

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxyveto 500 mg/g powder for use in drinking water/milk replacer for cattle (pre-ruminant), pigs, chickens

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
Citric acid, anhydrous (E330)
Lactose monohydrate

Fine yellow, homogeneous powder.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (pre-ruminant), pigs, chickens (broilers, breeders, chicks for replacement).

3.2 Indications for use for each target species

Treatment of below mentioned infections of the respiratory and gastrointestinal tract caused by micro-organisms sensitive to doxycycline.

Cattle (pre-ruminant):

- Bronchopneumonia and pleuropneumonia caused by *Pasteurella spp*,
Streptococcus spp, *Trueperella pyogenes*, *Histophilus somni* and *Mycoplasma spp.*.

Pigs:

- Atrophic rhinitis caused by *Pasteurella multocida* and *Bordetella bronchiseptica*;
- Bronchopneumonia caused by *Pasteurella multocida*, *Streptococcus suis* and *Mycoplasma hyorhinis*;
- Pleuropneumonia caused by *Actinobacillus pleuropneumoniae*.

Chickens:

- Respiratory infections caused by *Mycoplasma spp*, *Escherichia coli*, *Haemophilus paragallinarum* and *Bordetella avium*;
- Enteritis caused by *Clostridium perfringens* and *Clostridium colinum*.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to tetracyclines or to any of the excipients.
Do not use in animals with serious liver or kidney deficiency.
Do not use in ruminating cattle.

3.4 Special warnings

There is a high resistance rate documented against tetracyclines in *E. coli* isolated from chickens. Therefore the product should only be used for the treatment of infections caused by *E. coli* after susceptibility testing has been carried out. Resistance to tetracyclines has also been reported in some EU countries in pathogens of pigs (*A. pleuropneumoniae*, *S. suis*) and pathogens of calves (*Pasteurella spp.*).

3.5 Special precautions for use

Special precautions for safe use in the target species:

As a result of a likely variation (in the course of time or geographically) in the susceptibility of bacteria to doxycycline, bacteriological testing and susceptibility testing of micro-organisms from diseased animals on a farm is strongly recommended.

As complete elimination of the target pathogens may not be achieved, the medicinal product should be combined with good management practices, such as good hygiene, proper ventilation and no overstocking.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

- This veterinary medicinal product may cause contact dermatitis and/or hypersensitivity reactions if contact is made with the skin or eyes (powder and solution), or if the powder is inhaled.
- People with known hypersensitivity to doxycycline or to tetracyclines should avoid contact with the veterinary medicinal product. 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.
- Do not smoke, eat or drink while handling the veterinary medical product.
- In the case of eye or skin contact, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical advice.

- 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 the package leaflet or the label to the physician. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

3.6 Adverse events

Cattle (pre-ruminant), pigs, chickens (broilers, breeders, replacement chicks)

Rare (1 to 10 animals / 10 000 animals treated)	Allergic reaction Photosensitivity Gastrointestinaldisorder
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If suspected adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Commented [VHM1]: Adapted after EU comment PVAR3

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic or 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 or lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Not to be administered in combination with bactericidal antibiotics, such as penicillins and cephalosporins.

Tetracyclines may chelate cations (eg. Mg, Mn, Fe and Al) and this can lead to reduced bioavailability.

The combination with mycotoxin-binding agents can lead to both increased and decreased plasma concentrations of doxycycline and should therefore be avoided. The presence of food in the gastrointestinal tract reduces the likelihood of such interactions.

3.9 Administration routes and dosage

In drinking water/milk replacer use

- Cattle (pre-ruminant): 10 mg doxycycline hyclate/kg bw/day, equivalent to 20 mg veterinary medicinal product per kg bw during 3-5 consecutive days. The daily dose should be given in 2 administrations.
- Pigs: 10 mg doxycycline hyclate/kg bw/day, equivalent to 20 mg veterinary medicinal product per kg bw, during 3-5 consecutive days.
- Chickens: 25 mg doxycycline hyclate/kg bw/day, equivalent to 50 mg veterinary medicinal product per kg bw, during 3-5 consecutive days.

