SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

XEDEN 15 mg tablet for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

In cats: treatment of upper respiratory tract infections

4.3 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 the case that there is 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 4.7 and 4.8.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 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

4.8 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.

4.9 Amounts to be administered and administration route

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

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing
The tablets are flavoured. They may be administered directly in the mouth of the cat or added to food if necessary.
Do not exceed the recommended treatment dose.

4.10 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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QJ01MA90
Pharmacotherapeutic group: Fluoroquinolones

5.1 Pharmacodynamic properties

Enrofloxacin is a synthetic fluoroquinolone antibiotic that exerts its activity by inhibiting topoisomerase II, an enzyme involved in the mechanism of bacterial replication.

Enrofloxacin exerts bactericidal activity concentration-dependant with similar values of minimal inhibit concentration and minimal bactericide concentrations. It also possesses activity against bacteria in the stationary phase by an alteration of the permeability of the outer membrane phospholipid cell wall.

In general, enrofloxacin exhibits good activity against most gram-negative bacteria, especially those of the Enterobacteriacea. *Escherichia coli*, *Klebsiella spp*., *Proteus spp*., and *Enterobacter spp*. are generally susceptible.

Pseudomonas aeruginosa is variably susceptible and, when it is susceptible, usually has a higher MIC than other susceptible organisms.
Staphylococcus aureus and *Staphylococcus intermedius* usually are susceptible.
Streptococci, enterococci, anaerobic bacteria can generally be considered resistant.

Induction of resistance against quinolones can develop by mutations in the gyrase gene of bacteria and by changes in cell permeability towards quinolones.

5.2 Pharmacokinetic particulars

Enrofloxacin is approximately 100% bioavailable after oral administration. It is unaffected by food. Enrofloxacin is rapidly metabolised to form an active compound, ciprofloxacin.
After oral administration of XEDEN 15 (5 mg/kg) in cats:

- The maximal plasma concentration of enrofloxacin of 2.9µg/mL was observed one hour following administration.
- The maximal plasma concentration of ciprofloxacin (0.18 µg/ml) was observed 5 hours following administration.

Enrofloxacin is widely distributed in the body. The tissue concentrations are often higher than the serum concentrations. Enrofloxacin crosses the blood-brain barrier. The degree of protein binding in serum is 8% in cats. The half-life in serum is 3-4 hours in cats (5 mg/kg). Approximately 25 % of the dose of enrofloxacin is excreted in the urine and 75 % via faeces. Approximately 15 % of the dose is excreted as unchanged enrofloxacin and the remainder as metabolites, amongst others ciprofloxacin. The total clearance is approximately 9 ml/minute/kg bodyweight.

Environmental properties

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pig liver powder
Malted yeast
Cellulose microcrystalline
Croscarmellose Sodium
Silica colloidal anhydrous
Magnesium stearate
Lactose Monohydrate

6.2 Incompatibilities

Not known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
3 years
Shelf-life of half tablets:
24 hours

6.4 Special precautions for storage

Store in the original container.
Protect from light.
This medicinal product does not require any special temperature storage conditions.
Any half tablets should be returned to the original blister for storage.
Any half tablets remaining after 24 hours should be discarded.

6.5 Nature and composition of immediate packaging

Blister complex: PVDC-TE-PVC/Aluminium heat sealed blisters with 12 tablets / blister
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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 15052/4121

9. DATE OF FIRST AUTHORISATION

29 October 2008

10. DATE OF REVISION OF THE TEXT

October 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed in accordance with national requirements.

Approved 17 October 2022