PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box small and big

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrox Flavour 50 mg Tablets for dogs
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 50 mg of Enrofloxacin.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

10 tablets
100 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
The tablet is given orally once daily or as a divided dose twice daily with or without food.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Return any halved tablet to the opened strip-pack and use within 24 hours.
User warnings - please read the package leaflet.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4008

17. MANUFACTURER'S BATCH NUMBER

Lot :

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrox Flavour 50 mg Tablets for dogs
Enrofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

Enrox Flavour 50 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:
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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrox Flavour 50 mg Tablets for dogs (United Kingdom, Austria, Belgium, Germany, Denmark, Greece, Ireland, Italy, Luxembourg, Netherlands)
Enrox Sabor 50 mg Tablets for dogs (Spain, Portugal)
Enroxil Flavour 50 mg Tablets for dogs (Bulgaria, Czech Republic, Hungary, Lithuania, Latvia, Poland, Romania, Slovenia, Slovakia)
Enrofloxacin

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

Each tablet contains 50 mg of Enrofloxacin.
Round slightly biconvex, cream to light brownish tablets with possible visible white or darker spots, one side scored. The tablets can be divided into halves.

4. INDICATION(S)

The product is for use in dogs in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, secondary wound infections and otitis externa where clinical experience indicates enrofloxacin as the drug of choice.

5. CONTRAINDICATIONS

Articular cartilage may be affected during the period of rapid growth, therefore 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.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs having seizure disorders, since enrofloxacin may cause stimulation of the central nervous system.
Do not use for prophylaxis.

6. ADVERSE REACTIONS

During the period of rapid growth, enrofloxacin may affect the development of articular cartilage.
In very rare cases (less than 1 animal in 10,000 animals, including isolated reports) vomiting and anorexia are observed.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

Do not exceed the recommended dosage. Dog should be given 5 mg/kg of the product orally once daily or as a divided dose twice daily for 5 to 10 days with or without food.
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 to avoid underdosing.
The daily dose for medium dogs is one tablet per 10 kg bodyweight.

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 PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Return any halved tablet to the opened strip-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 carton and blister after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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 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 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 product with caution in dogs with severe renal or hepatic impairment.

As enrofloxacin passes into maternal milk, use only according to the benefit/risk assessment by the responsible veterinarian.

Do not combine with other drugs, such as 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 (the drugs that prevent the clotting of blood).
Do not combine with theophylline (a drug used in medicine as a bronchial dilator) 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.

In accidental overdose, vomiting, diarrhoea and central nervous system /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.

User warnings
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 allergy to (fluoro)quinolones (a group of antimicrobials) should avoid contact with the product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

Polyamide/Aluminium/Polyvinyl chloride film (OPA/Al/PVC), heat sealed with aluminium foil containing 10 tablets / blister. Each cardboard carton contains 100 tablets in a 10 blister packs.
Polyamide/Aluminium/Polyvinyl chloride film (OPA/Al/PVC), heat sealed with aluminium foil containing 10 tablets / blister. Each cardboard carton contains 10 tablets in 1 blister pack.

Not all pack sizes may be marketed.

Approved 22 April 2021