1.B.2 LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marboflox 20 mg Chewable Tablets for Dogs
(in Czech Republic, Hungary, Poland,)
Marboxidin 20 mg Chewable Tablets for Dogs
(in Belgium, France, Germany, Ireland, Luxembourg, Netherlands, Spain, United Kingdom)
Marbofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substances	mg/tablet
Marbofloxacin	20.0

3. PHARMACEUTICAL FORM

Chewable tablet.
Brownish, oval, divisible, centre scored chewable tablets.
The tablets can be divided into equal halves.

4. PACKAGE SIZE

Box containing 1 blister strip of 14 chewable tablets (14 chewable tablets)
Box containing 2 blister strips of 14 chewable tablets (28 chewable tablets)
Box containing 4 blister strips of 14 chewable tablets (56 chewable tablets)
Box containing 10 blister strips of 14 chewable tablets (140 chewable tablets)

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral use only.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Tablet halves should be used within 2 days.

11. SPECIAL STORAGE CONDITIONS

This medicinal product does not require any special storage conditions.

Each time an unused half tablet is stored it should be returned to the open blister space and inserted back into the folding box and kept in a safe place out of the reach of children.

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

Disposal: read package leaflet.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Lavet Pharmaceuticals Ltd.,
1161 Budapest, Ottó u. 14., Hungary

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marboflox 20 mg Chewable Tablets for Dogs
(in Czech Republic, Hungary, Poland,)
Marboxidin 20 mg Chewable Tablets for Dogs
(in Belgium, France, Germany, Ireland, Luxembourg, Netherlands, Spain, United Kingdom)
Marbofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Lavet

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

1.B.3 PRODUCT INFORMATION

PACKAGE LEAFLET

Marboflox/Marboxidin 5 mg Chewable Tablets for Dogs and Cats
Marboflox/Marboxidin 20 mg Chewable Tablets for Dogs
Marboflox/Marboxidin 80 mg Chewable 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:
Lavet Pharmaceuticals Ltd.,
1161 Budapest, Ottó u. 14., Hungary

Responsible for batch release:
Lavet Pharmaceuticals Ltd.,
Kistarcsa, 2143 Batthyány u. 6., Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Marboflox 5 mg Chewable Tablets for Dogs and Cats
(in Czech Republic, Hungary, Poland,)
Marboxidin 5 mg Chewable Tablets for Dogs and Cats
(in Belgium, France, Germany, Ireland, Luxembourg, Netherlands, Spain, United Kingdom)
Marboflox 20 mg Chewable Tablets for Dogs
(in Czech Republic, Hungary, Poland,)
Marboxidin 20 mg Chewable Tablets for Dogs
(in Belgium, France, Germany, Ireland, Luxembourg, Netherlands, Spain, United Kingdom)
Marboflox 80 mg Chewable Tablets for Dogs
(in Czech Republic, Hungary, Poland,)
Marboxidin 80 mg Chewable Tablets for Dogs
(in Belgium, France, Germany, Ireland, Luxembourg, Netherlands, Spain, United Kingdom)
Marbofloxacin

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

	Marboflox/ Marboxidin 5 mg	**Marboflox/ Marboxidin 20 mg**	**Marboflox/ Marboxidin 80 mg**
Active substance	mg/tablet	mg/tablet	mg/tablet
Marbofloxacin	5.0	20.0	80.0

4. INDICATION(S)

In dogs
Marbofloxacin is indicated in the treatment of:

- skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis) caused by strains of microorganisms susceptible to marbofloxacin*;*
- urinary tract infections (UTI) associated or not with prostatitis or epididymitis caused by strains of microorganisms susceptible to marbofloxacin (*Proteus mirabilis* and *Escherichia coli*)*;*
- respiratory tract infections caused by strains of microorganisms susceptible to marbofloxacin.

