1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 15 mg tablets for cats and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Enrofloxacin 15.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Maize starch
Povidone K25
Cellulose, powdered
Croscarmellose sodium
Crospovidone
Colloidal anhydrous silica
Magnesium stearate

A slightly yellow, round, convex tablet with a cross-shaped break line on one side.
Tablets can be divided into 2 or 4 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Dogs:
Treatment of lower urinary tract infections (associated or not with prostatitis) and upper urinary tract infections caused by *Escherichia coli* or *Proteus mirabilis*.
Treatment of superficial and deep pyoderma.

Cats:
Treatment of upper respiratory tract infections.

3.3 Contraindications

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed) as the veterinary medicinal product may cause epiphyseal cartilage alterations in growing puppies).
Do not use in young, growing cats, because of the possibility of the development of cartilage lesions (cats aged less than 3 months or weighing less than 1 kg).
Do not use in cats or dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.

Do not use in cases of hypersensitivity to the active substance or other fluoroquinolones or to any of the excipients.
Do not use in case of resistance to quinolones, as there exists almost complete cross-resistance to other quinolones and complete cross-resistance to other fluoroquinolones.
Do not use with tetracyclines, phenicols or macrolides because of potential antagonistic effects.
Pregnant and lactating animals, please see section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Retinotoxic effects, including blindness, can occur in cats when the recommended dose is exceeded.

It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions that have responded poorly, or are expected to respond poorly, to other classes of antibiotics. Whenever possible, fluoroquinolones should only be used based on susceptibility testing. Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.
Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential cross-resistance.

Use the veterinary medicinal product with caution in cats or dogs with severe renal or hepatic impairment.
Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with a 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. In case of contact with the eyes, rinse immediately with plenty of water.
Wash hands after handling the veterinary medicinal product.

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

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Vomiting Anorexia
Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction Central nervous system disorder Joint cartilage disorder [a]

[a] Possible joint cartilage alterations in growing puppies (see section 3.3 ‘Contraindications’).

Cats:

Undetermined frequency (cannot be estimated from the available data):	Hypersensitivity reaction Central nervous system disorder Vomiting [b], Diarrhoea [b]

[b] May appear during the treatment. These signs regress spontaneously and generally do not require treatment discontinuation.

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:
Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and chinchillas have not produced any evidence of teratogenic, foetotoxic or maternotoxic effect.

Lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent use of flunixin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.
Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.
Concurrent use of magnesium or aluminium containing substances (such as antacids or sucralfate) may reduce absorption of enrofloxacin. These drugs should be administered two hours apart.
Do not administer simultaneously with tetracyclines, phenicols or macrolides because of potential antagonistic effects.
Do not administer simultaneously with non-steroidal anti-inflammatory drugs, convulsions can occur.

3.9 Administration routes and dosage

Oral use.

Dogs:
5 mg of enrofloxacin/kg/day as a single daily dosing, i.e. one tablet for 3 kg daily for:

- 10 days in lower urinary tract infections.
- 15 days in upper urinary tract infections and lower urinary tract infections associated with prostatitis.
- Up to 21 days in superficial pyoderma depending on clinical response.
- Up to 49 days in deep pyoderma depending on clinical response.

Cats:
5 mg of enrofloxacin/kg body weight once daily for 5 to 10 consecutive days.

- Either 1 tablet for 3 kg body weight as a single daily dosing.
- Or ½ tablet for 1.5 kg body weight as a single daily dosing.

The treatment should be considered in case of lack of clinical improvement at half of the treatment duration.
The tablets may be administered directly in the mouth of the dog or cat or simultaneously with food if necessary.
Do not exceed the recommended treatment dose.

After breaking a tablet, use the remaining tablet half for the next dose. Store the tablet half in the original blister pocket.

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

Overdosing can cause vomiting and nervous signs (muscle tremor, incoordination and convulsions) which may require treatment discontinuation.
In the absence of any known antidote, apply drug elimination methods and symptomatic treatment.
If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
According to literature, signs of overdosage with enrofloxacin in dogs such as inappetence and gastrointestinal disturbance were observed at approximately 10 times the recommended dose when administered for two weeks. No signs of intolerance were observed in dogs administered 5 times the recommended dose for a month.
In laboratory studies, ocular adverse effects in cats have been observed from 20 mg/kg.
The toxic effects on the retina caused by overdosing may be such that they lead to irreversible blindness in the cat.

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 ATCvet code: QJ01MA90

4.2 Pharmacodynamics

Enrofloxacin is a synthetic fluoroquinolone antibiotic that exerts its activity by inhibiting topoisomerase II, an enzyme involved in the mechanism of bacterial replication.

Enrofloxacin exerts bactericidal activity concentration-dependent with similar values of minimal inhibit concentration and minimal bactericide concentrations. It also possesses activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

In general, enrofloxacin exhibits good activity against most gram-negative bacteria, especially those of the Enterobacteriaceae. *Escherichia coli*, *Enterobacter* spp., *Klebsiella* spp. and *Proteus* spp. are generally susceptible.
Pseudomonas aeruginosa is variably susceptible and, when it is susceptible, usually has a higher MIC than other susceptible organisms.
Staphylococcus aureus and *Staphylococcus intermedius* usually are susceptible.
Streptococci, enterococci, anaerobic bacteria can generally be considered resistant.

Induction of resistance against quinolones can develop by mutations in the gyrase gene of bacteria and by changes in cell permeability towards quinolones.

4.3 Pharmacokinetics

Enrofloxacin is approximately 100% bioavailable after oral administration. It is unaffected by food.
Enrofloxacin is rapidly metabolized to form an active compound, ciprofloxacin.
After a dose of 5 mg/kg body weight, maximum plasma levels of approximately 1.5 µg/mL in dogs and approximately 2.5 µg/mL in cats are reached after 0.5 to 2.0 hours.

Enrofloxacin is primarily excreted via the kidneys. A major portion of the parent drug and its metabolites is recovered in urine.
Enrofloxacin is widely distributed in the body. The tissue concentrations are often higher than the serum concentrations. Enrofloxacin crosses the blood-brain barrier. The degree of protein binding in serum is 14% in dogs and 8% in cats. The half-life lies between 3.0 and 6.8 hours for dogs and cats, respectively.
Approximately 25% of the dose of enrofloxacin is excreted in the urine and 75% via the faeces.
Approximately 60% (dogs) or 15% (cats) of the dose is excreted as unchanged enrofloxacin in the urine and the remainder as metabolites, amongst others ciprofloxacin. The total clearance is approximately 9 mL/minute/kg bodyweight.

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 of divided tablets: 24 hours.

5.3 Special precautions for storage

Veterinary medicinal product as packaged for sale: No special precautions for storage.
Divided tablets: Store below 25 °C.
Divided tablets should be stored in the blister pack.

5.4 Nature and composition of immediate packaging

Alu-PVC/PE/PVDC blister or Alu-PVC/PVDC blister with 10 tablets;
Cardboard box with 1 blister (10 tablets);
Cardboard box with 2 blisters (20 tablets);
Cardboard box with 3 blisters (30 tablets);
Cardboard box with 5 blisters (50 tablets);
Cardboard box with 6 blisters (60 tablets);
Cardboard box with 10 blisters (100 tablets);
Cardboard box with 15 blisters (150 tablets).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet BV

7. MARKETING AUTHORISATION NUMBER(S)

VPA10816/006/001

8. DATE OF FIRST AUTHORISATION

03/09/2010

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

12/11/2024

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).