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 15 mg
Enrofloxacin

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 15 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 cats and dogs.

6. INDICATION(S)

The product is indicated 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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cats and Dogs: 1 Tablet per 3 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 15 mg tablets are not divisible.

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.

In cats, retinotoxic effects including blindness can occur when the recommended dose is exceeded. 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.

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.

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.
POM-V

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 53540/4000

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 15 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 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
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 indicated 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

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

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 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.

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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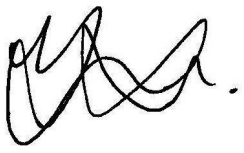

Approved: 01 March 2022