SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 50 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance
Enrofloxacin 50.0 mg

Excipients
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
A white to slightly yellow, round, convex tablet.
The tablet can be divided into two equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

In 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.

4.3 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 product may cause epiphyseal cartilage alterations in growing puppies).
Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use in dogs with known hypersensitivity to fluoroquinolones or to any of the excipients of the product.

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 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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 product is used. Use of the 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 product with caution in 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 any contact with the product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.
Wash hands after handling the product.
In case of contact with the eyes, rinse immediately with plenty of water.

4.6 Adverse reactions (frequency and seriousness)

- Hypersensitivity reactions
- Alterations in Central Nervous System

Possible joint cartilage alterations in growing puppies (see 4.3 contraindications).
In rare cases vomiting and anorexia are observed.

4.7 Use during pregnancy, lactation or lay

Use during pregnancy:
Studies in laboratory animals (rat, chinchilla) have not produced any evidence of a teratogenic, foetotoxic, maternotoxic effect. Use only according to the benefit/risk assessment by the responsible veterinarian.

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

4.8 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.

4.9 Amounts to be administered and administration route

Oral use

5 mg of enrofloxacin/kg/day as a single daily dosing, i.e. one tablet for 10 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

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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Fluoroquinolone antibiotics
ATCvet code: QJ01MA90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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 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. The half-life is approximately 3.0 hours for dogs.

Approximately 25% of the dose of enrofloxacin is excreted in the urine and 75% via the faeces. Approximately 60% 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Povidone K25
Cellulose, powdered
Croscarmellose sodium
Crospovidone
Colloidal anhydrous silica
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life of divided tablets: 24 hours

6.4 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.

6.5 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 19994/4008

9. DATE OF FIRST AUTHORISATION

02 September 2010

10. DATE OF REVISION OF THE TEXT

May 2021

Approved 14 May 2021