SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocin Flavoured Tablets 50 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each tablet contains:

Enrofloxacin	50.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
Off white to light brown coloured, round scored tablets, debossed with 'F scoreline L' on one side and '50' on other side. The tablet can be divided into two equal parts.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the drug of choice.

4.3 Contraindications

Not for use in dogs less than 1 year of age or in exceptionally large breeds of dog with a longer growth period under 18 months of age, as articular cartilage may be affected during the period of rapid growth.
The product should not be used for prophylaxis.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dosage.

Official and local antimicrobial policies should be taken into account when the product is used.
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, fluoroquinolones should only be used based on susceptibility testing.
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 for cross resistance.

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

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

In dogs enrofloxacin may affect articular cartilage during the period of rapid growth.

4.7 Use during pregnancy, lactation or lay

The product may be used safely in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The dosage rate of enrofloxacin is 5 mg/kg given orally once daily or as a divided dose twice daily for 3 to 10 days with or without food.
The daily dose is achieved as follows:
Medium dogs: One 50 mg tablet per 10 kg bodyweight.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not exceed the recommended dose.
In accidental overdose vomiting, diarrhoea and CNS/behavioural changes may occur. There is no antidote and treatment should be symptomatic.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, fluoroquinolones

ATC vet code: QJ01MA90.

5.1 Pharmacodynamic properties

Enrofloxacin is bactericidal in action with activity against Gram positive and Gram-negative bacteria and mycoplasmas. The mechanism of action of the quinolones is unique among antimicrobials – they act primarily to inhibit bacterial DNA gyrase, an enzyme responsible for controlling the supercoiling of bacterial DNA during replication. Resealing of the double standard helix is inhibited resulting in irreversible degradation of the chromosomal DNA. The fluoroquinolones also possess activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

Resistance to fluoroquinolones has been reported to arise from five sources, (i) point mutations in the genes encoding for DNA gyrase and/or topoisomerase IV leading to alterations of the respective enzyme, (ii) alterations of drug permeability in Gram negative bacteria, (iii) efflux mechanisms, (iv) plasmid mediated resistance and (v) gyrase protecting proteins. All mechanisms lead to a reduced susceptibility of the bacteria to fluoroquinolones. Cross-resistance within the fluoroquinolone class of antimicrobials is common.

5.2 Pharmacokinetic particulars

The pharmacokinetics of enrofloxacin in dogs and cats are such that oral and parenteral administration leads to similar serum levels. Enrofloxacin possesses a high distribution volume. Tissue levels 2-3 times higher than that found in the serum, have been demonstrated in laboratory animals and target species. Organs in which high levels can be expected are the lungs, liver, kidney, skin, bone and lymphatic system. Enrofloxacin also distributes into the cerebrospinal fluid, the aqueous humour and the foetus in pregnant animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch

Microcrystalline cellulose
Povidone
Magnesium stearate
Silica colloidal anhydrous
Artificial powdered flavour

6.2 Major incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the blister in the outer carton.
Any remaining tablet portion should be returned to the blister and given at the next administration.

6.5 Nature and composition of immediate packaging

Container material:	**Lidding material**: Plain 25-micron hard tempered Al foil coated with 7 GSM heat sealable lacquer **Base foil & Forming foil**: Multilayer cold form film (25-micron OPA/ 45-micron soft tempered Aluminium Foil/ 60-micron PVC film).
Pack size:	10, 20, 30, 50, 100 tablets packed in blisters of 10 tablets consisting of Aluminium / Aluminium foils Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Felix Pharmaceuticals PVT Limited
25-28 North Wall Quay
Dublin 1
D01H104
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 53540/4001

9. DATE OF FIRST AUTHORISATION

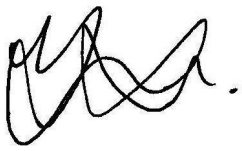
01 March 2022

10. DATE OF REVISION OF THE TEXT

March 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.



Approved: 01 March 2022