

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

200 g and 1 kg bags

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Karidox 500 mg/g powder for use in drinking water for pigs, chickens and turkeys [ES, NL, HU, PL, PT, RO and LT]

Doxycycline

Karidox Doxycycline 500 mg/g Powder for use in Drinking Water for Pigs, Chickens and Turkeys [UK]

Doxycycline

Beladox 500 mg/g powder for use in drinking water for pigs, chickens and turkeys [DE]

Doxycycline

Supradox 500 mg/g powder for use in drinking water for pigs, chickens and turkeys [DK]

Doxycycline

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One gram contains:

Active substance:

Doxycycline (as hyclate) 500.0 mg

3. PHARMACEUTICAL FORM

Powder for use in drinking water.

Yellowish powder.

4. PACKAGE SIZE

200g bag

1kg bag

5. TARGET SPECIES

Pigs (fattening pigs after weaning), chickens (broilers, broiler breeders) and turkeys (broilers, breeders).

6. INDICATION(S)

Pigs (fattening pigs after weaning): treatment of clinical respiratory infections caused by *Mycoplasma hyopneumoniae* and *Pasteurella multocida* susceptible to doxycycline.

Chickens (broilers, broiler breeders) and turkeys (broilers, breeders): treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be administered in drinking water.

In pigs and chickens, 23.1 mg doxycycline hyclate per kg of body weight daily (equivalent to 40.0 mg product per kg of body weight), administered in the drinking water for 5 consecutive days.

In turkeys, 28.8 mg doxycycline hyclate per kg of body weight daily (equivalent to 50.0 mg product per kg of body weight), administered in the drinking water 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:

$$\frac{\begin{array}{c} \text{X g veterinary} \\ \text{product/ kg} \\ \text{b.w./day} \end{array} \times \begin{array}{c} \text{Mean body} \\ \text{weight (kg) of} \\ \text{animals to be} \\ \text{treated} \end{array}}{\text{Mean daily water consumption (l) per animal}} = \begin{array}{c} \text{X g veterinary} \\ \text{product per l} \\ \text{drinking water} \end{array}$$

To ensure a correct dosage body weight should be determined as accurately as possible. The uptake of medicated water is dependant on the clinical condition of the animals. In order to obtain the correct dosage, the concentration in drinking water may have to be adjusted.

The use of suitably calibrated weighing 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. It is recommended to prepare a concentrated pre-solution and to dilute this further to therapeutic concentrations if required. Alternatively, the concentrated solution can be used in a proportional water medicator.

Medicated water should be refreshed every 24 hours. The medicated water should be the only source of drinking water, throughout the treatment period. The medicated water must not be prepared or stored in a metal container.

The maximum solubility of the product in water is 72 g/L. Solubility of the product is pH dependent and it will precipitate if it is mixed in an alkaline solution.

8. WITHDRAWAL PERIOD

Pigs:	Meat and offal:	4 days
Chickens:	Meat and offal:	5 days
Turkeys:	Meat and offal:	12 days

Not permitted for use in laying birds producing eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Special warnings for each target species

The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of drinking water, animals should be treated parenterally.

Special precautions for use

Special precautions for use in animals:

Inappropriate use of the product may increase the prevalence of bacteria resistant to tetracycline due to the potential for cross resistance.

Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

The safety of the product has not been established in piglets before weaning. Avoid administration in oxidized drinking equipment.

Do not use when tetracycline resistance has been detected in the herd/flock 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:

During preparation and administration direct contact of the product with the skin, eyes and mucous membranes and inhalation of dust particles should be avoided.

People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.

Wear protective gloves (e.g. rubber or latex), goggles and an appropriate dust mask (either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143), when reconstituting or administering the solution. Wash exposed skin after preparation. In case of accidental projection into the eyes, rinse abundantly with water. Do not smoke, eat or drink when handling the product.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Inflammation of the face, lips or eyes or respiratory difficulties are the most serious signs which require urgent medical attention.

Use during pregnancy, lactation or lay:

Laboratory studies in rats and rabbits have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effects.

The safety of the product has not been established in pregnant or lactating sows. The use is not recommended during pregnancy and lactation. Do not use in birds in lay and within 4 weeks before the onset of the laying period.

Interaction with other medicinal products and other forms of interaction:

Do not administer concurrently with feed overloaded with polyvalent cations such as Ca^{2+} , Mg^{2+} , Zn^{2+} and Fe^{3+} because the formation of doxycycline complexes with these cations is possible. Do not administer together with antacids, kaolin and iron preparations as tetracyclines are bacteriostatic antimicrobials, do not administer in conjunction with bactericidal antibiotics like beta-lactams. It is advised that the interval between administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracycline.

Doxycycline increases the action of anticoagulants.

Overdose (symptoms, emergency procedures, antidotes), if necessary:

During the target animal tolerance study, no adverse effect was observed even at the fivefold therapeutic dose administered for two times the recommended duration in either target animal species.

If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.

10. EXPIRY DATE

EXP:

Shelf-life after first opening the container: 3 months

Shelf-life after dilution: 24 hours

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder and manufacturer for the batch release:

LABORATORIOS KARIZOO, S.A.

Polígono Industrial La Borda

Mas Pujades, 11-12

08140 – CALDES DE MONTBUI (Barcelona)

SPAIN

16. MARKETING AUTHORISATION NUMBER(S)
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17. MANUFACTURER'S BATCH NUMBER
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Batch

18. FURTHER INFORMATION

Contraindications

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

Do not use in animals with hepatic dysfunction.

Adverse reactions

As for all tetracyclines, on rare occasions allergic reactions and photosensitivity may occur. If suspected adverse reactions occur, treatment should be discontinued

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Date on which the package leaflet was last approved: