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

250 mL bottle
1 L bottle
5 L barrel

1. 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]
FLUONIX 100 mg/ml Solution for use in drinking water for chickens, turkeys and rabbits [DE]

2. COMPOSITION

Each ml contains:

Active substance:
Enrofloxacin 100.0 mg

Excipients:
Benzyl Alcohol (E 1519) 0.014 ml

An aqueous, clear, yellowish solution

3. PACKAGE SIZE

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

4. TARGET SPECIES

Chickens (broilers)
Turkeys (for meat production)
Rabbits

5. INDICATIONS FOR USE

Indications for use

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*.

6. CONTRAINDICATIONS

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

7. SPECIAL WARNINGS

Special warnings

Special warnings:

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

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

Special precautions for for safe use in the target species:

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 and show the package leaflet or the label to the physician. Swelling of the face, lip or eye or difficulty with breathing are more serious symptoms and require urgent medical attention.
Do not smoke, eat or drink while handling this product.

Pregnancy, 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:

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.

Special restrictions for use and special conditions for use:

[ES]: Administration under the control or direct responsibility of a veterinary surgeon

Major Incompatibilities:

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

8. ADVERSE REACTIONS

Adverse events

None 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 on this label, 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><the local representative of the marketing authorisation holder> using the contact details on this label, or via your national reporting system <{national system details}.>

9. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Dosage for each species, routes 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:

$$\frac{\text{ml veterinary medicinal product/kg body weight day} \times \text{Average body weight (kg) of animals to be treated}}{\text{average daily water intake (l/animal)}} = \text{ml veterinary medicinal product per litre of drinking water}$$

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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

11. WITHDRAWAL PERIODS

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

Turkeys:
Meat and offal: 13 days

Rabbits:
Meat and offal: 2 days

Not for use in birds producing eggs for human consumption.
Do not administer to layer replacement birds within 14 days of coming into lay.

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 THE 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

[CY, DE, ES, EL, HR, HU, IT, PT]: Veterinary medicinal product subject to prescription

15. MARKETING AUTHORISATION NUMBER AND PACK SIZES

{Marketing authorization number}

Pack sizes
250 mL bottle
1 L bottle
5 L barrel

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST APPROVED

Date on which the label was last revised
{DD/MM/YYYY}

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

17. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 – BARCELONA
Spain
+34 608589898

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

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

18. OTHER INFORMATION

Other information
[ES]:
Administration under the control or direct responsibility of a veterinary surgeon.

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

EXP {month/year}

Once opened, use by ….
Once opened use within 3 months.
Shelf life after dilution according to directions: 24 hours

21. BATCH NUMBER

Lot {number}