

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

1L Bottles and 5 barrels

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder and manufacturer responsible for batch release:

CENAVISA, S.L.
Camí Pedra Estela s/n
43205 Reus (SPAIN)

2. Name of the veterinary medicinal product

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

3. Statement of the active substance (s) and other ingredients

Each ml contains:

Active substance:

Enrofloxacin200 mg

Excipiente, q.s.

Clear, light yellow solution

4. Pharmaceutical form

Solution for use in drinking water

5. Package size

1 L

5 L

6. Indication(s)

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.

7. Contraindications

Do not use for prophylaxis.

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

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

8. Adverse reactions

Not known.

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 inform your veterinary surgeon.

9. Target species

Chickens, turkeys and rabbits.

10. Dosage for each species, route(s) and method of administration

Administer in the drinking water. 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.

Calculate the daily quantity (ml) of product required for treatment period as follows:

Total number of birds x Average body weight in kg x 0.05= Total volume (ml) 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.

Calculate the daily quantity (ml) of product required for treatment period as follows:

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

11. 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. Determine the bodyweight of the birds as accurately as possible in order to avoid underdosing.

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.

12. Withdrawal period(s)

Chickens: Meat and offal: 7 days

Turkeys: Meat and offal: 13 days

Rabbits: Meat and offal: 3 days

Not authorised for use in birds producing eggs for human consumption.

Do not administer to layer replacement birds within 14 days of coming into lay.

13. Special storage precautions
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Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Shelf life after first opening the container: 6 months.

Shelf life after dilution according to directions: 24 hours

14. Special warning(s)

Special warnings for each target species:

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

Special precautions for use in animals:

Official and local antimicrobial policies should be taken into account when the 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 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:

Those with known hypersensitivity to (fluoro)quinolones should avoid contact with this product.

Use gloves and handle carefully the product to avoid contact while its incorporation to the drinking water.

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

If signs appear after exposition to the product, like cutaneous rash, seek medical advice and show these precautions. Inflammation of the face, lips or eyes or breathing disturbances are more serious signs that require urgent medical attention.

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

Lay:

Do not administer to layer replacement birds within 14 days of coming into lay.

Not authorised for use in birds producing eggs for human consumption.

Interaction 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 (symptoms, emergency procedures, antidotes):

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.

Incompatibilities:

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

15. Special precautions for the disposal of unused product or waste materials, if any

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

16. Date on which the label was last approved

17. Other information

Package size: 1 L bottle
5 L barrel

Not all pack sizes may be marketed.

18. 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.
Administration by a veterinarian surgeon or under their direct responsibility.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

Once opened use by...

21. Marketing authorisation number(s)

22. Manufacturer's batch number

Lot