ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box
Multipack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxybactin 200 mg tablets for dogs
doxycycline

2. STATEMENT OF ACTIVE SUBSTANCES

1 tablet contains:
Active substance

Doxycycline (as doxycycline hyclate) 200 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

10 tablets
20 tablets
30 tablets

10 x 10 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP:
Shelf life of divided tablets: 3 days

11. SPECIAL STORAGE CONDITIONS

Store below 30°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/4020

17. MANUFACTURER'S BATCH NUMBER

Lot.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium-PVC/PE/PVDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxybactin 200 mg tablets
doxycycline

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory BV

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Doxybactin 200 mg tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for the batch release:
Lelypharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

Only the site testing and releasing the batches will be mentioned on the printed leaflet.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxybactin 200 mg tablets for dogs
doxycycline

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 tablet contains:
Active substance:
200 mg doxycycline as doxycycline hyclate

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. INDICATION(S)

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

Rhinitis (inflammation of the nasal mucosa) caused by *Bordetella bronchiseptica* and *Pasteurella* spp.;
Bronchopneumonia (lobular inflammation of the lung) caused by *Bordetella* spp. and *Pasteurella* spp.;
Interstitial nephritis (inflammation of part of the kidney tissue) caused by *Leptospira* spp.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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 binding of tetracyclines to calcium phosphate.
Hypersensitivity reactions, photosensitivity and in exceptional cases photo-dermatitis 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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

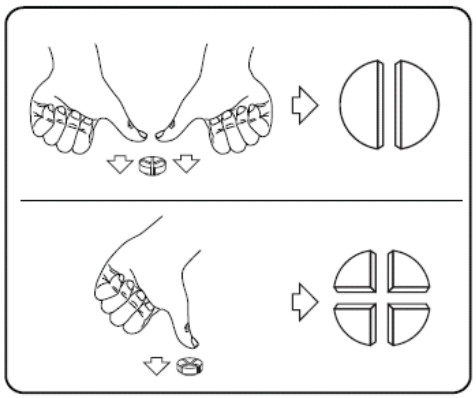
The following table is intended as a guide to dispensing the product at the standard dose rate of 10 mg per kg bodyweight per day.

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

9. ADVICE ON CORRECT ADMINISTRATION

Tablets should be administered together with the food (see section 12, Special warnings). 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.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the package after EXP.
The expiry date refers to the last day of that month.
Shelf life of divided tablets: 3 days

12. SPECIAL WARNING(S)

Special precautions for use in animals:
The product should be administered with caution to animals with dysphagia (difficulty swallowing) or diseases accompanied with vomiting, since administration of doxycycline hyclate tablets has been associated with oesophageal erosion (injuries to the gullet). 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 bind 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

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.
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.

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

Overdose (symptoms, emergency procedures, antidotes):
In cases of overdose no symptoms are to be expected other than those mentioned in the section on adverse reactions.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

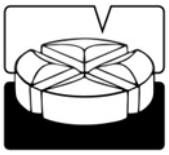
Medicines should not be disposed of via wastewater <or household waste>.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

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.



Divisible tablet

Approved: 27 October 2022