PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xeden 150 mg tablet

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Enrofloxacin 150.0 mg

3. PACKAGE SIZE

2 x 6 tablets
20 x 6 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {month/year}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd

14. MARKETING AUTHORISATION NUMBER

Vm 15052/4122

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (BLISTERS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xeden

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

150 mg of enrofloxacin

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Xeden 150 mg tablets for dogs

2. Composition

Each tablet contains:
Active substance:
Enrofloxacin 150.0 mg

Clover-shaped scored beige tablet

3. Target species

Dogs

4. Indications for use

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. Special warnings

Special precautions for safe use in the target species
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.

Pregnancy and lactation:
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 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:
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.

7. Adverse events

Dog:

Rare (1 to 10 animals / 10,000 animals treated):	Vomiting Anorexia Hypersensitivity reaction[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological signs (Ataxia, Tremor, Seizure, Excitation) Joint cartilage disorder[2]

[1]In this case, the administration of the product should be stopped.
[2]Possible alterations in growing puppies.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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 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 periods

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: 3 days.
Any divided tablets remaining after 3 days should be discarded.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 15052/4122

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing Authorisation Holder and contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel: 00800 35 22 11 51
Email for the reporting of adverse events: pharmacovigilance@ceva.com

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

17. Other information

POM-V

For animal treatment only

Gavin Hall
Approved: 30 September 2025