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

250 mL bottle
1 L bottle
5 L barrel

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

Marketing authorisation holder:
VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 – BARCELONA
Spain

Manufacturer responsible for batch release:
LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

2. Name of the veterinary medicinal product

LEVOFLOK 100 mg/ml Solution for use in drinking water for chickens, turkeys and rabbits [ES, CY, EL, HR, HU, IT, PT, PL]
Enrofloxacin
FLUONIX 100 mg/ml Solution for use in drinking water for chickens, turkeys and rabbits [DE]
Enrofloxacin

3. Statement of the active substance and other ingredients

Each ml contains:

Active substance:
Enrofloxacin..... 100.0 mg

Excipients:
Benzyl Alcohol (E 1519)..... 0.014 ml

An aqueous, clear, yellowish solution

4. Pharmaceutical form

Solution for use in drinking water

5. Package size

Bottle of 250 mL
Bottle of 1 L
Barrel of 5 L

6. Indications

Treatment of infections caused by the following microorganisms susceptible to enrofloxacin:

Chickens
Mycoplasma gallisepticum
Mycoplasma synoviae
Avibacterium paragallinarum
Pasteurella multocida

Turkey
Mycoplasma gallisepticum
Mycoplasma synoviae
Pasteurella multocida

Rabbits:
Treatment of respiratory infections caused by *P. multocida*.

7. 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, to any other (fluoro)quinolone or to any of the excipients.

8. Adverse reactions

None known.

If you notice any side effects, even those not already listed in this label, or think that the medicine has not worked, please inform your veterinary surgeon.

9. Target species

Chickens (broilers)
Turkeys (turkeys for meat production)
Rabbits

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

In drinking water use.

Chickens and turkeys
10 mg enrofloxacin/kg bodyweight per day (equivalent to 0.1 ml. product/kg b.w./day) for 3-5 consecutive days. Administer 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.

Rabbits
10 mg enrofloxacin/kg bodyweight per day for 5 consecutive days (equivalent to 0.1 ml. product/kg b.w./day).

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage the concentration of enrofloxacin has to be adjusted accordingly.

According to the recommended dose, the number and weight of the animals which should be treated, the exact daily dose of the product should be calculated using the following formula:

$$\text{ml of the product/L water} = \frac{\text{0.1 ml of the product/kg bw/day x average bw of the animal (kg)}}{\text{average water consumption per animal (L/day)}}$$

The medicated water should be made up fresh each day just before it is offered to the animals. Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. The drinking water must be medicated throughout the treatment period, and no other water source should be available.

Use appropriate and properly calibrated dosing equipment.

11. Advice on correct administration

See section Dosage for each species, route and method of administration.

12. Withdrawal periods

Withdrawal periods:
Chickens (broilers):
Meat and offal: 7 days

Turkeys:
Meat and offal: 13 days

Rabbits:
Meat and offal: 2 days

Not authorised for use in birds producing eggs for human consumption.
Do not use within 2 weeks of the start of the laying period.

13. Special storage precautions

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.

14. Special warnings

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.

Wherever possible, fluoroquinolones should be used based on susceptibility testing.

Use of the product deviating from instructions given in the label 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.

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

(Fluoro)quinolones may cause hypersensitivity (allergy) in sensitised people. People with known hypersensitivity to (fluoro)quinolones should avoid contact with the veterinary medicinal product.

Avoid contact with skin and eyes. Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product. In case of accidental contact, rinse immediately with plenty of water. If such symptoms as skin rash appear after being exposed to this product, seek for medical advice. Face, lip or eye swelling, as well as difficult breathing, are serious signs requiring urgent medical assistance.

Do not smoke, eat or drink while handling this product.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of teratogenic effects. Studies performed in female rabbits do not show teratogenic effects for the foetus.

Studies carried out in lactating rabbits do not show toxic effects for the lactating young rabbits within the first 16 days. Rabbits older than this age have the ability to eliminate enrofloxacin.

Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

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 aluminum, ferrum or calcium can reduce absorbtion of enrofloxacin. Don't combine in solution or vials with aluminum, calcium, ferrum and zinc because chelate compounds may be formed.

Overdose (symptoms, emergency procedures, antidotes):

At the dosage of 20 mg/kg b.w. (twice the recommended dosage) administered for 15 days (3 times the recommended duration of treatment) adverse reactions were not observed. In case of overdosage, the symptoms would be a weak stimulation of the spontaneous motility, so the treatment should be ceased.

Overdose by fluoroquinolones may cause sickness, vomiting and diarrhoea.

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 products 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 sizes: 250 ml, 1 L and 5 L
Not all pack sizes may be marketed.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder

[ES]:

Administration under the control or direct responsibility of a veterinary surgeon.

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.

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 ….
Shelf life after first opening the container: 3 months
Shelf life after dilution according to directions: 24 hours

21. Marketing authorisation number

22. Manufacturer's batch number

Batch