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 using the following formula:

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

The intake of medicated water/milk replacer depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of doxycycline in the drinking water/milk replacer possibly 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 in such manner that all medication is taken up in 24 hours. Medicated drinking water should be freshly prepared every 24 hours. Half the daily amount is to be added to milk replacer in such manner that all medication is taken up in 2 hours. It is recommended to prepare a concentrated stock solution - not exceeding 150 grams veterinary medical product per litre of drinking water - and to dilute this further to therapeutic concentrations if required.

Instead, the concentrated solution may also be used in a water-driven medicator for proportional administration. Milk replacer: half the daily amount is to be added to milk replacer in such manner that all medication is taken up in 2 hours.

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

In calves, acute and sometimes fatal myocardial degeneration following a single or repeated administration may occur. Since this is often caused by overdosing, it is important to accurately weigh the dosage.

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

Cattle (pre-ruminant):
Meat and offal: 7 days
Not authorised for use in animals producing milk for human consumption.

Pigs:
Meat and offal: 8 days

Chicken:
Meat and offal: 5 days
Not for use in birds producing or intended to produce eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:QJ01AA02

4.2 Pharmacodynamics

Doxycycline is a broad spectrum antibiotic. It inhibits bacterial protein synthesis intracellularly by binding to the 30S ribosomal subunits. The entry of aminoacyl-tRNA to the acceptor site on the mRNA ribosome complex is blocked in this manner, whereby coupling of the amino acids to the forming peptide chain is prevented.

Doxycycline inhibits bacteria, Mycoplasmata, Chlamydia, Rickettsia, and certain protozoa.

In general, four resistance mechanisms against tetracyclines obtained by micro-organisms have been reported: reduced accumulation of tetracyclines (reduced permeability of the bacterial cell wall and active efflux), protein protection of the bacterial ribosome, enzymatic inactivation of the antibiotic and rRNA-mutations (which prevents the binding of tetracycline to the ribosome). Resistance to tetracycline is usually obtained via plasmids or other mobile elements (e.g. conjugative transposons). Cross resistance between tetracyclines has also been described. Because of the greater lipid solubility and improved ability to cross cell membranes (as compared to tetracycline), doxycycline retains a certain level of activity against micro-organisms with an acquired resistance to tetracyclines.

4.3 Pharmacokinetics

Doxycycline is quickly and almost completely absorbed from the intestine. Presence of food in the intestine has no effect on the actual absorption of doxycycline. The distribution of doxycycline in the body and the penetration in most tissues is good. Following absorption, tetracyclines are hardly metabolized. Doxycycline is unlike other tetracyclines mainly excreted in the faeces.

Calves

After a dose of 10 mg / kg body weight / day for 5 days, an elimination half-life was found ranging from 15 to 28 hours. The doxycycline plasma level reached a mean of 2.2 to 2.5 µg / ml.

Swine

In pigs, no accumulation of doxycycline was found in plasma after treatment via the drinking water. Mean plasma levels of 0.44 ± 0.12 µg / ml were found after 3 days of medication with a mean dose of 10 mg / kg body weight.

Chickens

Steady state plasma concentrations of 2.05 ± 0.47 µg / ml were reached within 6 hours after the start of the medication and varied between 1.28 and 2.18 µg / ml with a dose of 25 mg / kg body weight for 5 days.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Bag

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after reconstitution in water according to directions: 24 hours.
Shelf life after reconstitution in milk replacer according to directions: 2 hours.

Jar

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after reconstitution in water according to directions: 24 hours.
Shelf life after reconstitution in milk replacer according to directions: 2 hours.

5.3 Special precautions for storage

Bag:

Store below 25 °C.
Tightly reclose the bags after first opening in order to protect from light.
Protect the medicated drinking water from direct sunlight.

Jar:

Store below 25 °C.
Tightly reclose the jars after first opening in order to protect from light.
Protect the medicated drinking water from direct sunlight.

5.4 Nature and composition of immediate packaging

Multi-layer laminated bags (polyester/aluminium/polyethylene) containing 1 kg.
Polyethylene jars with polypropylene lid with a carton/aluminium/polyethylene inner-layer containing 100 g or 1 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 products

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

VMD NV

7. MARKETING AUTHORISATION NUMBER

Vm 19968/4005

8. DATE OF FIRST AUTHORISATION

29 January 2018

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

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 05 March 2026