PACKAGE LEAFLET

Enrocill flavour 50 mg Tablets for cats and 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:
Hifarmax, Lda, Av. Marechal Craveiro Lopes nº96 R/C Dto 2775-696 Carcavelos, Portugal

Manufacturer for the batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocill Flavour 50 mg Tablets for cats and dogs
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 and bevel-edged.

4. INDICATION(S)

Treatment of infections caused by gram-positive bacteria, gram-negative bacteria and mycoplasmas susceptible to enrofloxacin in dogs and cats: *Staphylococcus* spp., *E.coli, Haemophilus* spp. *Pasteurella* spp. and *Salmonella* spp.

The product is indicated for treatment of mono or mixed bacterial infections of the respiratory, digestive and urinary tract, ear, skin and wound infections.

If there is no clinical improvement within three days, further susceptibility testing and possibly a change in antimicrobial therapy should be considered.

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 cats less than 8 weeks of age.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals having seizure disorders, since enrofloxacin may cause stimulation of the central nervous system.
Do not use in cases of known resistance to (fluoro)quinolones.

6. ADVERSE REACTIONS

Occasionally gastrointestinal disturbances may occur. Hypersensitivity reactions and CNS disturbaces may be observed.
Possible joint cartilage alterations in growing puppies (see 5. Contraindications).
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats and dogs

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

The dosage rate of enrofloxacin is 5 mg/kg/day (i.e. one 50 mg tablet per 10 kg per day), for 5 days. In chronic and severe cases, treatment duration can be extended to 10 days.

9. ADVICE ON CORRECT ADMINISTRATION

Tablets may be given directly into the mouth or masked in food.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight 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 after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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.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.

If there is no clinical improvement within three days, further susceptibility testing and possibly a change in antimicrobial therapy should be considered.
Use the product with caution in cats or dogs with severe renal or hepatic impairment.
Retinotoxic effects including blindness can occur in cats if recommended dose is exceeded.Do not use in pregnant or lactating bitches and queens.

Do not combine with other drugs, such as tetracyclines, phenicols or macrolides because there is a potential that these drugs nullify the desired effect.
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.
Do not use simultaneously with NSAIDs (convulsions may occur).
Concurrent use of flunixin and enrofloxacin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.
Concurrent administration of magnesium, calcium or aluminum containing substances may be followed by retarded absorption of enrofloxacin.
Excessive alkalinisation of the urine should be avoided in animals subjected to rehydration.

In case of overdose, sickness, vomiting, diarrhoea, and CNS/behavioural changes may occur and the treatment must be suspended.

User warnings

People with known hypersensitivity to fluoroquinolones should avoid contact with the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet of the label to the physician.
Avoid contact with the eyes. In case of contact with the eyes, wash immediately with water.
Wash hands after use.
Do not smoke, eat or drink while handling 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

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.