

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DFV DOXIVET 500 mg/g, powder for use in drinking water for pigs and chickens.

CZ: DFV DOXYCYCLINE 500 mg/g, oral powder for use in drinking water for pigs and chickens.

IT: Doxycycline 500 mg/g DFV, oral powder for use in drinking water for pigs and chickens

DK: Doxycycline Divasa-Farmavic Vet.

SE: Doxycycline Divasa-Farmavic 500 mg/g pulver för användning i dricksvatten

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:

Doxycycline hyclate 500 mg

Equivalent to 433 mg doxycycline

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Silica colloidal anhydrous	
Citric acid anhydrous	

Yellow to pale yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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).

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for 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 product and inhalation of dust particles should be avoided.

Personal protective equipment consisting of impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) 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.

Take measures to avoid producing dust when incorporating the product into water. Avoid direct contact with skin and eyes when handling the veterinary medicinal product to prevent sensitisation and contact dermatitis.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Photosensitivity Allergic reaction
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If suspected adverse reactions occur, treatment should be discontinued.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet or the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

Pregnancy and lactation:

The use is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

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 administered 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.

3.9 Administration routes and dosage

In drinking water use.

The recommended dose in pigs is:

12.5 mg doxycycline hyclate (25 mg 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 (20 mg 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 (40 mg 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 the animals to be treated, the exact daily concentration of the veterinary medicinal products should be calculated according to the following formula:

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

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 has to be adjusted accordingly. 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 refreshed or replaced 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. Alternatively, the concentrated solution can be used in a proportional water medicator. Solubility of the product is pH dependent and it may precipitate if it is mixed in hard alkaline drinking water. Use at minimum concentrations of 200 mg powder per litre drinking water in areas with hard alkaline drinking water (hardness above 10.2 °d and pH more than 8.1). During the treatment period animals should not have access to other water sources than the medicated water.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :QJ01AA02

4.2 Pharmacodynamics

Doxycycline belongs to the group of the tetracycline antibiotics. These antibiotics have a broad spectrum of antimicrobial activity, sharing the same basic structure of polycyclic naphthacenecarboxamide.

Doxycycline is primarily a bacteriostatic drug. It exerts its action by inhibiting the protein synthesis of the bacterial cell. Inhibition of bacterial protein synthesis results in disturbance of all functions necessary for the life of bacteria. Especially cell-division and the formation of the cell wall are impaired.

Doxycycline is a broad-spectrum antibiotic, active against a large number of Gram-positive and Gram-negative, aerobe and anaerobe micro-organisms, Mycoplasmata, Chlamydiae and Rickettsia.

For *Ornithobacterium* rhinotracheale results demonstrate a great variation from high to low susceptibility, depending on the geographical region where isolates came from.

In pig pathogens resistance against doxycycline may also vary; especially susceptibility figures of *A. pleuropneumoniae* may differ from country to country and even farm to farm.

Four resistance mechanisms acquired by microorganisms against tetracyclines in general have been reported: Decreased accumulation of tetracyclines (decreased permeability of the bacterial cell wall and active efflux), protein protection of the bacterial ribosome, enzymatic inactivation of the antibiotic and rRNA mutations (preventing the tetracycline binding to ribosome). Tetracycline resistance is usually acquired by means of plasmids or other mobile elements (e.g. conjugative transposones). Cross resistance between tetracyclines has also been described. Due to the greater liposolubility and greater facility to pass through cell membranes (in comparison to tetracycline), doxycycline retains a certain degree of efficacy against microorganisms with acquired resistance to tetracyclines.

4.3 Pharmacokinetics

Doxycycline is absorbed in the stomach and the first part of the duodenum. Compared to the older tetracyclines the absorption of doxycycline is less affected by the presence of bivalent cations in food. Bioavailability in non-fasted pigs is approximately 21%.

Following oral administration at a dose of 12.8 mg/kg body weight, steady state concentrations during

medication range between a C_{min} of 0.40 µg/ml in the early morning to a C_{max} of 0.87 µg/ml in the late afternoon in pigs.

Following administration of doxycycline hyclate at an actual dose of 21 mg/kg body weight to chickens mean plasma concentrations above 1 µg/ml were reached within 6 hours and lasted for 6 hours after cessation of medication. From 24 h up to 96 h after start of treatment the doxycycline plasma concentrations exceeded 2 µg/ml. Following administration of doxycycline hyclate at an actual dose of 10 mg/kg body weight steady state plasma concentrations ranged from 0.75 to 0.93 µg/g between 12 and 96 hours after start of medication.

