PARTICULARS TO APPEAR ON THE OUTER PACKAGE {BOX (12 and 72 tablets)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocare flavour 80 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:
Marbofloxacin 80.0 mg

3. PACKAGE SIZE

12 tablets
72 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
The recommended dose rate is 2 mg/kg/day in a single daily administration (see table below).

Body Weight	Tablets
15 – 20 kg	½
21 – 40 kg	1
41 – 60 kg	1 ½
61 – 80 kg	2

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Unused divided tablets should be returned to the blister pack and any divided tablet portions remaining after 96 hours (4 days) should be discarded.

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

Emdoka

14. MARKETING AUTHORISATION NUMBERS

UK(GB) Vm 34534/5012

UK(NI) Vm 34534/3005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocare flavour

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Marbofloxacin 80 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

Marbocare flavour 80 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance: Marbofloxacin 80.0 mg

Beige brown spotted oblong tablets, deep score line upper side, score line lower side.

The tablet can be divided into halves.

3. Target species

Dogs.

4. Indications for use

Marbofloxacin is indicated in the treatment of the following infections caused by susceptible strains of organisms (see Section ”Other Information”):

- Skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis,cellulitis).
- Urinary tract infections (UTI) associated or not with prostatitis or epididymitis.
- Respiratory tract infections.

5. Contraindications

Do not use in dogs aged less than 12 months, or less than 18 months for exceptionally large breeds of dogs, such as Great Danes, Briard, Bernese, Bouvier and Mastiffs, with a longer growth period.
Do not use in cats. For the treatment of this species, a 5 mg tablet is available.

Do not use in cases of hypersensitivity to the active substance or other (fluoro)quinolones or to any of the excipients.

Do not use in cases of confirmed or suspected resistance to fluoroquinolones (cross resistance).

6. Special warnings

Special warnings:

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.

Special precautions for safe use in the target species:

The fluoroquinolones have been shown to induce erosion of articular cartilage in juvenile dogs and care should be taken to dose accurately especially in young animals. However at the therapeutic recommended dosage, no severe side-effects are to be expected in dogs.

Some fluoroquinolones at high doses may have an epileptogenic potential. Cautious use is recommended in dogs diagnosed as suffering from epilepsy.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to other classes of antimicrobials. Whenever possible, use of fluoroquinolones should be based on susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the (fluoro)quinolones and may decrease effectiveness of treatment with other quinolones due to the potential for cross-resistance. Official and local antimicrobial policies should be taken into account when the product is used.

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

Avoid contact of the skin and eyes with the product.
People with known hypersensitivity to fluoroquinolones should avoid using this product. In case of accidental ingestion seek medical attention and show the package leaflet or the label to the physician. Wash hands after use.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, embryotoxic and maternotoxic effects with marbofloxacin at therapeutic doses.

The safety of marbofloxacin has not been assessed in pregnant and lactating dogs. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Fluoroquinolones are known to interact with orally administered cations (Aluminium, Calcium, Magnesium, Iron). In such cases, the bioavailability may be reduced.

When administered together with theophylline, the half-life and thus the plasma concentration of theophylline increase. Hence, in case of concurrent administration the dose of theophylline should be reduced.

Do not use in combination with tetracyclines, macrolides because of the potential antagonist effect.

Overdose:

Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

7. Adverse events

Dog:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], soft stool[1], modification of thirst[1], Hyperactivity[1,2]

[1] These signs cease spontaneously after treatment and do not necessitate cessation of treatment.
[2] Transient.

If you notice any side effects, even those not already listed in this package leaflet, or if you think 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 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 recommended dose rate is 2 mg/kg/day in a single daily administration (see table below).
The tablet can be divided into halves as appropriate.

Body Weight	Tablets
15 – 20 kg	½
21 – 40 kg	1
41 – 60 kg	1 ½
61 – 80 kg	2

To ensure a correct dosage body weight should be determined as accurately as possible.

- In skin and soft tissue infections, treatment duration is at least 5 days. Depending on the course of the disease, it may be extended up to 40 days.
- In urinary tract infections, treatment duration is at least 10 days. Depending on the course of the disease, it may be extended up to 28 days.

- In respiratory infections, treatment duration is at least 7 days and depending on the course of the disease, it may be extended up to 21 days.

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
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 blister and carton after Exp.. The expiry date refers to the last day of that month.
Unused divided tablets should be returned to the blister pack and any divided tablet portions remaining after 96 hours (4 days) should be discarded.

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 applicable.

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

UK(GB) Vm 34534/5012

UK(NI) Vm 34534/3005

Pack sizes
Box containing 2 blisters of 6 tablets (12 tablets)
Box containing 12 blisters of 6 tablets (72 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:
Emdoka, John Lijsenstraat 16, B-2321 Hoogstraten, Belgium
+32 (0)3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:
Lelypharma BV, Zuiveringsweg 42, 8243 PZ Lelystad, The Netherlands

Local representatives and contact details to report suspected adverse reactions:
Animalcare, Moorside, Monks Cross, York, YO32 9LB, United Kingdom
+44 3308189717, animalcare@animalcare.co.uk

17. Other information

POM-V

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. It is effective against a wide range of Gram positive bacteria (in particular Staphylococci,Streptococci) and Gram negative bacteria (Escherichia coli, Salmonella typhimurium, Citrobacter freundii, Enterobacter cloacae, Serratia marcescens, Morganella morganii, Proteus spp., Klebsiella spp., Shigella spp., Pasteurella spp., Haemophilus spp., Moraxella spp., Pseudomonas spp. and Brucella canis) as well as Mycoplasma spp.

Bacterial strains with a MIC ≤ 1 µg/ml are susceptible, strains with a MIC of 2 µg/ml are intermediately susceptible and strains with a MIC ≥ 4 µg/ml are resistant to marbofloxacin (CLSI, 2004).
Resistance to fluoroquinolones occurs mostly by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.
Marbofloxacin is not active against anaerobes, yeasts or fungi.

Gavin Hall

Approved 04 September 2025