

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet {1L/5L}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DFV DOXIVET 200 mg/ml, solution for use in drinking water for pigs and chickens.

2. COMPOSITION

Each ml contains:

Active substances:

Doxycycline hyclate 230 mg
Equivalent to 200 mg doxycycline base

Clear yellow-brown solution.

3. PACKAGE SIZE

1 l
5 l

4. TARGET SPECIES

Pigs and chickens (broiler, pullet, chicken for reproduction).

5. INDICATIONS FOR USE

Indications for use

Pigs: For the treatment of the clinical signs associated with porcine respiratory disease caused by *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, and *Mycoplasma hyopneumoniae* susceptible to doxycycline.

Chickens: Where clinical disease is present in the flock, to reduce mortality, morbidity, and clinical signs and to reduce lesions due to Pasteurellosis caused by *Pasteurella multocida* or to reduce morbidity and lesions in respiratory infections caused by *Ornithobacterium rhinotracheale* (ORT).

6. CONTRAINDICATIONS

Contraindications

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

Do not use in animals with an impaired liver function.

7. SPECIAL WARNINGS

Special precautions for safe use in the target species:

Due to likely variability (time, geographical) in susceptibility of bacteria for doxycycline, especially susceptibility of *A. pleuropneumoniae* and *O. rhinotracheale* may differ from country to country and even farm to farm,

bacteriological sampling and susceptibility testing are recommended. Use of the veterinary medicinal product should be based on culture and sensitivity of micro-organisms from diseased cases on farm. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

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: If you know you are allergic to the tetracycline class of antibiotics, special care should be taken when handling this veterinary medicinal product or the medicated solution.

During preparation and administration of the medicated drinking water, skin contact with the veterinary medicinal product should be avoided. Personal protective equipment consisting of impermeable gloves (e.g. rubber or latex) should be worn when handling the veterinary medicinal product..

In the event of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention. Wash hands and contaminated skin immediately after handling the veterinary medicinal product.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show this warning to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Do not smoke, eat or drink while handling the veterinary medicinal product.

Avoid direct contact with skin and eyes when handling the veterinary medicinal product to prevent sensitisation and contact dermatitis.

Pregnancy and lactation:

Doxycycline has a low affinity for forming complexes with calcium and studies have demonstrated that doxycycline scarcely affects skeleton formation. No negative effects were observed in poultry after the administration of therapeutic doses of doxycycline. The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

In the absence of specific studies the use of the product is not recommended during pregnancy or lactation.

Interaction with other medicinal products and other forms of

interactions: Do not combine with antibiotics that are bacteriocidal e.g. penicillins or cephalosporins.

Absorption of doxycycline can be decreased in the presence of high quantities of calcium, iron, magnesium or aluminium in the diet. Do not administer together with antacids, kaolin and iron preparations.

It is advised that the interval between the administration of other products containing polyvalent cations should be 1-2 hours because they limit the absorption of tetracyclines.

Doxycycline increases the action of anticoagulants.

The solubility of the product is pH dependent and will precipitate if mixed in alkaline solution.

Do not store the drinking water in metallic containers.

Overdose:

Overdoses up to 1.6 times the label recommended dose resulted in no clinical signs that could be attributed to treatment. Poultry tolerate double overdoses of doxycycline (40 mg/kg body weight) without any clinical effect.

Major incompatibilities:

Solubility of doxycycline is pH dependent. Precipitation will occur in an alkaline solution. In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water or liquid feed containing biocidal products, feed additives or other substances used in drinking water.

8. ADVERSE EVENTS

Adverse events

Pigs and chickens (broiler, pullet, chicken for reproduction).

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Photosensitivity Allergic reaction

If suspected adverse reactions occur, treatment should be discontinued.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

In drinking water use

The recommended dose in pigs is: 12.5 mg doxycycline hyclate (0.054 ml product) per kg body weight per day for 4 consecutive days. If no improvement in clinical signs is seen within this time, the diagnosis should be reviewed and treatment changed. In case of severe infections the medication period may be prolonged for a maximum of 8 consecutive days as determined by the attending veterinary surgeon.

The recommended dose in chickens is: 10 mg doxycycline hyclate (0.043 ml product) per kg body weight per day for 3-4 consecutive days in case of infections

caused by *P. multocida* and 20 mg doxycycline hyclate (0.087 ml product) per kg body weight per day for 3-4 consecutive days in case of infections caused by *O. rhinotracheale*.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{....ml veterinary medicinal product/ kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{....ml veterinary medicinal product per litre of drinking water}$$

To ensure a correct dosage body weight should be determined as accurately as possible. The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of doxycycline may need to be adjusted accordingly. The use of suitably calibrated measuring equipment is recommended. 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 refreshed or replaced every 24 hours. Solubility of the product is pH dependent and it may precipitate if it is mixed in hard alkaline drinking water. During the treatment period animals should not have access to other water sources than the medicated water.

Weight can also be used to measure the product quantity to be added in drinking water. In this case the density correction should be used, according to the following formula:

$$\text{Amount to be added in drinking water (g/L)} = \text{amount to be added in drinking water (ml/L) x 1.075 (g/ml)}$$

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIODS

Pigs:

- Meat and offal: 4 days

Chickens

- Meat and offal: 3 days, following a dose rate of 10 mg/kg body weight for 4 days.

- Meat and offal: 12 days, following a dose rate of 20 mg/kg body weight for 4 days.

- Eggs: Not authorised for use in laying birds producing eggs for human consumption. Do not use within 4 weeks before the start of the laying period

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of the veterinary medicinal products

Veterinary medicinal product subject to prescription

15. MARKETING AUTHORIZATION NUMBER AND PACK SIZES

Vm 33229/4001

Pack sizes

1 litre and 5 litres. Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Divasa - Farmavic S.A
Carretera Sant Hipolit
KM 71 PO Box 79
08503 Gurb-Vic
Barcelona
Spain
Tel: 938860100
Email: pharmacovigilance@divasa-farmavic.com

Local representatives and contact details to report suspected adverse reactions:

DUGV (UK) Ltd.
Union House, 111 New Union Street Coventry
CV1 2NT
United Kingdom

Tel: +353 (0)504 43169
Email: pv@dugganvet.ie

18. OTHER INFORMATION

19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 6 months.

Shelf-life after dilution or reconstitution according to directions: 24 hours after dilution in drinking water.

Once opened, use by: _____

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 22 December 2025