ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxytab vet. 400 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains

Doxycycline	400 mg
(as doxycycline hyclate	461.7 mg)

3. PACKAGE SIZE

1 x 10 tablets
3 x 10 tablets
5 x 10 tablets
10 x 10 tablets
1 x 30 tablets
5 x 30 tablets
10 x 30 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

Vm 20916/4037

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium/ PVC/ PE/PVDC blister pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxytab vet. 400 mg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Doxycycline	400 mg/tablet
(as doxycycline hyclate	461,7 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doxytab vet. 400 mg Tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Doxycycline	400 mg
(as doxycycline hyclate	461,7 mg)

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. Target species

Dogs.

4. Indications for use

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..

5. Contraindications

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

6. Special warnings

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 this package leaflet 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.

Pregnancy and lactation:

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.

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.

Overdose:

In cases of overdose no symptoms are to be expected other than those mentioned as adverse events.

7. 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, inflammation of the oesophagus)[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.

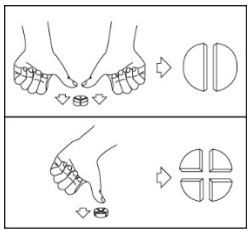
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. 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:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

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.
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.

9. Advice on correct administration

Tablets should be administered with food.
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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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.
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 carton and blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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 authorisation number and pack sizes

Vm 20916/4037

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.

15. 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.

16. Contact details

Marketing authorisation holder, and manufacturer responsible for batch release:

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany
Tel: +49-(0)5136-6066-0

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Great Britain (GB)
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Office 39 Lodge House, Lodge Park, Lodge Lane, Langham, Colchester, Essex, CO4 5NE
Tel: +44 (0) 1206 233528
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17. Other information

POM-V

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