1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocare flavour 20 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance: Marbofloxacin 20.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Povidone (K90)
Silica, colloidal hydrated
Crospovidone (Type A)
Castor Oil, Hydrogenated
Dessicated pork liver powder
Dried yeast
Magnesium stearate

Beige brown spotted round tablets with a cross-snap tab on one side.
The tablet can be divided into halves or quarters.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Marbofloxacin is indicated in the treatment of the following infections caused by susceptible strains of organisms (see section 4.2):

- 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.

3.3 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).

3.4 Special warnings

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

3.5 Special precautions for use

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 fluoroquinolones 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 (fluoro)quinolones should avoid using this product. In case of accidental ingestion seek medical advice and show the package leaflet or the label to the physician. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 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.

3.9 Administration route and dosage

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 or quarters as follows;

- Place the tablet on a flat surface with the scored side facing up.
- Break the tablet into four equal parts by pressing down with your thumb or finger onto the scored side.

Body Weight	Tablets
1.3 – 2.5	¼
2.6 – 5 kg	½
5.1 – 7.5 kg	¾
7.6 – 10 kg	1
10.1 – 12.5 kg	1 ¼
12.6 – 15 kg	1 ½
15.1 – 20 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01MA93

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

After oral administration in dogs at the recommended dose of 2 mg/kg, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 1.5 µg/ml within 2 hours.

Its bioavailability is close to 100%.

It is weakly bound to plasma proteins (less than 10%), extensively distributed and in most tissues (liver, kidney, skin, lung, bladder, digestive tract) it achieves higher concentrations than in plasma. Marbofloxacin is eliminated slowly (t½ß = 14 hours in dogs) predominantly in the active form in urine (2/3) and faeces (1/3).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life of tablet portions: 96 hours

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Unused divided tablets should be returned to the blister pack and any divided tablet portions remaining after 96 hours (4 days) should be discarded.

5.4 Nature and composition of immediate packaging

The product is packaged in Aluminium- PVC/aluminium/polyamide blister
Box containing 1 blister of 10 tablets (10 tablets)

Box containing 2 blisters of 10 tablets (20 tablets)
Box containing 10 blisters of 10 tablets (100 tablets)

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

7. MARKETING AUTHORISATION NUMBER(S)

VPA10534/004/002

8. DATE OF FIRST AUTHORISATION

20/09/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03/09/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database. *(https://medicines.health.europa.eu/veterinary*)