

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Enrocin Flavoured Tablets 50 mg  
Enrofloxacin

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains 50 mg Enrofloxacin 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)**

The product is indicated 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.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

*Dogs:* 1 tablet per 10 kg bodyweight (5 mg enrofloxacin per kg bodyweight) given orally once daily or as a divided dose twice daily for 3 to 10 days with or without food. The 50 mg tablets can be divided into two equal parts.

**8. WITHDRAWAL PERIOD(S)**

Not applicable.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.  
Do not exceed the recommended dose.

Do not use for prophylaxis.

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.

#### **10. EXPIRY DATE**

EXP {month/year}

#### **11. SPECIAL STORAGE CONDITIONS**

This product does not require any special temperature storage conditions.

Keep the tablets in the carton.

Any remaining tablet portion should be returned to the blister and given at the next administration.

#### **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.

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#### **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 PVT Limited  
25-28 North Wall Quay  
Dublin 1  
D01H104  
Ireland

#### **16. MARKETING AUTHORISATION NUMBER(S)**

Vm 53540/4001

#### **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 50 mg  
Enrofloxacin

**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.

## **B. PACKAGE LEAFLET**

**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 BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Enrocin Flavoured Tablets 50 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  
Off white to light brown coloured, round tablets, debossed with 'FL' on one side and  
'15' on other side.

Enrocin Flavoured Tablets 50 mg  
Off white to light brown coloured, round scored tablets, debossed with 'F score-line L'  
on one side and '50' on other side. The tablet can be divided into two equal parts.

Enrocin Flavoured Tablets 150 mg  
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. INDICATION(S)**

The product is for use in dogs and cats 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.

#### **5. CONTRAINDICATIONS**

The product should not be used for prophylaxis.

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.

Not recommended for use in cats less than 8 weeks of age.

#### **6. ADVERSE REACTIONS**

During the period of rapid growth, enrofloxacin may affect articular cartilage development.

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 inform your veterinary surgeon.

#### **7. TARGET SPECIES**

For cats (15 mg tablet only) and dogs (15, 50 and 150 mg tablets).

#### **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 or as a divided dose twice daily for 3 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. The 15 mg tablets are not divisible.

##### **Medium Dogs**

Enrocin Flavoured Tablets 50 mg: 1 tablet per 10 kg bodyweight. The 50 mg tablets can be divided into two equal parts.

##### **Large Dogs**

Enrocin Flavoured Tablets 150 mg: 1 tablet per 30 kg bodyweight. The 150 mg tablets can be divided into two equal parts.

#### **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 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.

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

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

Cats: Retinotoxic effects including blindness can occur when the recommended dose is exceeded.

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 package leaflet 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.

Pregnancy and lactation:

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

Interaction with other medicinal products and other forms of interaction:  
None known.

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 more than 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 irreversible ocular 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 OR WASTE MATERIALS, IF ANY**

Dispose of any unused veterinary medicinal product, or waste materials, in accordance with local requirements. Medicines should not be disposed of via wastewater. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

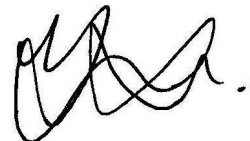
**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

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

To be supplied only on veterinary prescription.

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Approved: 01 March 2022