A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 g polypropylene container with polypropylene lid and inner bag of LDPE.
1 kg round polypropylene container with polypropylene lid and inner bag of LDPE.
1 kg square polypropylene container with polypropylene lid and inner bag of LDPE.
5 kg round polypropylene container with polypropylene lid and inner bag of LDPE.
5 kg square polypropylene container with polypropylene lid and inner bag of LDPE.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pulmodox 500 mg/g granules for oral solution for pigs, chickens and turkeys

Doxycycline (as hyclate)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Granules for oral solution

4. PACKAGE SIZE

100 g
1 kg
5 kg

5. TARGET SPECIES

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

6. INDICATION(S)

Pigs: treatment of clinical respiratory infections caused by *Mycoplasma hyopneumoniae* and *Pasteurella multocida* 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

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal of pigs: 4 days.
Meat and offal of chickens: 5 days.
Meat and offal of turkeys: 12 days.
Not permitted for use in laying birds producing eggs for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening of container: 3 months
Shelf life after reconstitution in drinking water: 24 hours.
Once broached/opened, use by ……..

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original container tightly closed in order to protect from moisture.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

Lavet Pharmaceutical Ltd.
1161 Budapest
Ottó u. 14.
Hungary

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32823/5000

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PACKAGE LEAFLET
Pulmodox 500 mg/g granules for oral solution for pigs, chickens and turkeys

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Lavet Pharmaceuticals Ltd., 1161 Budapest, Ottó u. 14., Hungary
Manufacturer responsible for batch release:
Lavet Pharmaceuticals Ltd., 2143 Kistarcsa, Batthyány u. 6., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pulmodox 500 mg/g granules for oral solution for pigs, chickens and turkeys

Doxycycline (as hyclate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)
Active substance:

Doxycycline 500.0 mg
(equivalent to Doxycycline hyclate 580.0 mg)

Yellow, free-flowing granules.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use when tetracycline resistance has been detected in the herd/flock due to the potential for cross resistance.
Do not use in animals with hepatic dysfunction.

6. 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.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage:
In pigs and chickens
20.0 mg doxycycline 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
25 mg doxycycline 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.

9. ADVICE ON CORRECT ADMINISTRATION

The following dosage advice should be followed:
In pigs and chickens
20.0 mg doxycycline 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
25 mg doxycycline 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.
Administration:
Based on the recommended dose, and the number and weight of the animals to be treated, the exact daily amount of the product should be calculated according to the following formula:

$$\frac{\text{..... mg product per kg body weight per day} \times \text{Mean body weight (kg) of animals to be treated}}{\text{Mean daily water consumption (litre per animal)}} = \text{.... mg product per litre of drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible.
The uptake of medicated water is dependant on the clinical conditions 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. 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. The maximum solubility of the product in water is 72 g/L. Alternatively; the concentrated solution can be used in a proportional water medicator.

It should be ensured that all animals intended to treat should have free access to the drinking facilities. At the end of treatment, the watering equipment should be cleaned adequately to avoid the uptake of remaining quantities in sub-therapeutic doses.
The medicated water should be the only source of drinking water, throughout the treatment period. The medicated water must not be made or stored in a metal container and use in oxidized drinking equipment. Solubility of the product is pH dependent and it will precipitate if it is mixed in an alkaline solution.

10. WITHDRAWAL PERIOD

Meat and offal of pigs: 4 days.
Meat and offal of chickens: 5 days.
Meat and offal of turkeys: 12 days.
Not permitted for use in laying birds producing eggs for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25°C.
Store in the original container tightly closed in order to protect from moisture.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 3 months.
Shelf-life after dilution or reconstitution according to directions: 24 hours.

12. SPECIAL WARNING(S)

Special precautions for use in animals
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.
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of water, animals should be treated parenterally.

Inappropriate use of the product may increase the prevalence of bacteria resistant to tetracycline 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 animals 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.
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.
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-lactames. 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.
Doxycycline may form insoluble complexes with divalent ions, especially iron or calcium, zinc and magnesium.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
Direct contact of the product with the skin, eyes and mucous membranes should be avoided.
People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
Wear protective gloves and goggles 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
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.

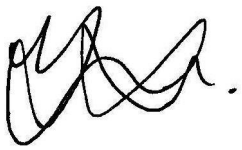
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
100 g polypropylene container with polypropylene lid and inner bag of LDPE.
1 kg round polypropylene container with polypropylene lid and inner bag of LDPE.
1 kg square polypropylene container with polypropylene lid and inner bag of LDPE.
5 kg round polypropylene container with polypropylene lid and inner bag of LDPE.
5 kg square polypropylene container with polypropylene lid and inner bag of LDPE.
Not all pack sizes may be marketed.

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

On the UK package leaflet:
When the container is opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.



Approved: 16 March 2022