[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 50 mg tablets for dogs
Floxabactin Vet. (DK)
Floxabactin Vet. 50 mg tablets for dogs (FI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Enrofloxacin 50.0 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 white to 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.

3.2 Indications for use for each target species

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.

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 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:
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 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 3.3 ‘Contraindications’).

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.

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.

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.

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 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.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

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

{DD/MM/YYYY}

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).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 50 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Enrofloxacin 50.0 mg

3. PACKAGE SIZE

10/20/30/50/60/100/150 tablets.

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Use divided tablets within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Divided tablets: Store below 25 °C.
Divided tablets should be stored in the blister pack.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

enrofloxacin
50 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Floxabactin 50 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:
Enrofloxacin 50.0 mg

A white to 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. Target species

Dogs.

4. Indications for use

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.

5. 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 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.

6. Special warnings

Special precautions for safe use in the target species:
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 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.

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.

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.

Overdose:
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.

7. 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 ‘Contraindications’).

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

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.

Do not exceed the recommended treatment dose.

9. Advice on correct administration

The tablets are flavoured, and are well accepted by dogs. The tablets may be administered directly in the mouth of the dog or simultaneously with food if necessary.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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. After breaking a tablet, use the remaining tablet half for the next dose.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after “Exp”. The expiry date refers to the last day of that month.

Shelf life of divided tablets: 24 hours.

12. Special precautions for disposal

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

Ask your veterinary surgeon or pharmacist 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

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.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Lelypharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

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

17. Other information