Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Efex 100 mg chewable tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains:
Active substance:
Marbofloxacin ..... 100.0 mg

Excipient(s):
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet
Clover-shaped scored beige tablet. The tablet can be divided into four equal parts.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

In dogs

Marbofloxacin is indicated in the treatment of:
- skin and soft tissue infections (skinfold pyoderma, impetigo, folliculitis, furunculosis, cellulitis) caused by susceptible strains of *organisms.*
- urinary tract infections (UTI) caused by susceptible strains of organisms associated or not with prostatitis or epididymitis.
- respiratory tract infections caused by susceptible strains of *organisms*.

4.3 Contraindications

Do not use in dogs aged less than 12 months, or less than 18 months for giant breeds of dogs with a longer growth period.
Do not use in cases of hypersensitivity to the active substance, other (fluoro)quinolones or any of the excipients.

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

Special precautions for use in animals
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the 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. 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.

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 or other components of the formulation 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)

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

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals (rat, rabbit) 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 interactions

Fluoroquinolones are known to interact with orally administered cations (Aluminium, Calcium, Magnesium, Iron). In such cases, the bioavailability may be reduced.
Serum levels of theophylline should be carefully monitored when theophylline and marbofloxacin are used concomitantly, as fluoroquinolones may increase serum levels of theophylline.

4.9 Amounts to be administered and administration route

For oral administration
The recommended dose rate is 2 mg/kg/d (1 tablet for 50 kg per day) in single daily administration.

Dogs:
- 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.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The chewable tablets may be accepted by dogs or can be administered directly into the mouth of the animals.
Instruction on how to divide the tablet: Put the tablet on an even surface, with its scored side facing down (convex face up). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves. Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

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 or IMMUNOLOGICAL 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 and topoisomerase IV.. It has a broad-spectrum activity in vitro against Gram-positive bacteria (in particular staphylococci *and* streptococci) and, Gram-negative bacteria (*Escherichia coli, Enterobacter cloacae, Proteus* spp*., Klebsiella* spp*., Shigella* spp*., Pasteurella* spp*., Pseudomonas* spp*.) as well as Mycoplasma* spp..
A report on microbiological susceptibility including two European field surveys covering hundreds of canine and feline pathogens sensitive to marbofloxacin was published on 2009

Micro-organisms	MIC (µg/ml)
Staphylococcus intermedius	0,23 - 0,25
Escherichia coli	0,125 - 0,25
Pasteurella multocida	0,04
Pseudomonas aeruginosa	0,94

MIC breakpoints have been determined for Enterobacteriaceaeand *Staphylococcus* spp in dogs and cats (skin, soft tissue, UTI). CLSI, July 2013 as
≤1 µg/ml for sensitive, 2 µg/ml for intermediate and ≥4 µg/ml for resistant bacterial strains to marbofloxacin.

Marbofloxacin is not active against anaerobes, yeasts or fungi.
The activity of marbofloxacin against the target bacterial species is bactericidal concentration-dependant.

Resistance to fluoroquinolones occurs by chromosomal mutations with the following mechanisms: decrease in bacterial cell wall permeability, expression change of genes coding for efflux pumps or mutations in genes encoding enzymes responsible for molecule binding. Plasmid-mediated resistance to fluoroquinolones, which confers reduced susceptibility, has also been described. Depending on the underlying resistance mechanism, cross-resistance to other (fluoro)quinolones and co-resistance to other antimicrobial classes can occur.

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
Copovidone
Silica, colloidal anhydrous
Croscarmellose sodium
Hydrogenated castor oil
Pig liver powder
Malted yeast
Cellulose microcrystalline

6.2 Major incompatibilities

Not applicable

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale:
Blister: PVC-TE-PVDC – aluminium heat sealed: 3 years
Blister: PA-AL-PVC – aluminium heat sealed: 3 years

Shelf-life after first opening the immediate packaging: 72 hours:

6.4 Special precautions for storage

Blister: PVC-TE-PVDC – aluminium heat sealed: Do not store above 30°C
Blister: PA-AL-PVC – aluminium heat sealed: This veterinary medicinal product does not require any special temperature storage conditions.
Tablet portions should be stored in the blister pack
Any tablet portions remaining after 72 hours should be discarded
Keep the blister in the outer carton.

6.5 Nature and composition of immediate packaging

- (Polyvinyl chloride-Thermo-elast-P olyvinylidene chloride – aluminium heat sealed) containing 6 tablets per blister
- (Polyamide-Aluminium-Polyvinyl chloride – aluminium heat sealed) containing 6 tablets per blister

Cardboard box of 6 tablets containing 1 blister of 6 tablets
Cardboard box of 12 tablets containing 2 blisters of 6 tablets
Cardboard box of 120 tablets containing 20 blisters of 6 tablets
Cardboard box of 240 tablets containing 40 blisters of 6 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 products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/036/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th August 2013
Date of last renewal: 9th March 2018

10 DATE OF REVISION OF THE TEXT

May 2021