SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocin Flavoured Tablets 150 mg

2. QUALITATIVE AND QUANTITATIVE

COMPOSITIONActive substance:
Each tablet contains:

Enrofloxacin	150.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.
Off white to light brown coloured, round tablets, debossed with 'F score line L' on one side and ‘150’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 veterinary medicinal product is for use in dogs in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, wound infections and otitis externa caused by bacteria susceptible to enrofloxacin.

4.3 Contraindications

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed)) as the product may cause epiphyseal cartilage alterations in growing puppies. Enrocin Flavoured Tablets 150mg should not be used for prophylaxis.
Not recommended for use in animals with already existing changes in the development of cartilage.
Do not use in dogs that have seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use in cases of hypersensitivity to the active substance, or to any of the excipient(s).

4.4 Special warnings for each target species

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.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have respondedpoorly, 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 instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones dueto the potential for cross resistance.
Official and local antimicrobial policies should be taken into account when the product is used.

Consideration should be given to official and local antimicrobial guidance when using this veterinarymedicinal product.
Whenever possible, fluoroquinolones should be administered based on sensitivity tests.
It is prudent to reserve fluoroquinolones for the treatment of clinical conditions that have had, or they areexpected to have a poor response to other classes of antibiotics.
Skin infections are mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.
Administration of this veterinary medicinal product, outside of the approved indications, may increase prevalence of bacterial resistance to fluoroquinolones and decrease the effectiveness of treatment withother quinolones due to the potential cross-resistance.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dosage.
Renal excretion is an important elimination route for enrofloxacin. As for the others quinolones, theexcretion of enrofloxacin may be reduced in animals with impaired renal function, therefore, enrofloxacin should be used with caution in these animals.

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

People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinarymedicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet of the labelto 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.

Other
precautions

None.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, gastrointestinal disturbances have been observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Use during pregnancy:
Studies in laboratory animals (rat, chinchilla) have not produced any evidence of a teratogenic,foetotoxic, maternototoxic effect. Use only according to the benefit/risk assessment by the responsible veterinarian.
Use during lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use enrofloxacin and antimicrobial substances simultaneously that counteract the effect ofquinolones (e.g. macrolides, tetracyclines or phenicols).
Do not use simultaneously with theophylline as the clearance of theophylline may be delayed.
Use flunixin and enrofloxacin carefully at the same time. in the dog. The reduction in drug clearanceresulting from the concomitant administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase.

In dogs, the concomitant administration of enrofloxacin and flunixin induced an increase in AUC andelimination half-life of flunixin, as well as an increase of the elimination half-life and a reduction in theCmax of enrofloxacin.
The concomitant oral administration of substances containing calcium, aluminium hydroxide or of magnesium (e.g. antacids), or multivitamin complexes containing iron and zinc, can interfere with theintestinal absorption of fluoroquinolones. Enrofloxacin cannot therefore be simultaneously used with these products.

4.9 Amounts to be administered and administration route

The recommended dosage rate of enrofloxacin is 5 mg/kg given orally once daily for 5-10 consecutivedays.
The daily dose is achieved as follows:
Medium dogs: 1 Enrocin Flavoured Tablet 150 mg per 30 kg bodyweight.The tablet can be administered directly or mixed with food.
If there is no clinical improvement in a period of 3 days, it is recommended to perform a new sensitivitytest and eventually a change in therapy.

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:
Anti-infective for systemic use (fluoroquinolone -

enrofloxacin)ATC vet code: QJ01MA90.

5.1 Pharmacodynamic properties

Enrofloxacin is a member of the fluoroquinolone class of chemical compounds. The substance has bactericidal activity, which is the result of its binding to the A-subunit of bacterial DNA gyrase, therebyselectively inhibiting that enzyme.
DNA gyrase belongs to a class of enzymes known as topoisomerases, which are involved in thereplication, transcription and recombination of bacterial DNA.
Fluoroquinolones also control bacteria in the stationary phase by altering the permeability of the bacterialcell wall.
Enrofloxacin exerts a concentration-dependent bactericidal action with similar values for minimalinhibitory concentration and minimal bactericidal concentrations.
Enrofloxacin has antimicrobial activity against the following enrofloxacin-sensitive Gram-negative andGram-positive bacteria: Staphylococci, E. coli, Haemophilus spp. and Pasteurella spp.
Induction of resistance against quinolones can develop by mutations in the gyrase gene of bacteria and by changes in cell permeability towards quinolones. Both mechanisms result in decreased susceptibilityof bacteria to fluoroquinolones.

