PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrox Flavour 150 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains: Enrofloxacin 150 mg.

3. PACKAGE SIZE

10 tablets
100 tablets

4. TARGET SPECIES

Dogs

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}
Return any halved tablet to the opened blister pack and use within 24 hours.

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 01656/4009

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrox Flavour

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

150 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Enrox Flavour 150 mg tablets for dogs

2. Composition

Each tablet contains:

Active substances:
Enrofloxacin 150 mg

Round slightly biconvex, cream to light brownish tablets with possible visible white or darker spots, one side scored and bevel-edged.
The tablets can be divided into halves.

3. Target species

Dogs.

4. Indications for use

The veterinary medicinal product is for use in dogs for 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 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.
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.

7. Adverse events

Dogs:

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[1]

[1]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

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

Oral use.

Do not exceed the recommended dose. 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:
Large dogs: one tablet per 30 kg body weight.

9. Advice on correct administration

The tablet is given orally once daily or as a 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.

Return any halved tablet to the opened blister pack and use within 24 hours.

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 01656/4009

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.

16. Contact details

Marketing authorisation holder:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Manufacturer responsible for the 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

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