ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xeden 15 mg tablet for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients:

Qualitative composition of excipients and other constituents
Pig liver powder
Malted yeast
Cellulose microcrystalline
Croscarmellose Sodium
Silica colloidal anhydrous
Magnesium stearate
Lactose Monohydrate

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

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Treatment of upper respiratory tract infections.

3.3 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 3.7 and 3.8.

3.4 Special warnings

None.

3.5 Special precautions for use

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 veterinary medicinal 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 veterinary medicinal product is used.
Use the veterinary medicinal 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 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 handling the veterinary medicinal product.
In case of contact with eyes, rinse immediately with plenty of water.

Special precautions for the protection of the environment:
Not applicable

3.6 Adverse events

Cats:

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

[1]Regress spontaneously and generally do not require treatment discontinuation.
[2]In this case, the administration of the veterinary medicinal product should be stopped.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. Seethe package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Laboratory studies in rats and chinchillas have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects. Use only according to the benefit/risk assessment by the responsible veterinarian.

Lactation:
As enrofloxacin passes into the maternal milk, the use is not recommended during lactation.

3.8 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.

3.9 Administration routes and dosage

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 .
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.

3.10 Symptoms of overdose verdose (and where applicable, emergency procedures, and antidotes)

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.

3.11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1. ATCvet code:

QJ01MA90

4.2 Pharmacodynamics

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 concentrations 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 Enterobacteriaceae. *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.

4.3 Pharmacokinetics

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 the veterinary medicine product in cats:

- The maximal plasma concentration of enrofloxacin of 2.9 mcg/mL was observed one hour following administration.
- The maximal plasma concentration of ciprofloxacin (0.18 mcg/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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not known.

5.2 Shelf life

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

5.3 Special precautions for storage

Store in the original container.
Protect from light.
This veterinary 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.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{mm/yyyy}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database.
(https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xeden15 mg tablet

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Enrofloxacin ..... 15.0 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{mm/yyyy}
Any half tablets remaining after 24 hours should be discarded.

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.
Protect from light.
Any half tablets should be returned to the original blister for storage.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Xeden

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

15 mg of enrofloxacin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Xeden 15 mg tablet for cats

2. Composition

Each tablet contains:
Active substance:
Enrofloxacin ..... 15 mg
Oblong scored beige tablet. The tablet can be divided into two equal parts.'

3. Target species

Cats.

4. Indications for use

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 "Pregnancy", "Lactation" and "Interaction with other medicinal products and other forms of 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 veterinary medicinal 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 veterinary medicinal product is used.
Use the veterinary medicinal 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 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 handling the veterinary medicinal product.
In case of contact with eyes, rinse immediately with plenty of water.

Pregnancy:
Laboratory studies in rats and chinchillas have not produced any evidence of teratogenic, foetotoxic, maternotoxic effects. Use only according to the benefit/risk assessment by the responsible veterinarian .

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:
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.

Major incompatibilities:
None known.

7. Adverse events

Cats:

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

[1]Regress spontaneously and generally do not require treatment discontinuation.

[2]In this case, the administration of the veterinary medicinal product should be stopped.

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 or its local representative using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes 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.

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 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 veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after Exp. The expiry date refers to the last day of that month.
Any half tablets should be returned to the original blister for storage.
Any half tablets remaining after 24 hours should be discarded.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

(MA)

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.

15. Date on which the package leaflet was last revised

{mm/yyyy}
Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
(Name and address to be completed nationally)
Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

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

17. Other information