SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocare flavour 80mg tablets for dogs (UK and IE)
Marbocare F 80mg tablets for dogs (FR)
Odimar 80mg tablets for dogs (BE, LU, NL)
Marbofloxacin WDT 80mg flavoured tablets for dogs (AT, DE)
Marbofloxacino Emdoka 80mg tablets for dogs (ES)
Marbofloxacina Emdoka 80mg tablets for dogs (PT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Marbofloxacin	80.0mg

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
Beige brown spotted oblong tablets, deep score line upper side, score line lower side.
The tablet can be divided into halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Marbofloxacin is indicated in the treatment of the following infections caused by susceptible strains of organisms (See section 5.1);

- 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.

4.3 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 animals with known hypersensitivity to marbofloxacin or other (fluoro)quinolones or to any of the excipients.

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

4.4 Special warnings

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

4.5 Special precautions for use

Special precautions for use in animals

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.

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

People with known hypersensitivity to (fluoro)quinolones should avoid using this product. In case of accidental ingestion seek medical attention and show product label and/or package leaflet to the doctor. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Mild side effects such as vomiting, softening of faeces, modification of thirst or transient increase in activity may occasionally occur. These signs cease spontaneously after treatment and do not necessitate cessation of treatment.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals (rats, rabbits) showed no teratogenicity, embryotoxicity and maternotoxicity with marbofloxacin at therapeutic doses.

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

4.8 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.

4.9 Amounts to be administered and administration route

For oral administration.

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 to avoid underdosing.

- 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; Fluoroquinolones; Marbofloxacin.

ATC vet code: QJ01MA93

5.1 Pharmacodynamic properties

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, 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). MIC_{90} values of marbofloxacin for strains of *Staphylococcus (pseudo)intermedius, Escherichia coli* and *Pasteurella multocida* isolated from diseased cats and dogs in Germany were 0.5 µg/ml, 0.5 µg/ml and 0.06 µg/ml, respectively.

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.

5.2 Pharmacokinetic particulars

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 h in dogs) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone (K90)
Silica, colloidal hydrated
Crospovidone (Type A)
Castor Oil, Hydrogenated
Dessicated pork liver powder
Dried yeast Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4. 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.

6.5 Nature and composition of immediate packaging

The product is packaged in Aluminium- PVC/aluminium/polyamide blister
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.

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

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

7. MARKETING AUTHORISATION HOLDER

Emdoka Bvba
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 34534/4005

9. DATE OF FIRST AUTHORISATION

04 September 2013

10. DATE OF REVISION OF THE TEXT

September 2013

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

DISTRIBUTED BY
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Approved: **04/09/2013**