<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

Powdox 500 mg/g powder for use in drinking water for pigs, chickens and turkeys [AT, BG, DE, DK, EL, ES, , HU, IT, , PL, PT]
Doxycycline (hyclate)

Powdox Doxycycline 500 mg/g powder for use in drinking water for pigs, chickens and turkeys [IE, UK]
Doxycycline

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains:

Active substance:
Doxycycline 500.0 mg
(equivalent to doxycycline hyclate 580.0 mg)

3. PHARMACEUTICAL FORM

Powder for use in drinking water.
Yellowish powder.

4. PACKAGE SIZE

200g bag
1kg bag

5. TARGET SPECIES

Pigs for fattening, chickens (broilers, chicken for reproduction) and turkeys (broilers, turkeys for reproduction).

6. INDICATION(S)

Pigs: treatment of clinical respiratory infections caused by *Mycoplasma hyopneumoniae* and *Pasteurella multocida* strains susceptible to doxycycline.
Chickens and turkeys: treatment of clinical respiratory infections associated with *Mycoplasma gallisepticum* susceptible to doxycycline.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water use. 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:

mg product / kg body weight / day	x	Mean body weight (kg) of animals to be treated	= .... mg product per l drinking water
Mean daily water consumption (l) per animal			

To ensure a correct dosage body weight should be determined as accurately as possible. The uptake of medicated water is dependent 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(S)

Withdrawal period:

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

Not for use in birds producing or intended to produce 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.
Under-dosing and/or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.

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 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.
The safety of the product has not been established in piglets before weaning. Avoid administration in oxidised drinking equipment.
Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance.
Due to likely variability (time, geographical) in the occurrence of resistance of bacteria for doxycycline, bacteriological sampling and susceptibility testing are 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.
. Personal protective equipment consisting of 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) should be worn when handling the veterinary medicinal product. 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 veterinary medicinal 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. 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.
Do not administer together with antacids, kaolin or iron preparations.
Do not administer in conjunction with bactericidal antibiotics such as beta-lactams as tetracyclines are bacteriostatic antimicrobials.
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.

Incompatibilities:
Doxycycline may form insoluble complexes with divalent ions, especially iron or calcium, zinc and magnesium.
Do not mix with any other veterinary medicinal product.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 3 months. Use by…
Once diluted use within 24 hours
Do not use this veterinary medicinal product after the expiry date. The expiry date refers to the last day of that month.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

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

Medicines should not be disposed of via wastewater.
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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L
Les Corts, 23
08028 Barcelona
SPAIN

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

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch

18. FURTHER INFORMATION

Contraindications
Do not use in cases of hypersensitivity to the active substance or to any of the excipient.
Do not use in animals with hepatic dysfunction.

Adverse reactions
On rare occasions allergic reactions and photosensitivity may occur. If suspected adverse reactions occur, treatment should be discontinued.

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-leaflet 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}.

Date on which the package leaflet was last approved