ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycare Flavour 40 mg Tablets for Cats and Dogs

doxycycline

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains

Active substance:
Doxycycline 40 mg (equivalent to 47.88 mg of doxycycline hyclate)

3. PHARMACEUTICAL FORM

Tablet

Tablets can be divided into 2 or 4 equal parts.

4. PACKAGE SIZE

10 tablets
20 tablets
30 tablets
40 tablets
50 tablets
60 tablets
70 tablets
80 tablets
90 tablets
100 tablets
250 tablets

5. TARGET SPECIES

Cats and Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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 THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV
Legeweg 157-I
B-8020,
Oostkamp,
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32742/4014

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycare Flavour 40mg Tablets for Cats and Dogs

doxycycline

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

<Batch><Lot> {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Doxycare Flavour 40mg Tablets for Cats and 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

Ecuphar NV
Legeweg 157-I
B-8020,
Oostkamp,
Belgium

Manufacturer responsible for batch release:

Lelypharma B.V.
Zuiveringsweg 42
8243 PZ
Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycare Flavour 40mg Tablets for Cats and Dogs

doxycycline

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

Each tablet contains:

Doxycycline 40 mg
(equivalent to 47.88 mg of doxycycline hyclate)
Yellowish, round and convex tablet with a cross-shaped break line on one side.

Tablets can be divided into 2 or 4 equal parts.

4. INDICATION(S)

Dogs
For the treatment of respiratory tract infections including rhinitis, tonsillitis and bronchopneumonia caused by *Bordetella bronchiseptica* and *Pasteurella* spp. susceptible to doxycycline.

For the treatment of canine ehrlichiosis (a disease transmitted by ticks) caused by *Ehrlichia canis*.

Cats
For the treatment of respiratory tract infections including rhinitis, tonsillitis and bronchopneumonia caused by *Bordetella bronchiseptica* and *Pasteurella* spp. susceptible to doxycycline.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or any of the excipients.
Do not use in animals with renal or hepatic insufficiency.
Do not use in animals with diseases associates with vomiting or dysphagia (difficulty to swallow) (see also section 'Adverse reaction').
Do not use in animals with known photosensitivity (see also section 'Adverse reactions').
Do not use in puppies and kittens before completion of teeth enamel formation.

6. ADVERSE REACTIONS

Gastrointestinal adverse reaction including vomiting, nausea (signs the animal may be sick), salivation (drooling) , oesophagitis (irritation of the oesophagus) and diarrhoea have been reported very rarely in spontaneous reports.
Photosensitivity and photodermatitis (irritation of the skin) can occur following tetracycline therapy, after exposure to intense sunlight or ultraviolet light. (See also section 'Contraindications').
Use of tetracycline during the period of tooth development may lead to tooth discolouration.

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).

7. TARGET SPECIES

Cats and dogs

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

For oral use.
The dosage is 10 mg doxycycline per kilogram of bodyweight per day.
The dosage can be divided into two daily administrations. The duration of treatment might be adapted depending on the clinical response, after benefit/risk assessment by the veterinarian.

Disease	Dosage regimen	Duration of treatment
Respiratory tract infection	10 mg/kg per day	5-10 days
Canine ehrlichiosis	10 mg/kg per day	28 days

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.

Halves: press down with your thumbs or fingers on both sides of the tablet.
Quarters: press down with your thumb or finger in the middle of the tablet.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, bodyweight of the animals should be determined as accurately as possible to avoid overdosing or underdosing. In order to adjust the dosage, the tablets can be divided into 2 or 4 equal parts. Tablets should be administered with food in order to avoid vomiting.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Any remaining tablet portion should be 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 WARNING(S)

Special warnings for each target species
For the veterinarian
Ehrlichia canis infection: treatment should be initiated at the onset of clinical signs. Complete eradication of the pathogen is not always achieved, but treatment for 28 days generally leads to a resolution of the clinical signs and a reduction of the bacterial load. A longer duration of treatment, based on a benefit/risk assessment by the responsible veterinarian, may be required particularly in severe or chronic ehrlichiosis. All treated patients should be regularly monitored, even after clinical cure.

Special precautions for use in animals:

Tablets should be administered with food in order to avoid vomiting and to reduce the likelihood of oesophageal irritation.

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.

For the veterinarian
Use of the veterinary medicinal 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 veterinary medicinal 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.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.

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

People with known hypersensitivity to doxycycline or other tetracyclines should avoid contact with the veterinary medicinal product and personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
In case of skin irritation, seek medical advice immediately and show the package leaflet or the label to the physician.
Accidental ingestion, especially by children, may cause adverse reactions such as emesis. To avoid accidental ingestion, blisters should be inserted back into the outer packaging and kept in a safe place. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or embryotoxic effects (malformations or deformities) of doxycycline. However, as there is no information available in the target species, use is not recommended during pregnancy.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Doxycycline should not be used concurrently with other antibiotics especially bactericidal drugs such as the ß-lactams (for example penicillin, ampicillin). Cross-resistance to tetracyclines may occur.

The half-life of doxycycline is reduced by concurrent administration of barbiturates (some types of sedatives or tranquilisers), phenytoin and carbamazepine (two types of anti-epileptic medications). Dosage adjustments may be necessary in subjects under anticoagulant therapy (blood thinners), as tetracyclines depress the plasma activity of prothrombin.
Simultaneous administration of oral absorbents, antacids (protectants for the stomach) and preparations including multivalent cations should be avoided as they reduce doxycycline availability.

Overdose (symptoms, emergency procedure, antidotes), if necessary

Vomiting may occur in dogs with 5 times the recommended dose. Increased levels of ALT, GGT, ALP and total bilirubin were reported in dogs at 5-fold overdose.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2021

15. OTHER INFORMATION

Cardboard box of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, or 250 tablets

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

Approved: 13/01/22