In cats
Marbofloxacin is indicated in the treatment of skin and soft tissue infections (wounds, abscesses, phlegmons) and upper respiratory tract infections caused by strains of microorganisms susceptible to marbofloxacin.

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. Not recommended for use in cats aged less than 16 weeks.
Do not use in animals with known hypersensitivity to marbofloxacin or other (fluoro)quinolones.

6. ADVERSE REACTIONS
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.
Hypersensitivity (allergic) reactions may occur in treated animals. In this case, the treatment should be withdrawn.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES
Dogs (5 mg, 20 mg and 80 mg chewable tablets), cats (5 mg chewable tablets).

6. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Dosage and administration
The recommended dose rate is 2 mg/kg body weight/day in single oral daily administration, i.e.:
- one 5 mg chewable tablet per 2.5 kg body weight,
- one 20 mg chewable tablet per 10 kg body weight,
- one 80 mg chewable tablet per 40 kg body weight.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. Half of tablets can be admimistered.
Duration of treatment
Dogs:
- in skin and soft tissue infections, treatment duration is at least 5 days. In superficial and severe pyoderma, treatment duration is at least 10 and 20 days, respectively. 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.

Cats:
- for skin and soft tissue infections (wounds, abscesses, phlegmons) treatment duration is 3 to 5 days.
- for upper respiratory infections treatment duration is 5 days.

9. ADVICE ON CORRECT ADMINISTRATION
For oral administration only.

10. WITHDRAWAL PERIOD
Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

This medicinal product does not require any special storage conditions.
Each time an unused half tablet is stored it should be returned to the open blister space and inserted back into the folding box and kept in a safe place out of the reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species

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

Special precautions for use

i) 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.
The fluoroquinolones at high doses may have an epileptogenic potential. Cautious use is recommended in dogs diagnosed as suffering from epilepsy.
Official and local antimicrobial policies should be taken into account when the product is used.
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.

ii) Special precautions to be taken by the person administering the 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.

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 cats and dogs. Use only according 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.
The dose of theophylline should be reduced when used simultaneously, as fluoroquinolones may increase its concentration.

Overdose (symptoms, emergency procedures, antidotes)

Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically. Signs as salivation and vomiting, weight loss and decreased activity may occur.

Incompatibilities

None known.

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

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

15. OTHER INFORMATION

Marboflox/Marboxidin 5 mg chewable tablets for dogs and cats
Nature of container: PVC/Aluminium/Polyamide blister-forming laminate with aluminium lidding foil containing 14 chewable tablets. Folding box as an outer package.
Box containing 1 blister strip of 14 chewable tablets (14 chewable tablets)
Box containing 2 blister strips of 14 chewable tablets (28 chewable tablets)
Box containing 4 blister strips of 14 chewable tablets (56 chewable tablets)
Box containing 10 blister strips of 14 chewable tablets (140 chewable tablets)

Marboflox/Marboxidin 20 mg chewable tablets for dogs
Nature of container: PVC/Aluminium/Polyamide blister-forming laminate with aluminium lidding foil containing 14 chewable tablets. Folding box as an outer package.
Box containing 1 blister strip of 14 chewable tablets (14 chewable tablets)
Box containing 2 blister strips of 14 chewable tablets (28 chewable tablets)
Box containing 4 blister strips of 14 chewable tablets (56 chewable tablets)
Box containing 10 blister strips of 14 chewable tablets (140 chewable tablets)

Marboflox/Marboxidin 80 mg chewable tablets for dogs
Nature of container: PVC/Aluminium/Polyamide blister-forming laminate with aluminium lidding foil containing 7 chewable tablets. Folding box as an outer package.
Box containing 1 blister strip of 7 chewable tablets (7 chewable tablets)
Box containing 2 blister strips of 7 chewable tablets (14 chewable tablets)
Box containing 4 blister strips of 7 chewable tablets (28 chewable tablets)
Box containing 10 blister strips of 7 chewable tablets (70 chewable 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.