Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Boflox flavour 80 mg tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance:
Marbofloxacin 80 mg

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Oblong beige tablets with brown speckles scored on both sides.
The tablets can be divided into halves.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

Treatment of infections caused by strains of microorganisms susceptible to marbofloxacin. Please 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

Marbofloxacin should not be used in dogs aged less than 12 months, or less than 18 months for exceptionally large breeds of dogs, such as Great Dane, Briard, Bernese, Bouvier and Mastiff, with a longer growth period.
Do not use in cases of hypersensitivity to fluoroquinolones or any of the excipients of the product.
Do not use in cases of resistance against quinolones, since (almost) complete cross-resistance exists against other fluoroquinolones.
Not suitable for infections resulting from strict anaerobes, yeast or fungi.
Do not use in cats. For the treatment of this species, a divisible 20 mg tablet is available.

4.4 Special warnings for each target species

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.
Pyoderma occurs mostly secondary to an underlying disease, thus, it is advisable to determine the underlying cause and treat the animal accordingly

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.

The fluoroquinolones are also known for their potential neurological side effects. 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. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may reduce 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 contact with the veterinary medicinal 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.

4.6 Adverse reactions (frequency and seriousness)

At the therapeutic recommended dosage, no severe side-effects are to be expected in dogs. In particular, no lesions of the articular joints were encountered in clinical studies at the recommended dose rate. However, joint pain and/or neurological symptoms (ataxia, aggressiveness, convulsion, depression) may occur on rare occasions.

Allergic reactions have been observed (temporary skin reactions) due to the histamine release that may occur.

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.

The frequency of adverse reactions is defined using the following convention:
-very common (more than 1 in 10 animals treated displaying adverse reactions during the course of one treatment)
-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).

4.7 Use during pregnancy, lactation or lay

Studies in pregnant rats and rabbits showed no side effects on pregnancy. However no specific studies have been carried out in pregnant dogs.
Use in pregnant and lactating animals should be in accordance with the benefit/risk assessment performed by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

Fluoroquinolones are known to interact with orally administered cations (Aluminium, Calcium, Magnesium, Iron). In such cases, the bioavailability may be reduced.

Do not use in combination with tetracyclines, macrolides because of the potential antagonist effect.

When administered together with theophylline, the half-life and thus the plasma concentration of theophylline increases. Hence, 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/d (1 tablet for 40 kg per day) in single daily administration. To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. Tablets may be divided along score lines to facilitate accurate dosing.
Duration of treatment: 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 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 cartilage damage in the joints and acute signs in the form of neurological disorders (e.g. salivation, streaming eyes, shivering, myoclonia, seizures), which should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolone.
ATCvet code: QJ01MA93.

5.1 Pharmacodynamic properties

Marbofloxacin is a synthetic, bactericidal antimicrobial, belonging to the fluoroquinolone group which acts by inhibition of DNA gyrase and Topoisomerase IV. It is effective against a wide range of Gram positive bacteria and Gram negative bacteria. Efficacy was established in particular in:

- Skin and soft tissue infections caused by *Staphylococcus* spp. (*S. aureus* and *S. intermedius*), *E. coli*, *Pasteurella multocida* and *Pseudomonas aeruginosa*
- Urinary tract infections caused by *Staphylococcus* spp. (*S. aureus* and *S. intermedius*), *Streptococcus* spp, *Enterobacteriaceae* (*E. coli*, *Proteus* spp., *Klebsiella* spp., *Citrobacter freundii*, *Enterobacter cloacae*) and *Pseudomonas aeruginosa*
- Respiratory tract infections infections caused by *Pasteurella multocida*, *Enterobacteriaceae* (*E. coli, Klebsiella pneumoniae*), *Staphylococcus* spp. (*S. aureus, S. intermedius*), *Pseudomonas aeruginosa*, *Bordetella bronchiseptica* and *Streptococcus* spp. Cases of resistance have been observed in *Streptococcus*.Strains from dermal infections in cats and dermal and UTI infections in dogs with MIC < 1µg/ml are sensitive to marbofloxacin (CLSI, 2008) whereas strains with MIC ≥ 4 µg/ml are resistant to marbofloxacin.Resistance to fluoroquinolones occurs by chromosomal mutation with the following mechanisms: Decrease in bacterial cell wall permeability, expression of genes coding for efflux pump or mutations in genes encoding enzymes responsible for molecule binding. Plasmid-mediated resistance to fluoroquinolones confer only decreased susceptibility of bacteria, however, it can facilitate development of mutations in genes of target enzymes and can be transferred horizontally. Depending on the underlying resistance mechanism cross-resistance to other (fluoro)quinolones and co-resistance to other antimicrobial classes can occur. 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 (elimination half-life is 14 hours 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
Cellulose, powdered
Povidone
Crospovidone
Silica, colloidal anhydrous
Calcium Behenate
Yeast
Beef flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years
Shelf life of tablet halves: 4 days

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Store the blisters in the original container.
If the tablets are divided, the remaining halves should be returned to the blister pocket.
Any divided tablets halves remaining after 4 days should be discarded.

6.5 Nature and composition of immediate packaging

Alu / PA-Alu-PVC blister each of 6 tablets.

Package sizes:

Box with 6 tablets
Box with 12 tablets
Box with 36 tablets
Box with 72 tablets
Box with 120 tablets
Box with 240 tablets

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10425/004/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 February 2017
Date of last renewal: 03 December 2021

10 DATE OF REVISION OF THE TEXT

December 2021