



DATA SHEET

Karidox™ 100 mg/ml Oral Solution

Presentation A clear, dense, brownish-yellow solution containing 100 mg doxycycline, as

doxycycline hyclate, per ml.

Uses In chickens, prevention and treatment of chronic respiratory disease (CRD) and

mycoplasmosis caused by microorganisms sensitive to doxycycline. In pigs, prevention of clinical respiratory disease due to *Pasteurella multocida* and

Mycoplasma hyopneumoniae sensitive to doxycycline. The presence of the disease in

the herd should be established before treatment.

Instructions for use

Karidox is to be administered in drinking water. For chickens, give 10 - 20 mg of doxycycline / kg liveweight / day for 3-5 days (i.e. 0.5-1.0 ml of product / litre of drinking water / day). For pigs, give 10 mg of doxycycline / kg b.w. / day for 5 days (i.e. 1 ml of product / 10 kg b.w. / day).

To ensure the correct dosage and avoid underdosing, liveweight should be determined as accurately as possible. The consumption of medicated water depends on the clinical condition of the animals. In order to achieve the correct dosage, the concentration of doxycycline has to be adjusted accordingly. Medicated water should be the only water available. The medicated water may be used only for 24 hours and should be made up freshly every day. If no improvement in clinical signs is seen within the recommended duration of treatment, the diagnosis should be reviewed and the treatment changed.

Contra-indications and warnings

Do not use Karidox in animals hypersensitive to tetracyclines, in animals with hepatic dysfunction or for laying hens. Allergic and photosensitivity reactions can occur. Intestinal flora may be affected if treatment is very prolonged, and this may result in digestive disturbance. Do not administer Karidox to laying birds from four weeks before the start of lay and during lay. It should not be used during pregnancy or lactation. Absorption of doxycycline may be reduced by high concentrations of calcium, iron, magnesium or aluminium in the diet. Do not administer with antacids, kaolin or iron preparations. Do not administer together with bactericidal antibiotics. The solubility of the product depends on acidity and will it precipitate if mixed in an alkaline solution. Do not administer with milk replacers.

Special precautions for use in animals Avoid administration in oxidized drinking equipment. Resistance against doxycycline may vary, so the use of this product should be based on culture and sensitivity of micro-organisms from diseased cases on the farm or on recent experience on the farm.

Special precautions to be taken by the person administering Karidox to animals Do not handle the product if you are hypersensitive to tetracyclines. Wear gloves, overalls and approved safety glasses. This product is acid and likely to be irritant. Avoid its contact with the skin and eyes. In case of contact with skin, rinse immediately with plenty of water. In case of contact with eyes, rinse immediately with copious amounts of water and seek medical advice. Do not smoke, eat or drink while handling this product. Administer the product with caution. The product can be harmful by skin contact and inhalation and may cause eye irritation. In case of

accidental ingestion seek medical advise and show the label to the doctor. If any clinical sign should appear, such as a cutaneous eruption, seek prompt medical advice. Swelling of the face, lips or eyes or respiratory difficulties are the most serious signs which require urgent medical attention.

Withdrawal period: 7 days.

Further information

Doxycycline is a bacteriostatic agent that acts by interfering with the bacterial protein syntesis of sensitive species. It is a semi-synthetic tetracycline derived from oxytetracycline. It acts on the subunit 30S of the bacterial ribosome, to which it is linked reversibly, blocking the union between aminoacyl-tRNA (transfer RNA) and the mRNA-ribosome complex, preventing the addition of new aminoacids to the growing peptide chain and thus interfering with protein synthesis. Doxycycline is active against Gram-positive and Gram-negative bacteria.

Spectrum of activity:

Streptococcus spp. Staphylococcus aureus Chlamydia spp. Salmonella spp. Pasteurella multocida Bordetella bronchiseptica

Mycoplasma spp.

In-vitro sensitivity of *Pasteurella multocida* and *Bordetella bronchiseptica* strains isolated from pigs to doxycycline has been determined by a plate-diffusion method, and against *Mycoplasma hyopneumoniae* by a dilution method. The MIC₉₀ values are 0.517 mcg/ml, 0.053 mcg/ml and 0.200 mcg/ml, respectively. According to the NCCLS standard, strains sensitive to doxycycline have MIC values below or equal to 4 mcg/ml and those resistant have MIC values above or equal to 16 mcg/ml.

Feeding can modify the oral bioavailability of doxycycline. After fasting, the bioavailability is 10-15% greater than in fed animals. Doxycycline is well distributed through the body, as it is highly lipid soluble. It accumulates in liver, kidney, bones and the intestine; enterohepatic recycling occurs. In the lungs, it always reaches higher concentrations than in plasma. Therapeutic concentrations have been detected in aqueous humour, myocardium, reproductive tissues, brain and mammary gland.

Pharmaceutical precautions

Do not mix Karidox with other veterinary medicinal products. The shelf-life of medicated water is 24 hours. The shelf-life after opening the primary packaging is 28 days. Do not store Karidox at temperatures above 25°C. Protect it from light.

Legal category

POM-V

Package quantities

Polyethylene bottles containining 1 litre.

Marketing authorization no.

Vm 31223/4000

Marketing authorization holder

Laboratorios Karizoo SA Poligono Industrial La Borda

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