LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1.25 kg polypropylene container with inner bag of LDPE.
6.25 kg polypropylene container with inner bag of LDPE.
12.5 kg polypropylene container with inner bag of LDPE.
12.5 kg multiwalled, polyethylene layered paper bag.
25 kg multiwalled, polyethylene layered paper bag.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ladoxyn 100 mg/g premix for medicated feeding stuff for pigs
(in Austria, Cyprus, Hungary, Italy, Portugal and Slovakia)
Ladoxyn 100 mg/g premix pro medikaci krmiva
(in Czech Republic)
Ladoxyn 100 mg/g Premezcla
(in Spain)
Pulmodox 100 mg/g premix for medicated feeding stuff for pigs
(in Germany, Greece and United Kingdom)

Doxycycline (as hyclate)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:	Doxycycline (as hyclate)	100.0 mg/g
	(equivalent to 115.4 mg doxycycline hyclate)	
Excipients:	Lactose monohydrate	

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff

4. PACKAGE SIZE

1.25 kg
6.25 kg
12.5 kg

25 kg

5. TARGET SPECIES

Pigs (weaned piglet).

6. INDICATION(S)

Treatment and prevention of clinical respiratory infections caused by *Mycoplasma hyopneumoniae* and *Pasteurella multocida* susceptible to doxycycline. The presence of disease in the herd should be established before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For in-feed use.
Average dose: 12.5 mg doxycycline per kg of body weight daily administered for 8 days.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 7 days.

9. SPECIAL WARNING(S), IF NECESSARY

Direct contact of the product with the skin, eyes and mucous membranes
is dangerous. Read package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening of container: 3 months
Shelf life after incorporation in meal or pelleted feed: 3 months
The product may be incorporated into pelleted feed, conditioned at a maximum temperature of 75 ºC.
Once broached/opened, use by ……..

11. SPECIAL STORAGE CONDITIONS

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

Keep the plastic container tightly closed, or re-close the paper bag mechanically as much as possible.

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 Pharmaceuticals Ltd.
1161 Budapest
Ottó u. 14.
Hungary

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

PRODUCT INFORMATION

PACKAGE LEAFLET
Ladoxyn 100 mg/g premix for medicated feeding stuff for pigs

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., H-1161 Budapest, Ottó u. 14., Hungary

Manufacturer for the batch release:
Lavet Pharmaceuticals Ltd., H-2143 Kistarcsa, Batthyány u. 6., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ladoxyn 100 mg/g premix for medicated feeding stuff for pigs
(in Austria, Cyprus, Hungary, Italy, Portugal and Slovakia)
Ladoxyn 100 mg/g premix pro medikaci krmiva
(in Czech Republic)
Ladoxyn 100 mg/g Premezcla
(in Spain)
Pulmodox 100 mg/g premix for medicated feeding stuff for pigs
(in Germany, Greece and United Kingdom)

Doxycycline (as hyclate)

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

Yellow, free-flowing granules.
Active substance: Doxycycline (as hyclate) 100.0 mg/g
(equivalent to 115.4 mg/g doxycycline hyclate)
Excipients: lactose monohydrate

4. INDICATION(S)

Treatment and prevention of clinical respiratory infections caused *by Mycoplasma hyopneumoniae* and *Pasteurella multocida* susceptible to doxycycline. The presence of disease in the herd should be established before use.

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 due to the potential of cross resistance.

6. ADVERSE REACTIONS

As for all tetracyclines, on very 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 package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (weaned piglet).

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

To be administered orally, in medicated feeding stuff.
Dosage:
12.5 mg doxycycline per kg of body weight daily, administered for 8 days.

9. ADVICE ON CORRECT ADMINISTRATION

Administration:
An inclusion rate of 2.5 g Ladoxyn 100 mg/g premix for medicated feeding stuff for pigs (equivalent to 250 mg doxycycline) per kg of feed should provide the recommended dose in growing pigs between 10 and 50 kg of body weight. When medicating larger pigs including breeding animals or where inappetance occurs, the inclusion level may need adjusting as follows to give the correct dose.
Example: Dose - 12.5 mg doxycycline per kg of body weight.

$$\frac{\text{.....mg Ladoxyn 100 mg/g premix per kg body weight and day} \times \text{Average pig body weight (kg)}}{\text{Average daily feed intake (kg/animal)}} = \text{....mg Ladoxyn 100 mg/g premix per kg of feed}$$

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The required doses should be measured by suitably calibrated weighing equipment. To achieve good mixture and homogeneity of incorporation, the use of a pre-mixture is recommended. The required quantity of veterinary medicinal product is thoroughly mixed with a feed ingredient of similar physical nature in the proportion: 1 part Ladoxyn 100 mg/g premix to 10 parts feed ingredient. This pre-mixture is added to the mixer containing the

feeding stuff ingredients and mixed thoroughly to produce a homogeneous medicated feeding stuff for incorporation into dry food at the registered mill. Medicated feed may be pelleted using a pre-conditioning step with steam at temperatures not exceeding 75°C.
A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

10. WITHDRAWAL PERIOD

Meat and offal: 7 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25°C.
Store in the original container in order to protect from moisture.
Keep the plastic container tightly closed, or re-close the paper bag mechanically as much as possible (e.g. by a knot on the plastic bag).
Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 3 months.
Shelf-life after incorporation into meal or pelleted feed: 3 months.
When the container is broached (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 carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

During the target animal tolerance study, no adverse effect was observed even at the threefold therapeutic dose administered for two times the recommended duration.
If suspected toxic reactions do occur due to extreme overdose, the medication should be discontinued and appropriate symptomatic treatment should be initiated if necessary.
Inappropriate use of the veterinary medicinal product may increase the prevalence of bacteria resistant to doxycycline.
The uptake of medication by animals can be altered as a consequence of illness. In case of insufficient uptake of feed, animals should be treated parenterally.
Use of the veterinary medicinal product should be based on susceptibility testing and take into account official and local antimicrobial policies. The use of the veterinary medicinal product should be limited to herds where the disease has been diagnosed.
Handle this veterinary medicinal product with care to avoid exposure during incorporation into feed and administration of medicated feed to the animals, taking all recommended precautions. Mix the veterinary medicinal product into feed evenly and hygienically. Take adequate measures to avoid dust formation when incorporating the veterinary medicinal product into feed. Wear dust mask, gloves, overalls and approved safety glasses. Direct

contact of the veterinary medicinal product with the skin, eyes and mucous membranes should be avoided. In case of accidental exposure rinse abundantly with water. Do not smoke, eat or drink when handling the veterinary medicinal product.
People with known hypersensitivity to doxycycline should avoid contact with the veterinary medicinal 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.
The safety of the veterinary medicinal product has not been established in pregnant and lactating sows. The use is not recommended during pregnancy and lactation.
Do not incorporate the veterinary medicinal product in 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 and in conjunction with bactericidal antibiotics like beta-lactames.
Doxycycline increases the action of anticoagulants.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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:
1.25 kg polypropylene container with inner bag of LDPE.
6.25 kg polypropylene container with inner bag of LDPE.
12.5 kg polypropylene container with inner bag of LDPE.
12.5 kg multiwalled, polyethylene layered paper bag.
25 kg multiwalled, polyethylene layered paper bag.
Not all pack sizes may be marketed.

For animal treatment only – to be supplied only on veterinary prescription.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.