

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

{Cardboard box}

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

Enrox Flavour 15 mg tablets

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains: Enrofloxacin 15 mg

**3. PACKAGE SIZE**

10 tablets  
100 tablets

**4. TARGET SPECIES**

Dogs and cats



**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral use.  
The tablet is given orally once daily or as a divided dose twice daily with or without food.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

**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**

KRKA

**14. MARKETING AUTHORISATION NUMBERS**

Vm 01656/4007

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

{Blisters}

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

Enrox Flavour



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

15 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Enrox Flavour 15 mg tablets for dogs and cats

### 2. Composition

Each tablet contains:

**Active substances:**

Enrofloxacin 15 mg

Round slightly biconvex, cream to light brownish tablets with possible visible white or darker spots and bevel-edged.

### 3. Target species

Dogs and cats.



### 4. Indications for use

The veterinary medicinal product is for use in dogs and cats in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

### 5. Contraindications

Do not use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period less than 18 months of age, as articular cartilage may be affected during the period of rapid growth.

Do not use in cats less than 8 weeks of age.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.

Do not use for prophylaxis.

## **6. Special warnings**

### Special precautions for safe use in the target species:

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to other classes of antimicrobials.

Whenever possible, use of fluoroquinolones should be based on susceptibility testing. Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross-resistance.

Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

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 exceed the recommended dosage.

Retinotoxic effects including blindness can occur in cats when the recommended dose is exceeded.

Use the veterinary medicinal product with caution in dogs with severe renal or hepatic impairment.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after use.

In case of contact with the eyes, wash with plenty of clean water.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

### Lactation:

Enrofloxacin passes into maternal milk. Use only according to the benefit-risk assessment by the responsible veterinarian.

### Interaction with other medicinal products and other forms of interaction:

Do not combine with tetracyclines, phenicols or macrolides because there is a potential that these drugs nullify the desired effect.

Concurrent administration of fluoroquinolones may increase the action of oral anticoagulants.

Do not combine with theophylline as this could lead to a prolonged elimination of this substance.

Concurrent administration of magnesium or aluminum containing substances may be followed by retarded absorption of enrofloxacin.

### Overdose:

In accidental overdose, vomiting, diarrhoea and CNS/behavioural changes may occur.

There is no antidote and treatment should be symptomatic. If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.

In target animal species, cats have been shown to suffer ocular damage after receiving doses of more than 15 mg/kg once daily for 21 consecutive days. Doses of 30 mg/kg given once daily for 21 consecutive days have been shown to cause irreversible ocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

## 7. Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anorexia Vomiting
Undetermined frequency (cannot be estimated from the available data)	Joint cartilage disorder <sup>1</sup>

<sup>1</sup>During the period of rapid growth, articular cartilage development may be affected.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>  
e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

Oral use.

Do not exceed the recommended dosage. The dosage rate of enrofloxacin is 5 mg/kg given orally once daily or as a divided dose twice daily for 5 to 10 days.

The duration of treatment in dogs may be extended depending on the clinical response and the judgement of the responsible veterinary surgeon.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The daily dose is achieved as follows:

Cats and small dogs: one tablet per 3 kg body weight.

#### **9. Advice on correct administration**

The tablet should be given orally once daily or as divided dose twice daily with or without food.

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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

#### **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 01656/4007

100 tablets in 10 blister packs.  
10 tablets in 1 blister pack.

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](http://www.gov.uk).

#### **16. Contact details**

Marketing authorisation holder:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia  
Virbac S.A., 1ère avenue, 2065 m L.I.D., 06516 Carros Cedex, France  
KRKA - FARMA d.o.o., V. Holjevca 20/E, 10450 Jastrebarsko, Croatia

Local representatives and contact details to report suspected adverse reactions:

KRKA UK Ltd  
United Kingdom  
Tel: 02071 646 156  
[info.uk@krka.biz](mailto:info.uk@krka.biz)

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

**17. Other information**

**POM-V** To be supplied only on veterinary prescription

*Gavin Hall*  
Approved: 27 January 2025