PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

1 L bottles and 5 L barrels

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CENFLOX 200 mg/ml solution for use in drinking water for chickens, turkeys and rabbits

2. COMPOSITION

Each ml contains:

Active substance:
Enrofloxacin ……. 200 mg

Clear, light yellow solution

3. PACKAGE SIZE

1 l
5 l

4. TARGET SPECIES

Chickens, turkeys and rabbits.

5. INDICATIONS FOR USE

Indications for use

Chickens
Treatment of infections caused by the following bacteria susceptible to enrofloxacin:
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida.

Turkeys
Treatment of infections caused by the following bacteria susceptible to enrofloxacin:
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida.

Rabbits
For the treatment infectious diseases due to *Pasteurella multocida* and bacterial enteritis due to infection with *E. coli.*

Enrofloxacin should be used where clinical experience, supported where possible by sensitivity testing of the causal organism, indicates enrofloxacin as the active substance of choice.

6. CONTRAINDICATIONS

Contraindications

Do not use for prophylaxis.

Do not use when resistance/cross-resistance to (fluoro)quinolones is known to occur in the flock intended for treatment.

Do not use in cases of hypersensitivity to the active substance, other (fluoro)quinolones or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

Treatment of *Mycoplasma spp*. infections may not eradicate the organism.

Special precautions for safe use in the target species:

Official and local antimicrobial policies should be taken into account when the veterinary medicinal product is used.

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.

Whenever possible, fluoroquinolones should only be used based on susceptibility testing.

Use of the veterinary medicinal product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to cross resistance.

Since enrofloxacin was first authorised for use in poultry, there has been widespread reduction in susceptibility of *E. coli* to fluoroquinolones and emergence of resistant organisms. Resistance has also been reported in *Mycoplasma synoviae* in the EU.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product to avoid contact while its incorporation to the drinking water.

Avoid contact with skin and eyes. In case of accidental contact rinse immediately with plenty of water.

If you develop symptoms following exposure such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Do not eat, drink or smoke whilst using the veterinary medicinal product.

Laying birds:

Do not use in layer replacement birds within 14 days before the start of the laying period.
Not for use in birds producing or intended to produce eggs for human consumption.

Interactions with other medicinal products and other forms of interaction:

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous application of substances containing aluminium or magnesium can impair the absorption of enrofloxacin.

Overdose:

No adverse clinical symptoms were observed in chickens and turkeys treated respectively with doses up to 10 and 6 times higher than the therapy dose.

The use of fluoroquinolones during the growth phase combined with a marked and prolonged increase in the intake of drinking water, and hence active ingredient, possibly due to high temperatures, may potentially be associated with damage of the articular cartilage.

Special restrictions for use and special conditions for use:

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

Not known.

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 the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water use. The dilution should be prepared daily before its administration.

Chickens and turkeys:

10 mg enrofloxacin/kg bodyweight, equivalent to 0.05 ml veterinary medicinal product/kg bodyweight, per day for 3-5 consecutive days.

Treatment for 5 consecutive days in mixed infections and chronic progressive forms. If no clinical improvement is achieved within 2-3 days, alternative antimicrobial therapy should be considered based on susceptibility testing.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

Total number of birds x Average body weight in kg x 0.05= Total volume (ml) veterinary medicinal product per day

Rabbits:

10 mg of enrofloxacin/kg b.w., equivalent to 0.05 ml veterinary medicinal product/kg b.w., per day for 5 consecutive days.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

Total number of rabbits x Average body weight in kg x 0.05= Total volume (ml) veterinary medicinal product per day

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Administration in drinking water. Always make sure that the entire dose offered has been consumed. The medicated water should be made up fresh each day just before it is offered to the animals. The drinking water must be medicated throughout the treatment period, and no other water source should be available.
The intake of medicated water depends on the clinical condition of the animals.
In order to obtain the correct dosage, the concentration of enrofloxacin may need to be adjusted accordingly.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

Use only fresh pre-solutions, prepared every day before start of treatment. Pumping systems should be checked constantly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

11. WITHDRAWAL PERIODS

Withdrawal periods

Chickens: Meat and offal: 7 days.
Turkeys: Meat and offal: 13 days.
Rabbits: Meat and offal: 3 days.

Not for use in birds producing or intended to produce eggs for human consumption.
Do not use inlayer replacement birds within 14 days before the start of the laying period.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes:
1 l bottle
5 l barrel

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CENAVISA, S.L.
C/ dels Boters 4
43205 Reus (Spain)
Tel: +34 977 75 72 73
E-mail: farmacovigilancia@cenavisa.com

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use by…

Shelf life after first opening the immediate packaging: 6 months
Shelf life after dilution according to directions: 24 hours

21. BATCH NUMBER

Lot {number}