

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Efex 40 mg chewable tablets for dogs

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:  
Marbofloxacin 40.0 mg

**3. PACKAGE SIZE**

6 tablets  
8 tablets  
12 tablets  
16 tablets  
120 tablets  
240 tablets

**4. TARGET SPECIES**

Dogs

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

For oral administration

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

EXP {month/year}  
Any tablet portions remaining after 72 hours should be discarded.

**9. SPECIAL STORAGE PRECAUTIONS**

Blister: PVC-TE-PVDC – aluminium heat sealed: Do not store above 30°C  
Tablet portions should be stored in the blister pack  
Keep the blister in the outer carton.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Ceva Sante Animale  
8 rue de Logrono  
33500 Libourne  
France

**14. MARKETING AUTHORISATION NUMBERS**

UK (NI) Vm 14966/3035  
UK (GB) Vm 14966/5036

**15. BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS (BLISTERS)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Efex 

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

40 mg of marbofloxacin

**3. BATCH NUMBER**

Lot

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

Efex 40 mg chewable tablets for dogs

#### **2. Composition**

One tablet contains:

**Active substance:**

Marbofloxacin 40.0 mg

Chewable tablet

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

#### **3. Target species**

Dogs

#### **4. Indications for use**

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.

#### **5. 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.

#### **6. Special warnings**

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

##### 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.

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 fluoroquinolones 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:

No applicable.

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.

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.

Overdose:

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

## 7. Adverse events

### Dog:

Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):	Vomiting <sup>2</sup> , Soft stool <sup>2</sup> Hyperactivity <sup>1,2</sup> Modification of thirst <sup>2</sup>
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<sup>1</sup> Transient

<sup>2</sup> Cease spontaneously after treatment

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

For oral administration.

The recommended dose rate is 2 mg/kg/d (1 tablet for 20 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.

## 9. Advice on correct administration

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.

## **10. Withdrawal periods**

Not applicable.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Blister: Polyvinyl chloride-Thermo-elast-Polyvinylidene chloride – aluminium heat sealed: Do not store above 30°C.

Blister: Polyamide-Aluminium-Polyvinyl chloride – 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.

Do not use after the expiry date which is stated on the carton and blister after “EXP”.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

UK (NI) Vm 14966/3035

UK (GB) Vm 14966/5036

### Pack sizes:

Cardboard box with 6 tablets

Cardboard box with 8 tablets

Cardboard box with 12 tablets

Cardboard box with 16 tablets

Cardboard box with 120 tablets

Cardboard box with 240 tablets

Not all pack sizes may be marketed.

#### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### **16. Contact details**

##### Marketing Authorisation Holder

Ceva Sante Animale  
8 rue de Logrono  
33500 Libourne  
France

##### Contact details to report suspected adverse reactions:

Ceva Animal Health Ltd  
Explorer House  
Mercury Park  
Wycombe Lane  
Wooburn Green  
High Wycombe  
Buckinghamshire  
HP10 0HH  
United Kingdom  
Tel: 00800 35 22 11 51

Email for the reporting of adverse events: [pharmacovigilance@ceva.com](mailto:pharmacovigilance@ceva.com)

##### Manufacturer responsible for batch release:

Ceva Santé Animale  
Boulevard de la Communication  
Zone Autoroutière  
53950 LOUVERNE  
FRANCE

## 17. Other information

POM-V

Veterinary Medicinal product subject to prescription  
For animal treatment only

*Gavin Hall*

Approved: 03 October 2025