

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

1 l bottle

5 l barrel

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KARIDOX 100 mg/ml solution for use in drinking water for chickens and pigs [ES, UK]
DOXYSOL 10% solution pour solution buvable [FR]

2. COMPOSITION

Each ml contains:

Active substances:

Doxycycline100 mg
(equivalent to doxycycline hyclate 116.0 mg)

Clear, dense, brownish-yellow solution.

3. PACKAGE SIZE

1 l bottle
5 l barrel

4. TARGET SPECIES

Chicken (broilers) and pigs.

5. INDICATIONS FOR USE

Indications for use:

CHICKENS (BROILERS)

Treatment and metaphylaxis of chronic respiratory disease (CRD) and mycoplasmosis caused by microorganisms sensitive to doxycycline.

PIGS

Treatment and metaphylaxis 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 the metaphylactic treatment.

6. CONTRAINDICATIONS

Contraindications:

Do not use in case of hypersensitivity to tetracyclines or to any of the excipients.

Do not use in case of resistance to tetracyclines occurs.

Do not use in animals with hepatic dysfunction.

7. SPECIAL WARNINGS

Special warnings

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Sick animals may have a reduced appetite and altered drinking patterns and should, if necessary, be medicated parenterally.

In cases of altered food or drinking water uptake, the concentrations should be adjusted in such a way that the recommended dosage is achieved.

Do not administer to laying hens.

Special precautions for use in the target species

Prolonged or repeated use of this veterinary medicinal product is discouraged. Attention should be paid to avoidance of stressful conditions and improvement of management practices and hygiene standards.

Avoid administration in oxidised drinking equipment.

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional and farm level) epidemiological information about susceptibility of the target bacteria, taking into account official national antimicrobial policies. Inappropriate use of the product may increase the prevalence of bacteria resistant to doxycycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross-resistance.

Due to variability (time, geographical) in susceptibility of bacteria for doxycycline, bacteriological sampling and susceptibility testing of micro-organisms from diseased birds on farm are highly recommended.

A high resistance rate of *E.coli*, isolated from chickens, against tetracyclines has been documented. Therefore the product should be used for the treatment of infections caused by *E.coli* only after susceptibility testing has been carried out.

As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.

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

Tetracyclines may – in very rare cases – induce photosensitivity and allergic reactions.

People with known hypersensitivity to doxycycline should avoid contact with the veterinary medicinal product. Personal protective equipment consisting of gloves, work overall, safety glasses should be worn when handling the veterinary medicinal product. This veterinary medicinal product is acid and likely to be irritant. The veterinary medicinal product can be harmful by skin contact and inhalation and may cause eye irritation. Avoid contact with 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 veterinary medicinal product.

In case of accidental ingestion seek medical advice and show the package leaflet or the label to the physician.

If any symptom 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.

Pregnancy and lactation:

The use is not recommended during pregnancy or lactation.

Laying birds:

Do not use in birds in lay and breeding birds.

Interaction with other medicinal products and other forms of interaction:

Doxycycline absorption may be reduced by the presence of high quantities of calcium, iron, magnesium or aluminium in the diet. Do not administer together with antacids, kaolin and iron preparations.

Do not administer together with bactericidal antibiotics.

The solubility of the product is pH dependent and will precipitate if mixed in alkaline solution

Do not administer with milk replacers

Overdose:

No data available.

Major incompatibilities:

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

Chickens (broilers) and pigs.

Undetermined frequency (cannot be estimated from the available data):

Allergic reaction ¹ , photosensitivity ¹ . Disorder of gastrointestinal flora ^{1,2} , digestive tract disorder ^{1,2} .
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¹ If suspected adverse reactions occur, treatment should be discontinued.

² In very prolonged treatments.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details on this label, or via your national reporting system: {national system details}

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use

The following dosage advice should be followed:

- CHICKEN (broilers): 11.5 – 23 mg doxycycline hyclate / kg body weight / day, corresponding to 0.1 – 0.2 ml of the veterinary medicinal product per kg body weight, for 3-5 consecutive days

- PIGS: 11.5 mg doxycycline hyclate / kg body weight / day, corresponding to 0.1 ml of the veterinary medicinal product per kg body weight, for 5 consecutive days).

Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of the veterinary product should be calculated according to the following formula:

$$\frac{\text{X ml veterinary medicinal product/ kg bodyweight perday} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{X ml veterinary medicinal product per litre of drinking water}$$

Medicated water should be the only drinking source.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of doxycycline in drinking water may need to be adjusted accordingly.

The use of suitably calibrated measuring equipment is recommended if part packs are used. The daily amount is to be added to the drinking water such that all medication will be consumed in 24 hours. Medicated drinking water should be freshly prepared every 24 hours. It is recommended to prepare a concentrated pre-solution – approximately 100 grams product per litre drinking water – and to dilute this further to therapeutic concentrations if required. Alternatively, the concentrated solution can be used in a proportional water medicator.

The remaining medicated water should be disposed of in accordance with local requirements.

If no improvement in clinical signs are seen within the treatment duration, the diagnosis should be reviewed and treatment changed.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat & offal:

Chickens (broilers): 7 days.

Pigs: 7 days.

Eggs: Not for use in birds producing or intended to produce eggs for human consumption.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30 °C.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number:

Pack sizes:

1 bottle of 1 l

1 barrel of 5 l

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised:

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12

08140 – Caldes de Montbui (Barcelona)
Spain
Tel: +34 93 865 41 48

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”
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For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 3 months.

Use by...

Once diluted use within 24 hours.

21. BATCH NUMBER

Lot {number}