Veterinary Medicinal Product

Efex 100 mg chewable tablets for dogs

PART I B

A - LABELLING

Pharmaceutical Form

Chewable Tablet

Veterinary Medicinal product

Efex 100 mg chewable tablets for dogs

PART IB

A – LABELLING – "OUTER PACKAGE"

Pharmaceutical form

Chewable Tablet

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Efex 100 mg chewable tablets for dogs

Marbofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

6 tablets
12 tablets
120 tablets
240 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4097

17. MANUFACTURER'S BATCH NUMBER

Batch:

Veterinary Medicinal product

Efex 100 mg chewable tablets for dogs

PART IB

A – LABELLING – BLISTER

Pharmaceutical form

Chewable Tablet

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Efex 100 mg chewable tablets for dogs

Marbofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva logo

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Veterinary Medicinal product

Efex 100 mg chewable tablets for dogs

PART IB

B – PACKAGE LEAFLET

Pharmaceutical form

Chewable Tablet

PACKAGE LEAFLET

Efex 100 mg chewable tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 LOUVERNE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Efex 100 mg chewable tablets for dogs

Marbofloxacin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One tablet contains:
Active substance:
Marbofloxacin.....100.0 mg
Chewable tablet
Clover-shaped scored beige tablet. The tablet can be divided into four equal parts

4. INDICATION(S)

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.

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. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}".

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

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 PERIOD(S)

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 WARNING(S)

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

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.

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 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 (symptoms, emergency procedures, antidotes)
Overdosage may cause acute signs in the form of neurological disorders, which should be treated symptomatically.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

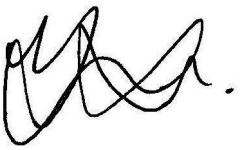
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

Pack sizes:
Cardboard box with 6 tablets
Cardboard box with 12 tablets
Cardboard box with 120 tablets
Cardboard box with 240 tablets
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 14 September 2022