PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

Package leaflet Karidox 125 mg/g Premix for medicated feeding stuff for pigs

Bags of 25 kg

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

<u>Marketing authorisation holder and manufacturer responsible for batch release:</u>

LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

2. Name of the veterinary medicinal product

Karidox 125 mg/g Premix for medicated feeding stuff for pigs
Doxycycline (hyclate)

3. Statement of the active substance (s) and other ingredients

Each g contains:

Active substance:

Doxycycline (hyclate)	125.0 mg
(as doxycycline hyclate	144.2 mg)

Excipients:
Flour of hazelnut and almond shell

Brown yellowish powder.

4. Pharmaceutical form

Premix for medicated feeding stuff.
Brown yellowish powder.

5. Package size

25 kg bags

6. Indication(s)

Treatment and metaphylaxis of pleuropneumonia caused by *Actinobacillus pleuropneumoniae* susceptible to doxycycline.
The presence of the disease in the herd should be established before use.

7. Contraindications

Do not use in cases of hypersensitivity to tetracyclines or to any of the excipients.
Do not use in animals with hepatic dysfunction.
See section "Use during pregnancy, lactation or lay".

8. Adverse reactions

As for all tetracyclines, on rare occasions allergic reactions and photosensitivity may occur.
In prolonged treatments digestive alterations may appear due to intestinal dysbiosis.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

9. Target species

Pig (Pig for fattening).

10. Dosage for each species, route(s) and method of administration

In-feed use.

The premix is administered directly mixed with feed according to the following dose:

10-12 mg of doxycycline/kg bodyweight/day, equivalent to 80-95 mg of the product/kg bodyweight/day.

Treatment should be continued for 8 days.

Since the intake of feed will vary depending on the clinical condition of the animals, in order to obtain the correct dosage the concentration of doxycycline has to be adjusted accordingly. To calculate the dosage of the veterinary medicinal product, the following formula could be used as an example:

$$\text{mg of veterinary medicinal product per kg of feed} = \frac{\text{80 – 95 mg veterinary medicinal product/kg b.w./day x mean body weight (kg) of animals to be treated}}{\text{Mean daily feed intake/animal (kg)}}$$

11. Advice on correct administration

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

The recommended incorporation rate into feed would be 2 kg of the veterinary medicinal product per tonne of feed.

The required doses should be measured by suitably calibrated weighing equipment.

12. Withdrawal period(s)

Withdrawal period(s):
Pigs for fattening:
Meat and offal: 5 days

13. Special storage precautions

Do not store above 30 ºC.
Keep the bags tightly closed in order to protect from light and to avoid the introduction of contamination.

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.

14. Special warning(s)

Special warnings for each target species:

The intake of medicated feed by animals can be altered as a consequence of illness. In case of insufficient intake of feed, animals should be treated parenterally.

Special precautions for use in animals:

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, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the product deviating from the instructions given in the SPC 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.

Consideration should be given to improvement of management practices on the farm. Particular attention should be paid to hygiene and ventilation, and management of pigs to avoid stress-related conditions.

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

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

Handle the veterinary medicinal product with care to avoid inhalation of dust particles and skin and eye contact during the incorporation of the premix into feed, taking into account the following specific recommendations:
Take the necessary measures to avoid producing dust during the incorporation of the premix into feed.

Personal protective equipment consisting of 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), impermeable gloves, overalls and approved safety goggles should be worn when handling the veterinary medicinal product.
Avoid skin and eye contact. In case of accidental exposure rinse immediately with plenty of water and if irritation occurs, seek medical attention.
Do not smoke, eat or drink while handling the product.

In case of accidental ingestion or if you develop symptoms following exposure such as skin rash, seek medical immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Pregnancy:
Laboratory studies in mice and rabbits have not produced any evidence of toxic effects. The safety of the veterinary medicinal product has not been established during pregnancy in sows, the use is not recommended during pregnancy.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation in sows, thus its use is not recommended during lactation.

Fertility:
Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:

The absorption of doxycycline can be reduced in the presence of high amounts of Ca^{2+}, Fe^{3+}, Mg^{2+} or Al^{3+} in the diet. Do not administer together with antacids, kaolin and iron preparations and in conjunction with bactericidal antibiotics like beta-lactams.

Overdose (symptoms, emergency procedures, antidotes):

Not described.

Incompatibilities:

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

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater or household waste
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

16. Date on which the label was last approved

February 2020

17. Other information

Package size:
Bag of 25 kg

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

18. 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. To be administered by the veterinarian or under veterinarian supervision.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}
Once opened use by…

Shelf life after first opening the container: 2 months
Shelf life after incorporation into meal or pelleted feed: 1 month

21. Marketing authorisation number(s)

22. Manufacturer's batch number

Lot {number}: