SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxybactin 400 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Doxycycline (as doxycycline hyclate) 400 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
Yellow with brown spots, round and convex flavoured tablet with a cross-shaped break line on one side. The tablets can be divided into 2 or 4 equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Treatment of the following conditions caused by bacteria sensitive to doxycycline:

Rhinitis caused by *Bordetella bronchiseptica* and *Pasteurella* spp.;
Bronchopneumonia caused by *Bordetella* spp. and *Pasteurella* spp.;
Interstitial nephritis caused by *Leptospira* spp.

4.3 Contraindications

Do not use in cases of hypersensitivity to tetracyclines or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
The product should be administered with caution to animals with dysphagia or diseases accompanied with vomiting, since administration of doxycycline hyclate tablets has been associated with oesophageal erosion.
In order to reduce the likelihood of oesophageal irritation as well as other gastrointestinal side effects, the product should be administered together with food.
Special care should be taken when administering the product to animals with liver disease, since increases in hepatic enzymes have been documented in some animals after doxycycline treatment.
The product should be administered with caution to young animals, since tetracyclines as a class may cause permanent discolouration of the teeth, when administered during tooth development. However, human literature indicates that doxycycline is less likely than other tetracyclines to cause these abnormalities, due to its reduced ability to chelate calcium.
Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local / regional level. Use of the product should be in accordance with official, national and regional antimicrobial policies. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to doxycycline and may decrease the effectiveness of treatment with other tetracyclines, due to the potential for cross-resistance.
As tablets are flavoured store tablets out of reach of the animals in order to avoid accidental ingestion.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Tetracyclines may cause hypersensitivity (allergy) reactions.
People with known hypersensitivity to tetracyclines should avoid contact with the veterinary medicinal product.
If you develop symptoms following exposure such as skin rash, seek medical advice immediately and show the package leaflet to the physician.
Doxycycline may cause gastrointestinal disturbances after accidental ingestion, especially by children. To avoid accidental ingestion, particularly by a child, unused tablet parts should be returned to the open blister space and inserted back into the carton. In case of accidental ingestion, particularly by children, seek medical advice.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Gastrointestinal disorders such as vomiting, diarrhoea and oesophagitis have been reported as side effects following doxycycline therapy very rarely.
In very young animals discoloration of the teeth may occur very rarely by the formation of a tetracycline-calcium phosphate complex.
Hypersensitivity reactions, photosensitivity and in exceptional cases photodermatitis may occur very rarely after exposure to intense daylight.
Retardation of skeletal growth of young animals (reversible upon discontinuation of therapy) is known to occur very rarely with use of other tetracyclines and might occur following administration of doxycycline.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Tetracyclines as a class can retard foetal skeletal development (fully reversible) and cause discolouration of the deciduous teeth. However, evidence from human literature suggests that doxycycline is less likely to cause these abnormalities than other tetracyclines. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with bactericidal antibiotics such as penicillins and cephalosporins. Oral absorbents and substances containing multivalent cations such as antacids and iron salts should not be used from 3 hours before to 3 hours after the administration of doxycycline. The half-life of doxycycline is reduced by concurrent administration of antiepileptic drugs such as phenobarbital and phenytoin.

4.9 Amounts to be administered and administration route

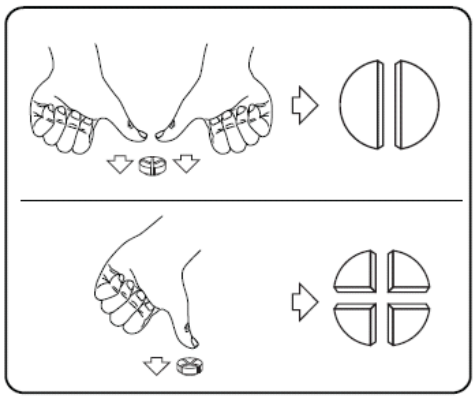
Oral use.
The recommended dose for dogs is 10 mg doxycycline per kg bodyweight per day. The majority of routine cases are expected to respond after between 5 and 7 days of therapy. Therapy should continue for 2 to 3 days beyond the clinical cure for acute infections. In chronic or refractory cases, a longer course of therapy, up to 14 days, may be required. In dogs with interstitial nephritis due to leptospirosis, treatment for 14 days is recommended. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. Tablets should be administered together with the food (see section 4.5).

