1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxytab vet. 200 mg Tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Doxycycline 200 mg
(as doxycycline hyclate 230.8 mg)

Excipients:

Qualitative composition of excipients and other constituents
Sodium starch glycolate (type A)
Silica, colloidal hydrated
Cellulose, microcrystalline
Lactose monohydrate
Chicken flavour
Magnesium stearate

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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..

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal 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 veterinary medicinal product should be administered together with food.
Special care should be taken when administering the veterinary medicinal product to animals with liver disease, since increases in hepatic enzymes have been documented in some animals after doxycycline treatment.
The veterinary medicinal 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.
As tablets are flavoured store tablets out of reach of the animals in order to avoid accidental ingestion.
Due to the likely variability (time, geographical) in the occurrence of resistance of bacteria for doxycycline, bacteriological sampling and susceptibility testing are recommended. Official, national and regional antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal 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.

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

This veterinary medicinal product may cause hypersensitivity 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. This veterinary medicinal product may cause serious gastrointestinal effects if ingested, especially by children. To avoid accidental ingestion, unused tablet parts should be returned to the open blister space and inserted back into the carton that should be stored in a safe place out of sight and reach of children. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Undetermined frequency (cannot be estimated from the available data)	Hypersensitivity reaction[1] Photosensitivity (including Photodermatitis)[1] Gastrointestinal disorders (e.g. vomiting, diarrhoea, oesophagitis)[2], discoloured teeth[3] Developmental bone and joint disorders (retardation of skeletal growth[4])

[1] After exposure to intense daylight.
[2] Following long term doxycycline therapy.
[3] In very young animals; by the formation of a tetracycline-calcium phosphate complex.
[4] In young animals (reversible upon discontinuation of therapy); known to occur with use of other tetracyclines and might occur following administration of doxycycline.

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 for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

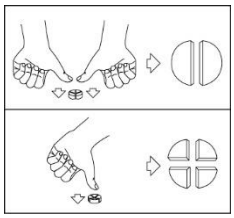
Tetracyclines as a class can retard foetal skeletal development (fully reversible) and cause discolouration of the deciduous teeth. However, evidence from human literature suggests that doxycycline is less likely to cause these abnormalities than other tetracyclines. Use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 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 as they reduce doxycycline availability. The half-life of doxycycline is reduced by concurrent administration of antiepileptic drugs such as phenobarbital and phenytoin.

3.9 Administration routes and dosage

Oral use.
The general recommended dose is 10 mg doxycycline per kg bodyweight (bw) per day. The daily dose may be split into two administrations per day (i.e. 5 mg/kg bw twice daily).
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.
Tablets should be administered together with the food (see section 3.5).
The most appropriate tablet strength should be used in order to minimise divided tablets to be kept until the next dosing.
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.

Return any divided tablets to the blister pack. Divided tablets should be used at the next administration. Any divided tablets remaining after the last administration of the veterinary medicinal product should be discarded.

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

In cases of overdose no symptoms are to be expected other than those mentioned in section 3.6.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QJ01AA02

4.2 Pharmacodynamics

Doxycycline is a second-generation tetracycline. The veterinary medicinal product is mainly bacteriostatic; it inhibits bacterial protein synthesis by blocking the binding of transfer RNA at the messenger RNA-ribosome-complex.
Resistance is mainly mediated by efflux pumps or ribosomal protection proteins.
Cross-resistance among tetracyclines is common but depends on resistance mechanisms: i.e. mutation in efflux pumps that renders resistance to tetracycline may still be sensitive to doxycycline. However, induction of the ribosomal protection proteins confers cross-resistance to doxycycline.

Bacterial species and origin	MIC_{90} (µg/ml)	Resistant[#] (%)
Pasteurella in dogs (FR 2017)		3 (N=101)
B. bronchiseptica in dogs and cats (DE 2016/2017)	1.0	

[#] = 100 – Susceptible (%), cut-off point for susceptibility ≤ 4 µg/ml, based on the recommendations of the French CA-SFM (Comité de l'Antibiogramme de la Société Française de Microbiologie)
N = total strains tested

4.3 Pharmacokinetics

After oral administration doxycycline is mainly absorbed from the duodenum and jejunum. Following oral administration, the bioavailability is > 50%.
The peak plasma concentration, C_{max} of 1710 ng/ml was reached in dogs between 0.5 and 6 hours after dosing 10 mg/kg bw during feeding. In some dogs a second plasma peak (variable in height) was noticed. The average AUC_t was 26300 h·ng/mL. The estimated half-life, based on a limited amount of dogs only, was 8.9 hours.
Doxycycline is widely distributed throughout the body and can accumulate intracellularly for example in leukocytes. It is deposited in active bone tissue and teeth. Doxycycline penetrates better to the cerebrospinal fluid than the older tetracyclines. Doxycycline is primarily eliminated through faeces by direct intestinal excretion and to a lesser extent by glomerular excretion and biliary secretion.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Keep the blister in the outer carton. Any remaining portions of divided tablets should be returned in the opened blister and given at the next administration.

5.4 Nature and composition of immediate packaging

Aluminium - PVC/PE/PVDC blister

Package sizes:
Cardboard box of 1, 3, 5 or 10 blisters containing 10 tablets.
Cardboard box of 1, 5 or 10 blisters containing 30 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

CP- Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10810/020/003

8. DATE OF FIRST AUTHORISATION

14/08/2020

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

20/02/2026

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).