PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Outer cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 15 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Enrofloxacin 15.0 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs and cats.

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

Le Vet B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 19994/3001
Vm 19994/5010

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
15 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Floxabactin 15 mg tablets for cats and dogs

2. Composition

Each tablet contains:

Active substance:
Enrofloxacin 15.0 mg

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. Target species

Dogs and cats.

4. Indications for use

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

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 young, growing cats, because of the possibility of the development of cartilage lesions (cats aged less than 3 months or weighing less than 1kg).
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.

6. Special warnings

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.

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.
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.

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').

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 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 at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

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.

Do not exceed the recommended treatment dose.

9. Advice on correct administration

The tablets are flavoured, and are well accepted by cats and dogs. The tablets may be administered directly in the mouth of the dog or cat 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.
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

Vm 19994/3001
Vm 19994/5010

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. 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.

16. Contact details

Marketing authorisation holder:
Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

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:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

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

17. Other information

POM-V

Gavin Hall

Approved: 01 April 2025