SUMMARY OF PRODUCT CHARACTERISTICS

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)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance:
Marbofloxacin 20 mg

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

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

- 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 *;*
- respiratory tract infections caused by strains of microorganisms susceptible to marbofloxacin*.*

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 animals with known hypersensitivity to marbofloxacin or other (fluoro)quinolones.

4.4 Special warnings for each target species

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

4.5 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 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.
Hypersensitivity (allergic) reactions may occur in treated animals. In this case, the treatment should be withdrawn.

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 according 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.
The dose of theophylline should be reduced when used simultaneously, as fluoroquinolones may increase its concentration.

4.9 Amounts to be administered and administration route
For oral administration.
The recommended dose rate is 2 mg/kg body weight/day (1 tablet for 10 kg BW per day) in single daily administration.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. Half of tablets can be administered.
Treatment duration:

- 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.

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. Signs as salivation and vomiting, weight loss and decreased activity may occur.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones. 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, Enterobacter cloacae, Proteus spp, Klebsiella spp, Pasteurella multocida, Pseudomonas aeruginosa).*

The MIC90 values of marbofloxacin against recent German isolates of *E. coli, P. multocida and S. intermedius* obtained from dogs and cats were found 0.03 µg/ml, 0.06 µg/ml and 0.5 µg/ml, respectively.

Marbofloxacin is not active against anaerobes, yeasts or fungi.

Resistance to fluoroquinolones occurs by chromosomal mutation with three mechanisms: decrease of the bacterial wall permeability, expression of efflux pump or mutation of enzymes responsible for molecule binding.

5.2 Pharmacokinetic particulars:

After oral administration in dogs at the recommended dose of 2 mg/kg body weight, marbofloxacin is readily absorbed and reaches maximal plasma concentrations of 2.2 µg/mlat 2.5 h.. Its bioavailability is close to 100%.

Marbofloxacin 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 = 12.2 h in dogs) predominantly in the active form in urine (2/3) and faeces (1/3).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol distearate
Artificial beef flavour
Cellulose, microcrystalline
Starch, pregelatinized
Sodium starch glycolate (Type A)
Talc
Magnesium stearate

6.2 Incompatibilities
None known.

6.3 Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 2 days.

6.4. Special precautions for storage

Return any halved tablet to the opened blister pack and use within 2 days.

6.5 Nature and composition of immediate packaging
The product is packaged in aluminium – PVC/aluminium/polyamide blister.
Carton box containing 1 blister strip of 14 tablets (14 tablets)
Carton box containing 2 blister strips of 14 tablets (28 tablets)
Carton box containing 4 blister strips of 14 tablets (56 tablets)
Carton box containing 10 blister strips of 14 tablets (140 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

Lavet Pharmaceuticals Ltd
H-1161 Budapest
Ottó u 14
Hungary

8. MARKETING AUTHORISATION NUMBER

Vm 32823/4013

9. DATE OF FIRST AUTHORISATION

08 March 2013

10. DATE OF REVISION OF THE TEXT

March 2013

Approved:  **08/03/2013**