5.2 Pharmacokinetic particulars

The pharmacokinetics of enrofloxacin in dogs 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, theaqueous humour and the foetus in pregnant animals.

After administration of this medicine at the recommended dose, orally, the maximum concentrationin serum and tissues is reached after 1-2 hours. Elimination is hepatic and renal.

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

None known.

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 storage conditions.

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 Aluminum Foil/ 60-micron PVC film).
Pack size:	10, 20, 30, 50, 100 tablets packed in blisters of 10 tablets consisting ofAluminium / Aluminium foils Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Felix Pharmaceuticals Private
Limited25 - 28 North Wall Quay
Dublin 1, Republic of Ireland

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD month
YYYYDate of last renewal: DD month
YYYY

10 DATE OF REVISION OF THE TEXT

MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocin Flavoured Tablets 150 mgEnrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 150 mg Enrofloxacin Ph. Eur. as active substance

3. PHARMACEUTICAL FORM

Tablets.

4. PACKAGE SIZE

10 Tablets
20 Tablets
30 Tablets
50 Tablets
100 Tablets

5. TARGET SPECIES

For dogs.

6. INDICATION(S)

Enrofloxacin is a synthetic, broad spectrum antimicrobial, bactericidal in action and effective againsta wide range of gram positive and gram-negative bacteria as well as mycoplasmas.
Enrocin Flavoured Tablets 150 mg are indicated for use in dogs in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, wound infections and otitis externa caused by bacteria susceptible to enrofloxacin.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs: 1 tablet per 30 kg bodyweight (5 mg enrofloxacin per kg bodyweight) given orally once daily for 5to 10 consecutive days with or without food.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not exceed the recommended dose.
Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed)) as the product may cause epiphyseal cartilage alterations in growing puppies.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

This product does not require any special storage condition. Keep the tablets in the carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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

Felix Pharmaceuticals Private
Limited25 - 28 North Wall Quay
Dublin 1, Republic of Ireland

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER STRIP

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocin Flavoured Tablets 150 mgEnrofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Felix Pharmaceuticals Pvt. Ltd., Ireland

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET: Enrocin Flavoured Tablets 15 mg Enrocin Flavoured Tablets 50 mg Enrocin Flavoured Tablets 150 mg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCHRELEASE, IF DIFFERENT

Marketing authorisation holder:

Felix Pharmaceuticals Pvt.
Ltd25-28 North Wall Quay
Dublin 1, Republic of
Ireland

Manufacturer responsible for batch release:

Wasdell Europe Limited
IDA Science and Technology Park,
MullagharlinDundalk, Co. Louth, A91
DET0, Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Enrocin Flavoured Tablets 15 mg Enrocin Flavoured Tablets 50 mg Enrocin Flavoured Tablets 150 mg

Enrofloxacin

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

Each tablet contains:	Enrofloxacin
Enrocin Flavoured Tablets	15 mg
Enrocin Flavoured Tablets	50 mg
Enrocin Flavoured Tablets	150 mg

4. INDICATION(S)

Enrofloxacin is a synthetic broad spectrum antimicrobial, bactericidal in action and effective against awide range of gram positive and gram negative bacteria as well as Mycoplasmas. Enrofloxacin is indicated for use in dogs and cats in the treatment of bacterial infections of the alimentary, respiratory and urogenital tracts, skin, wound infections and otitis externa caused by

bacteria susceptible to enrofloxacin. Enrocin Flavoured Tablets should not be used for prophylaxis.

