ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

XEDEN 15 mg tablet for cats
Enrofloxacin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One tablet contains:
Enrofloxacin.....15.0 mg

3. PHARMACEUTICAL FORM

Tablet.
Oblong scored beige tablet
The tablet can be divided into two equal parts.

4. PACKAGE SIZE

1 x 12 tablets
2 x 12 tablets
5 x 12 tablets
8 x 12 tablets
10 x 12 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP: month/year

11. SPECIAL STORAGE CONDITIONS

Store in the original container.
Protect from light.
For shelf life of divided tablets: see package leaflet.
Read the package leaflet before use

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4121

17. MANUFACTURER'S BATCH NUMBER

Batch:

A – LABELLING – BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

XEDEN 15 mg tablet for cats
Enrofloxacin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva logo

3. EXPIRY DATE

EXP month/year

4. BATCH NUMBER

Batch:

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

XEDEN 15 mg tablet for cats

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

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer responsible for batch release:
Ceva Santé Animale
Boulevard de la Communication
Zone Autoroutière
53950 Louverné
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

XEDEN 15 mg tablet for cats
Enrofloxacin

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

One tablet contains:
Enrofloxacin.....15 mg
Tablet.
Oblong scored beige tablet

4. INDICATION(S)

In cats: treatment of upper respiratory tract infections.

5. CONTRAINDICATIONS

Do not use in young, growing cats, because of the possibility of the development of cartilage lesions. (cats aged less than 3 months or weighing less than 1kg)
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 fluoquinolones.
Do not use in cats having seizure disorders, since enrofloxacin may cause CNS stimulation.

See also section “Use during pregnancy and lactation” and “Interactions”.

6. ADVERSE REACTIONS

Vomiting or diarrhoea may appear during the treatment. These signs regress spontaneously and generally do not require treatment discontinuation.
In rare case, hypersensitive reactions may occur. In this case, the administration of the product should be stopped.
Neurological signs (seizures, tremors, ataxia, excitation) can occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

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

Oral use
5 mg of enrofloxacin/kg body weight once daily for 5 to 10 consecutive days:

- either 1 tablet for 3 kg body weight as a single daily dosing.
- or ½ tablet for 1.5 kg body weight as a single daily dosing.

The treatment should be reconsidered in case of lack of clinical improvement at half of the treatment duration.

Number of tablets per day	Cat weight (kg)
½	≥ 1.1 - < 2
1	≥ 2 - < 4
1 ½	≥ 4 - < 5
2	≥ 5 - < 6.5
2 ½	≥ 6.5 - < 8.5

Do not exceed the recommended treatment dose.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing

9. ADVICE ON CORRECT ADMINISTRATION

The tablets are flavoured. They may be administered directly in the mouth of the cat or added to food if necessary.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original container.
Protect from light.
This medicinal product does not require any special temperature storage conditions.
Do not use after the expiry date stated on the blister and outer carton.
Any half tablets should be returned to the original blister for storage.
Shelf-life of half tablets: 24 hours.
Any half tablets remaining after 24 hours should be discarded.

12. SPECIAL WARNING(S)

Special precautions for use in animals
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.
Wherever possible, fluoroquinolones should 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 due to the potential for cross resistance.
Official and local antimicrobial policies should be taken into account when the product is used.
Use the product with caution in cats with severe renal or hepatic impairment.
The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Persons with a known hypersensitivity to (fluoro)quinolones should avoid any contact with the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet to the physician.
Wash hands after handling the product.
In case of contact with eyes, rinse immediately with plenty of water.

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.

Interaction with other medicinal products and other forms of interaction
Concurrent use of flunixin should be under careful veterinary monitoring, as the interactions between these drugs may lead to adverse events related to delayed elimination.

Concomitant administration of theophylline requires careful monitoring as serum levels of theophylline may increase.
Concurrent use of magnesium or aluminum containing substances (such as antacids or sucralfate) may reduce absorption of enrofloxacin. These drugs should be administered two hours apart.
Do not use with tetracyclines, phenicols or macrolides because of potential antagonistic effects.

Overdose (symptoms, emergency procedures, antidotes), if necessary
Overdosing can cause vomiting and nervous signs (muscle tremor, incoordination and convulsions) which may require treatment discontinuation.
In the absence of any known antidote, apply drug elimination and symptomatic treatment.
If necessary, administration of aluminium or magnesium containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
In laboratory studies, ocular adverse effects have been observed from 20 mg/kg.
The toxic effects on the retina caused by overdosing may be such that they lead to irreversible blindness in the cat.

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

Dispose of waste material in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Pack sizes:
Cardboard box with 1 blister of 12 tablets
Cardboard box with 2 blisters of 12 tablets
Cardboard box with 5 blisters of 12 tablets
Cardboard box with 8 blisters of 12 tablets
Cardboard box with 10 blisters of 12 tablets

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 17 October 2022