

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Floxabactin 150 mg tablets for dogs  
Enrofloxacin

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each tablet contains:  
Enrofloxacin                      150.0 mg

**3. PHARMACEUTICAL FORM**

Tablets

**4. PACKAGE SIZE**

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

**5. TARGET SPECIES**

Dogs

**6. INDICATIONS**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP: (month/year)

Shelf life of divided tablets: 24 hours.

**11. SPECIAL STORAGE CONDITIONS**

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.

**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 SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 19994/4009

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**BLISTERS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Floxabactin 150 mg tablets for dogs  
enrofloxacin

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

Le Vet B.V.

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only

## PACKAGE LEAFLET

Floxabactin 150 mg 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:

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

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Floxabactin 150 mg tablets for dogs

Enrofloxacin

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

Floxabactin 150 mg is a white to slightly yellow, round, convex tablet.  
The tablet can be divided into two equal parts.

Each tablet contains:

**Active substance:** Enrofloxacin 150.0 mg

### 4. INDICATION(S)

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 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.

## **6. ADVERSE REACTIONS**

- Hypersensitivity reactions
- Alterations in Central Nervous System

Possible joint cartilage alterations in growing puppies (see section 5 contraindications).

In rare cases vomiting and anorexia are observed.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dogs

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

Oral use

5 mg of enrofloxacin/kg/day as a single daily dosing, i.e. one tablet for 30 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.

## **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 PERIOD**

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

Veterinary medicinal product as packaged for sale: No special precautions for storage.

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

Divided tablets: Store below 25°C.

Divided tablets should be stored in the blister pack.

Shelf life of divided tablets: 24 hours.

## 12. SPECIAL WARNING(S)

### **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.

### **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.

### **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 (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.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

March 2021

**15. OTHER INFORMATION**

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.

Approved 14 May 2021