5. CONTRAINDICATIONS

Do not use in young or growing dogs (dogs aged less than 12 months (small breed) or less than 18 months (large breed)) as the product may cause epiphyseal cartilage alterations in growing puppies. Enrocin Flavoured Tablets 150mg should not be used for prophylaxis.
Not recommended for use in animals with already existing changes in the development of cartilage.
Do not use in cats or dogs that have seizure disorders, since enrofloxacin may cause CNS stimulation. Do not use in cases of hypersensitivity to the active substance, or to any of the excipient(s).

6. ADVERSE REACTIONS

In very rare cases, gastrointestinal disturbances have been observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that themedicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

For cats and dogs.

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

Dogs and Cats
The dose rate of enrofloxacin is 5 mg/kg given orally once daily for 5 to 10 days with or

without food.The daily dose is achieved as follows:

Cats and Small Dogs
Enrocin Flavoured Tablets 15 mg: 1 tablet per 3 kg bodyweight.
Medium Dogs
Enrocin Flavoured Tablets 50 mg: 1 tablet per 10 kg bodyweight.
Large Dogs
Enrocin Flavoured Tablets 150 mg: 1 tablet per 30 kg bodyweight.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD(S)

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.Keep the tablets in the carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton. Theexpiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.
Fluoroquinolones should be reserved for the treatment of clinical conditions which have respondedpoorly, 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 instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other quinolones dueto the potential for cross resistance.
Official and local antimicrobial policies should be taken into account when the product is used.
Consideration should be given to official and local antimicrobial guidance when using this veterinarymedicinal product.
Whenever possible, fluoroquinolones should be administered based on sensitivity tests.
It is prudent to reserve fluoroquinolones for the treatment of clinical conditions that have had, or they areexpected to have a poor response to other classes of antibiotics.
Skin infections are mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.
Administration of this veterinary medicinal product, outside of the approved indications, may increase prevalence of bacterial resistance to fluoroquinolones and decrease the effectiveness of treatment withother quinolones due to the potential cross-resistance.

Special precautions for use in animals:
Do not exceed the recommended dosage.
Renal excretion is an important elimination route for enrofloxacin. As for the others quinolones, theexcretion of enrofloxacin may be reduced in animals with impaired renal function, therefore, enrofloxacin should be used with caution in these animals.

Special precautions to be taken by the person administering the veterinary medicinal product toanimals:
People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinarymedicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet of the labelto 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.

Pregnancy and lactation:
Use during pregnancy:
Studies in laboratory animals (rat, chinchilla) have not produced any evidence of a teratogenic,foetotoxic, maternototoxic effect. Use only according to the benefit/risk assessment by the responsible veterinarian.
Use during lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during lactation.

Interaction with other medicinal products and other forms of interaction:
Do not use enrofloxacin and antimicrobial substances simultaneously that counteract the effect ofquinolones (e.g. macrolides, tetracyclines or phenicols).
Do not use simultaneously with theophylline as the clearance of theophylline may be delayed.
Use flunixin and enrofloxacin carefully at the same time. in the dog. The reduction in drug clearanceresulting from the concomitant administration of flunixin and enrofloxacin indicates that these substances interact during the elimination phase.
In dogs, the concomitant administration of enrofloxacin and flunixin induced an increase in AUC andelimination half-life of flunixin, as well as an increase of the elimination half-life and a reduction in theCmax of enrofloxacin.
The concomitant oral administration of substances containing calcium, aluminium hydroxide or of magnesium (e.g. antacids), or multivitamin complexes containing iron and zinc, can interfere with theintestinal absorption of fluoroquinolones. Enrofloxacin cannot therefore be simultaneously used with these products.

Overdose (symptoms, emergency procedures, antidotes):
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.
In target animal studies, cats have been shown to suffer ocular damage after receiving doses of morethan 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 irreversibleocular damage. At 50 mg/kg given once daily for 21 consecutive days, blindness can occur.

Incompatibilities:None known.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protectthe environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Strips of 10 tablets in blister foil supplied in dispensing cartons containing 10, 20, 30, 50 or 100tablets. Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.