Because doxycycline is highly lipid soluble, it has a good tissue penetration. Respiratory tract tissue: plasma ratios of 1.3 (healthy lungs), 1.9 (pneumonic lungs) and 2.3 (nasal mucosa) have been reported for doxycycline. Plasma protein binding is high (over 90%).

Doxycycline is scarcely metabolised. Doxycycline is primarily excreted with the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 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.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life after first opening the immediate packaging: 12 months.

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Nature of container:

Bag formed of polyester/aluminium/polyethylene laminate.

Package sizes:

Carton box 10 x 100 g

Carton box 50 x 100 g

Carton box 250 x 100 g

Bag 1 kg

Bag 2.5 kg

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such product

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

DIVASA-FARMAVIC S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorization:

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

05/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX: 10 X 100 g – 50 X 100 g – 250 X 100 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DFV DOXIVET 500 mg/g, powder for use in drinking water

CZ: DFV DOXYCYCLINE 500 mg/g, oral powder for use in drinking water.

IT: Doxycycline 500 mg/g DFV, oral powder for use in drinking water for

DK: Doxycycline Divasa-Farmavic Vet.

SE: Doxycycline Divasa-Farmavic 500 mg/g pulver för användning i dricksvatten

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

500 mg of doxycycline hyclate

Equivalent to 433 mg doxycycline

3. PACKAGE SIZE

10 x 100 g

50 x 100 g

250 x 100 g

4. TARGET SPECIES

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

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Administration route: In drinking water use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 12 months.

Shelf-life after dilution in drinking water: 24 hours.

9. SPECIAL STORAGE CONDITIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”
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Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”
--

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”
--

Keep out of the reach and sight of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

DIVASA-FARMAVIC S.A.

14. MARKETING AUTHORISATION NUMBER(S)
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15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – COMBINED LABEL AND PACKAGE LEAFLET

BAG of 1 kg AND 2.5 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DFV DOXIVET 500 mg/g, powder for use in drinking water for pigs and chickens.

CZ: DFV DOXYCYCLINE 500 mg/g, oral powder for use in drinking water for pigs and chickens.

IT: Doxycycline 500 mg/g DFV, oral powder for use in drinking water for pigs and chickens

DK: Doxycycline Divasa-Farmavic Vet.

SE: Doxycycline Divasa-Farmavic 500 mg/g pulver för användning i dricksvatten

2. COMPOSITION

Each gram contains:

Active substances:

Doxycycline hyclate 500 mg

Equivalent to 433 mg doxycycline

Yellow to pale yellow powder for use in drinking water

1 kg

2,5 kg

3. PACKAGE SIZE

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 warnings

Special precautions for 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 product and inhalation of dust particles should be avoided.

Personal protective equipment consisting of impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) 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.

Take measures to avoid producing dust when incorporating the veterinary medicinal product into water. Avoid direct contact with skin and eyes when handling the product to prevent sensitisation and contact dermatitis.

Use during pregnancy, lactation or lay:

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.

Interaction with other medicinal products and other forms of interaction:

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 administered 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 its local representative using the contact details on this label, or via your national reporting system.

Dosage for each species, routes and method of administration

In drinking water use.

The recommended dose in pigs is:

12.5 mg doxycycline hyclate (25 mg 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 (20 mg 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 (40 mg 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 to be used, and the number and weight of the animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

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 has to be adjusted accordingly. 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 refreshed or replaced 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. Alternatively, the concentrated solution can be used in a proportional water medicator. Solubility of the product is pH dependent and it may precipitate if it is

9. ADVICE ON CORRECT ADMINISTRATION

mixed in hard alkaline drinking water. Use at minimum concentrations of 200 mg powder per litre drinking water in areas with hard alkaline drinking water (hardness above 10.2 °d and pH more than 8.1). During the treatment period animals should not have access to other water sources than the medicated water.

Withdrawal periods

Pigs:

- Meat and offal: 4 days

10. WITHDRAWAL PERIODS

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.

11. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the reach and sight of children.

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

Do not use after the expiry date stated on the label.

