PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycare Flavour 200 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains

Active substance:
Doxycycline 200 mg (equivalent to 239.40 mg of doxycycline hyclate)

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cats and Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Not applicable

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

Ecuphar
An Animalcare Company

14. MARKETING AUTHORISATION NUMBER

Vm 32742/4015

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {BLISTERS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doxycare Flavour

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Doxycycline 200 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doxycare Flavour 200mg Tablets for Cats and Dogs

2. Composition

Each tablet contains:

Active substance:
Doxycycline 200 mg
(equivalent to 239.40 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.

3. Target species

Cats and dogs

4. Indications for use

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 events’).
Do not use in animals with known photosensitivity (see also section ‘Adverse events’).
Do not use in puppies and kittens before completion of teeth enamel formation.

6. Special warnings

Special warnings:

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 safe use in the target species:

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.

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:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic or embryotoxic effects (malformations or deformities) of doxycycline. The safety of

the veterinary medicinal product has not been established during pregnancy, therefore, 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:

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.

7. Adverse events

Cats and dogs:

Undetermined frequency (cannot be estimated from the available data):	Photosensitivity, photodermatitis[1] Dental discolouration[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal disorders (e.g. vomiting, nausea, hypersalivation, oesophageal irritation, diarrhoea)[3]

[1]can occur following tetracycline therapy, after exposure to intense sunlight or ultraviolet light (See also section 3.3).
[2]use of tetracycline during the period of tooth development.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
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 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 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 periods

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 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 numbers and pack sizes

Vm 32742/4015

Cardboard box of 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, or 250 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 contact details to report suspected adverse reactions:

Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium
Tel: +32 50 31 42 69
Email: info@ecuphar.be

Manufacturer responsible for batch release:

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

17. Other information

POM-V

Gavin Hall
Approved: 23 June 2025