The following table is intended as a guide to dispensing the product at the standard dose rate of 10 mg per kg bodyweight per day.

Body weight	Dose mg	Doxybactin 50 mg		Doxybactin 200 mg		Doxybactin 400 mg
0.75 kg – 1.25 kg	12.5			-		-
>1.25 kg – 2.5 kg	25			-		-
>2.5 kg – 3.75 kg	37.5			-		-
>3.75 kg – 5 kg	50			-		-
>5 kg – 6.25 kg	62.5			-		-
>6.25 kg – 7.5 kg	75			-		-
>7.5 kg – 10 kg	100			-		-
>10 kg – 12.5 kg	125			-		-
>12.5 kg – 15 kg	150					-
>15 kg – 20 kg	200	-				-
>20 kg – 25 kg	250		AND			-
>25 kg – 30 kg	300	-				-
>30 kg – 35 kg	350	-				-
>35 kg – 40 kg	400	-		-		
>40 kg – 45 kg	450		AND			
>45 kg – 50 kg	500	-			AND	
>50 kg – 60 kg	600	-			AND	
>60 kg – 70 kg	700	-			AND	
>70 kg – 80 kg	800	-		-		

 = ¼ Tablet  = ½ Tablet  = ¾ Tablet  = 1 Tablet

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



2 equal parts: press down with your thumbs on both sides of the tablet.
4 equal parts: press down with your thumb in the middle of the tablet.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In cases of overdose no symptoms are to be expected other than those mentioned in section 4.6.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use, tetracyclines
ATCvet code: QJ01AA02

5.1 Pharmacodynamic properties

Doxycycline is a broad-spectrum tetracycline-class antibiotic active against a large number of gram positive and gram negative bacteria including both aerobic and anaerobic species.

Doxycycline inhibits bacterial protein synthesis by binding to the 30-S ribosomal subunits. This interferes with binding of aminoacetyl-tRNA to the acceptor site on the mRNA ribosome complex and prevents coupling of amino acids to the elongating peptide chains; doxycycline has a predominantly bacteriostatic activity.

The penetration of doxycycline into the bacterial cell takes place by both active transport and passive diffusion.
The main mechanisms of acquired resistance to tetracycline class antibiotics include active efflux and ribosomal protection. A third mechanism is enzymatic degradation. The genes mediating resistance may be carried on plasmids or transposons, as for example, tet(M), tet(O), and tet(B) that can be found in both gram-positive and gram-negative organisms including clinical isolates.

Cross-resistance to other tetracyclines is common but depends on the mechanism conferring resistance. Due to the greater liposolubility and greater ability to pass through cell membranes (in comparison to tetracycline), doxycycline retains a certain degree of efficacy against microorganisms with acquired resistance to tetracyclines via efflux pumps. However, resistance mediated by ribosomal protection proteins confer cross-resistance to doxycycline.

5.2 Pharmacokinetic particulars

After oral administration doxycycline is mainly absorbed from the duodenum and jejunum. Following oral administration, the bioavailability is > 50%.
Doxycycline is widely distributed throughout the body and can accumulate intracellularly in for example leukocytes. It is deposited in active bone tissue and teeth. Doxycycline is primarily eliminated through faeces by direct intestinal excretion and to a lesser extent by glomerular excretion and biliary secretion.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium starch glycolate (type A)
Silica, colloidal anhydrous
Cellulose, microcrystalline
Yeast (dried)
Chicken flavour
Magnesium stearate

6.2 Major incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life of divided tablets: 3 days.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister
Cardboard box of 1, 2 or 3 blisters of 10 tablets.
Cardboard box containing 10 separate cardboard boxes, each containing 1 blister of 10 tablets.
Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

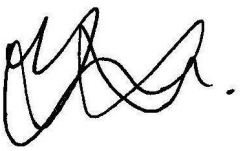
Vm 50406/4021

9. DATE OF FIRST AUTHORISATION

12 September 2017

10. DATE OF REVISION OF THE TEXT

October 2022



Approved: 27 October 2022