12. 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.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes

Box 10 x 100 g – 50 x 100 g and 250 x 100 g

Bag 1000 and 2500 g.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

16. CONTACT DETAILS

Contact details

Marketing authorisation holder , manufacturer responsible for batch release and contact details to report suspected adverse events:

DIVASA-FARMAVIC, S.A.

Ctra. Sant Hipòlit, km. 71

08503 Gurb-Vic (Barcelona)

Spain

Tel: 938860100

Email: pharmacovigilance@divasa-farmavic.com

Local representatives and contact details to report suspected adverse events:

17. OTHER INFORMATION

For animal treatment only. –

Exp {mm/yyyy}

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

18. EXPIRY DATE

Shelf-life after first opening the immediate packaging: 12 months.

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

Once opened, use by: _____

19. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**LABEL SACHET 100 g****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

DFV DOXIVET 500 mg/g, powder for use in drinking water

CZ: DFV DOXYCYCLINE 500 mg/g, oral powder for use in drinking water

IT: Doxycycline 500 mg/g DFV, oral powder for use in drinking water

DK: Doxycycline Divasa-Farmavic Vet.

SE: Doxycycline Divasa-Farmavic 500 mg/g pulver för användning i dricksvatten

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

500 mg of doxycycline hyclate

Equivalent to 433 mg doxycycline

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Oral use in drinking water.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS**6. EXPIRY DATE**

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 12 months.

Once broached, use by ...

Shelf-life after dilution in drinking water: 24 hours.

7. SPECIAL STORAGE PRECAUTIONS**8. NAME OF THE MARKETING AUTHORIZATION HOLDER**

DIVASA-FARMAVIC S.A.

9. BATCH NUMBER

Lot {number}

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B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

DFV DOXIVET 500 mg/g, powder for use in drinking water for pigs and chickens.

CZ: DFV DOXYCYCLINE 500 mg/g, oral powder for use in drinking water for pigs and chickens.

IT: Doxycycline 500 mg/g DFV, oral powder for use in drinking water for pigs and chickens

DK: Doxycycline Divasa-Farmavic Vet.

SE: Doxycycline Divasa-Farmavic 500 mg/g pulver för användning i dricksvatten

2. Composition

Active substances:

Each gram contains:

500 mg of doxycycline hyclate

Equivalent to 433 mg doxycycline

Yellow to pale yellow powder.

3. Target species

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

4. 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).

5. 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.

6. 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 product and inhalation of dust particles should be avoided.

Personal protective equipment consisting of impermeable gloves (e.g. rubber or latex) and an appropriate dust mask (e.g. disposable half-mask respirator conforming to European Standard EN149) 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.

Take measures to avoid producing dust when incorporating the product into water. 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.

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 interaction:

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 administered 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 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.

7. Adverse events

Pigs and chickens (broiler, pullet, breeder).

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 in this package leaflet, 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 its local representative using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

In drinking water use.

The recommended dose in pigs is:

12.5 mg doxycycline hyclate (25 mg 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 (20 mg 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 (40 mg 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 the animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

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

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 has to be adjusted

accordingly. 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 refreshed or replaced 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. Alternatively, the concentrated solution can be used in a proportional water medicator. Solubility of the product is pH dependent and it may precipitate if it is mixed in hard alkaline drinking water. Use at minimum concentrations of 200 mg powder per litre drinking water in areas with hard alkaline drinking water (hardness above 10.2 °d and pH more than 8.1). During the treatment period animals should not have access to other water sources than the medicated water.

9. Advice on correct administration

10. 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

11. Special storage precautions

Keep out of the reach and sight of children.

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

Do not use this veterinary medicinal product after the expiry date stated on the label.

Shelf-life of the veterinary medicinal product as packaged for

sale: 2 years. Shelf-life after first opening the immediate

packaging: 12 months.

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

Once opened, use by: _____

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

Carton box 10 x 100 g
Carton box 50 x 100 g
Carton box 250 x 100 g
Bag 1 kg
Bag 2.5 kg

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

05/2025

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder , manufacturer responsible for batch release and contact details to report suspected adverse events:

DIVASA-FARMAVIC, S.A.

Ctra. Sant Hipòlit, km. 71

08503 Gurb-Vic (Barcelona)

Spain

Tel: 938860100

Email: pharmacovigilance@divasa-farmavic.com

Local representatives and contact details to report suspected adverse events:

17. Other information