# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

XEDEN 150 mg tablet for dogs

Enrofloxacin

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One tablet contains:
Enrofloxacin.....150.0 mg

## 3. PHARMACEUTICAL FORM

Tablet
Clover-shaped scored beige tablet
The tablet can be divided into four equal parts.

## 4. PACKAGE SIZE

2 x 6 tablets
20 x 6 tablets

## 5. TARGET SPECIES

Dogs

## 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 15052/4122

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

# A – LABELLING – BLISTER

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

XEDEN 150 mg tablet for dogs

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 150 mg tablet for dogs

## 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 150 mg tablet for dogs

Enrofloxacin

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

One tablet contains:
Enrofloxacin.....150.0 mg
Tablet
Clover-shaped scored beige tablet

## 4. INDICATION(S)

In dogs:
- Treatment of lower urinary tract infections (associated or not with prostatitis) and upper urinary tract infections caused by *Escherichia Coli* or *Proteus mirabilis*.
- Treatment of superficial and deep pyoderma.

## 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.

Do not use in dogs having seizure disorders, since enrofloxacin may cause CNS stimulation.
Do not use in dogs with known hypersensitivity to fluoroquinolones or to any of the excipients of the product.
Do not use in the case of resistance to quinolones, as there exists almost complete cross resistance to other quinolones and complete cross resistance to other fluoroquinolones.
See also section “Use during pregnancy and lactation” and “Interactions”

## 6. ADVERSE REACTIONS

Possible joint cartilage alterations in growing puppies (see 4.3 contra-indications).
In rare cases vomiting and anorexia are observed.
In rare cases, hypersensitivity 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

Dogs

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

Oral use
5 mg of enrofloxacin/kg/day as a single daily dosing, i.e. one tablet for 30 kg daily for:

- 10 days in lower urinary tract infections
- 15 days in upper urinary tract infections and lower urinary tract infections associated with prostatitis
- Up to 21 days in superficial pyoderma depending on clinical response
- Up to 49 days in deep pyoderma depending on clinical response

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

The breakability method is the following: Put the tablet on a plain surface, with its scored side facing the surface (convex face up).
With the tip of forefinger, exert a slight vertical pressure on the middle of the tablet to break it in its width into halves. In order to obtain quarters, then exert a slight pressure on the middle of one half with forefinger to break it in its length.

The tablet is divisible and can be used as follows:

| XEDEN 50 mg Number of tablets per day | XEDEN 150 mg Number of tablets per day | Dog weight (kg) |
|---|---|---|
| ¼ | | ≥ 2 - < 4 |
| ½ | | ≥ 4 - < 6.5 |
| ¾ | ¼ | ≥ 6.5 - < 8.5 |
| 1 | ¼ | ≥ 8.5 - < 11 |
| 1 ¼ | ½ | ≥ 11 - < 13.5 |
| 1 ½ | ½ | ≥ 13.5 - < 17 |
| | ¾ | ≥ 17 - < 25 |
| | 1 | ≥ 25 - < 35 |
| | 1 ¼ | ≥ 35 - < 40 |
| | 1 ½ | ≥ 40 - < 50 |
| | 1 ¾ | ≥ 50 - < 55 |
| | 2 | ≥ 55 - < 65 |

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, and are well accepted by dogs. The tablets may be administered directly in the mouth of the dog or simultaneously with food if necessary.
Instruction on how to divide the tablet: Put the tablet on an even surface, with its scored side facing down (convex face up). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves. Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

## 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 divided tablets should be returned to the original blister for storage.
Shelf-life of divided tablets: 72 hours.
Any divided tablets remaining after 72 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 dogs with severe renal or hepatic impairment.
Pyoderma is mostly secondary to an underlying disease. It is advisable to determine the underlying cause and to treat the animal accordingly.
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: Laboratory 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) 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 methods and symptomatic treatment.
If necessary, administration of aluminium- or magnesium-containing antacids or activated carbon can be used to reduce absorption of enrofloxacin.
According to literature, signs of overdosage with enrofloxacin in dogs such as inappetence and gastrointestinal disturbance were observed at approximately 10 times the recommended dose when administered for two weeks. No signs of intolerance were observed in dogs administered 5 times the recommended dose for a month.

## 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 2 blisters of 6 tablets
Cardboard box with 20 blisters of 6 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