosomal protection and enzymatic inactivation, with active efflux being the most important mechanisms. There is a general cross-resistance between tetracyclines.
According to the CLSI (2008) standard, the cut-off points to classify the sensitivity to the tetracyclines are as follows:

Diameter (mm)	MIC (µg / ml)	Interpretation
≥ 19	≤ 4	Susceptible
15 - 18	5 - 15	Intermediate
≤ 14	≥ 16	Resistant

Pharmacokinetics:
Tetracyclines are incompletely absorbed from the gastrointestinal tract; absorption is decreased by the presence of soluble salts of divalent and trivalent metals. They bind to a variable degree to plasma proteins (approximately 25% oxytetracycline) and are widely distributed throughout the body, registering the highest concentrations in the kidney, liver, spleen and lung as well as in the active areas of ossification and lower concentrations in saliva, ocular humours and milk; They also cross the placental barrier. Oxytetracycline diffuses with difficulty to the cerebrospinal fluid, doing so to a greater degree when the meninges are inflamed. The elimination half-life of oxytetracycline is 8 hours.
They are excreted mainly in urine and faeces; renal excretion is by glomerular filtration (50-80%) finding the highest amounts in urine between 2-8 hours after administration. Faecal excretion may account for up to 10% of the dose.

Indications:
Porcine:
- Treatment of bacterial enteritis caused by microorganisms sensitive to oxytetracycline.
- Treatment of respiratory infections caused by Pasteurella multocida and Bordetella bronchiseptica sensitive to oxytetracycline.
- Treatment of leptospirosis caused by microorganisms sensitive to oxytetracycline.

Recommended Dosage:
Administration in feed.
Bacterial enteritis and respiratory infections: 30 mg of oxytetracycline/kg bw (equivalent at 150 mg premix/kg bw) /day, for 7 days.
Leptospirosis: 22 mg of oxytetracycline / kg bw (equivalent to 110 mg premix/kg bw) /day, for 7 days.

The consumption of feed depends on the clinical situation of the animal and the time of year. To ensure correct dosing, the concentration of the medicinal product in the feed should be adjusted taking into account daily consumption.
Use of the following formula is recommended to calculate the amount of premix to be added to the feed:

$$\text{kg premix / ton of feed} = \frac{\text{dose (mg/kg liveweight) x liveweight (kg)}}{\text{daily intake (kg) x premix dose (mg/g)}}$$

The weight of animals should be determined as accurately as possible to avoid underdosing.
During granulation, it is advisable to maintain a temperature below 70ºC.
It is not necessary to carry out a dilution prior to incorporation into the feed.

Mode of Administration: Oral

Contraindication:
- Do not use in case of hypersensitivity to tetracyclines or any of the excipients.
- Do not use in animals with liver or kidney disorders.
- Do not use in equids.

Warning and Precautions:
- Do not use between 2 days before and 10 days after vaccination against red disease.
- Feed intake can be modified as a result of the disease. In case of insufficient intake, administer an alternative parenteral treatment

Interaction with Other Medicinal Product:
Do not administer in conjunction with bactericidal antibiotics.
Divalent or trivalent cations (Mg2+, Fe2+, Ca2+, Al3+) can form chelates with tetracyclines. Tetracyclines should not be administered with antacids, gels containing aluminium and preparations containing vitamins or minerals, as insoluble complexes may form, decreasing the absorption of the antibiotic.

Pregnancy and Lactation:
Do not use this medicine during pregnancy or lactation.
The use of tetracyclines in pregnant animals may lead to adverse effects on the foetal bone and dental development.

Side Effects:
As with other tetracyclines, gastrointestinal disturbances have been observed and less frequently, allergic reactions and photosensitivity. Possible superinfection by non-sensitive microorganisms, especially fungi.

Symptoms and Treatment of Overdose:
In case of overdosage, alterations of the digestive flora and diarrhoea may appear.

Withdrawal Period:
Meat: 6 days

Storage Condition: Keep at a temperature below 30°C, in a dry place and protected from light.

Shelf Life: 3 years

Dosage Form: Powder

Packaging Available: 25kg

Date of Revision of Package Insert: 7rd March 2023

Name & Address of Manufacturer:
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