ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box (12 and 72 tablets)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocare flavour 80mg tablets for dogs

Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains;

Active substance:

Marbofloxacin	80.0mg

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. PACKAGE SIZE

Box containing 2 blister of 6 tablets (12 tablets)
Box containing 12 blisters of 6 tablets (72 tablets)

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

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

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

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

Do not use after the expiry date stated on the blister and carton after “EXP”

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

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

Emdoka Bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 34534/4005

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocare flavour 80mg tablets for dogs

Marbofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka Bvba

3. EXPIRY DATE

<EXP {month/year}>

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Marbocare flavour 80mg tablets for 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:

Emdoka Bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

Manufacturer responsible for batch release:

Lelypharma BV
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marbocare flavour 80mg tablets for dogs

Marbofloxacin

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

Each tablet contains:

Active substance:

Marbofloxacin 80.0mg

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

4. INDICATION(S)

Marbofloxacin is indicated in the treatment of the following infections caused by susceptible strains of organisms (see Section 15. 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 animals with known hypersensitivity to marbofloxacin 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. ADVERSE REACTIONS

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

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)

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

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.

DOGS:

- In skin and soft tissue infections, treatment duration is at least 5 days. Depending on the courseof 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 PERIOD

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”

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 WARNING(S)

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.

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

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:

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

Pregnancy and lactation

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.

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 (symptoms, emergency procedures, antidotes)

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

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

Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2020

15. OTHER INFORMATION

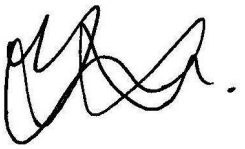
Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase. It is effective against a wide range of Gram positive bacteria (in particular *Staphylococci,Streptococci*) and Gram negative bacteria (*Escherichia coli, Salmonella 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).
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.

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 25 June 2020