1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Efex 10 mg chewable tablets for cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance:
Marbofloxacin .....10.00 mg

Excipient(s):

Qualitative composition of excipients and other constituents
Lactose monohydrate
Copovidone
Silica, colloidal anhydrous
Croscarmellose sodium
Hydrogenated castor oil
Pig liver powder
Malted yeast
Cellulose microcrystalline

Oblong scored beige tablet. The tablet can be divided in two equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Cats and Dogs

3.2 Indications for use for each target species

In cats:
Treatment of infections caused by strains of microorganisms susceptible to marbofloxacin :
-skin and soft tissue infections (wounds, abscesses, phlegmons),
-upper respiratory tract infections.

In dogs:
Treatment of infections caused by strains of microorganisms susceptible to marbofloxacin :
- 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.

3.3 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 cats aged less than 16 weeks.
Do not use in cases of hypersensitivity to the active substance, other (fluoro)quinolones or any of the excipients.

3.4 Special warnings

A low urinary pH could have an inhibitory effect on the activity of marbofloxacin.
Cross-resistance has been shown between marbofloxacin and other fluoroquinolones. Use of the product should be carefully considered when susceptibility testing has shown resistance to other fluoroquinolones because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 and cats diagnosed as suffering from epilepsy.
Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level." Use of the product should be in accordance with official, national and regional antimicrobial policies.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs, Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[2], Soft stool[2] Hyperactivity [1,2] Modification of thirst [2,3]

1 Transient
2 Cease spontaneously after treatment.
3 Increase or decrease.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
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 cats and dogs. Use only according to the benefit/risk assessment by the responsible veterinarian in pregnant and lactating animals.

3.8 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.
Serum levels of theophylline should be carefully monitored when theophylline and marbofloxacin are used concomitantly, as fluoroquinolones may increase serum levels of theophylline.

3.9 Administration routes and dosage

Oral use.
The recommended dose rate is 2 mg/kg/d (1 tablet for 5 kg per day) in single daily administration.

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.

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.
The chewable tablets may be accepted by cats and dogs or can be administered directly into the mouth of the animals.

3.10 Symptoms of overdose (and where applicable, emergency procedures, and antidotes)

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

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet code:

QJ01MA93

4.2 Pharmacodynamics

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 *Enterobacteriaceae* and *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.

4.3 Pharmacokinetics

After oral administration in dogs and cats 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 and 10h in cats) predominantly in the active form in urine (2/3) and faeces (1/3).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

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

5.3 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.

5.4 Nature and composition of immediate packaging

(Polyvinyl chloride-Thermo-elast-Polyvinylidene chloride – aluminium heat sealed) containing 10 tablets per blister.
(Polyamide-Aluminium-Polyvinyl chloride – aluminium heat sealed) containing 10 tablets per blister.

Cardboard box of 10 tablets containing 1 blister of 10 tablets
Cardboard box of 120 tablets containing 12 blisters of 10 tablets
Cardboard box of 240 tablets containing 24 blisters of 10 tablets

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.
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6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/036/001

8. DATE OF FIRST AUTHORISATION

22/04/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/11/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).