PROPOSAL FOR PACKAGING, LABELLING AND PACKAGE INSERT

Label-leaflet

LANFLOX 100 mg/ml Solution for use in drinking water for Chickens and Turkeys [FR, HU, NL, DE, RO, UK]
Enrofloxacin

250-mL jars
1-L bottles
5-L 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:
VETPHARMA ANIMAL HEALTH, S.L.
Gran Via Carles III, 98, 7ª
08028 Barcelona
Spain

Manufacturer for the 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

LANFLOX 100 mg/ml Solution for use in drinking water for Chickens and Turkeys [FR, HU, NL, DE, RO, UK]
Enrofloxacin

3. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition per ml:

Active substance:
Enrofloxacin.....100 mg

Excipients:
Benzyl Alcohol (E 1519).....14 mg
Excipients to.....1 ml

4. PHARMACEUTICAL FORM

Solution for use in drinking water
A clear, yellowish solution.

5. TARGET SPECIES

Chickens and turkeys

6. INDICATIONS

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

Chickens
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida.

Turkey
Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida.

7. CONTRAINDICATIONS

Do not use in birds producing eggs for human consumption.
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 or to any of the excipients.

8. ADVERSE REACTIONS

None.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

9. METHOD AND ROUTE OF ADMINISTRATION

For oral administration via the drinking water. This may be put directly into the header tanks, or via water proportioner systems.

10 mg enrofloxacin/kg bodyweight per day for 3-5 consecutive days.

Treatment for 3-5 consecutive days; 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.

Medication of the water supply should be continuous during the treatment period and no other source of water should be available.
Medicated water should be made every day, immediately prior to provision. Carefully calculate the total body mass to be treated and the total daily water consumption before each treatment.
The uptake of medicated water depends on age and clinical condition of the birds, ambient temperature, and light regime. In order to obtain the correct dosage the concentration of the product should be adjusted accordingly. Taking into consideration that 10 mg enrofloxacin per kg body weight corresponds to 0.1 ml of the product per kg body weight; the following calculation should be made to provide the required amount of the product per litre of drinking water:

$$\frac{0.1 \times \text{Average bodyweight of birds to be treated (kg)} \times \text{Number of birds}}{\text{Total water consumption (l) of the flock at the previous day}} = \text{ml product per litre of drinking water}$$

Care should be taken that the intended dose is completely ingested.
Use appropriate and properly calibrated dosing equipment.

10. ADVICE ON CORRECT ADMINISTRATION

Before use, header tanks should be emptied, thoroughly cleaned and then filled with a known volume of clean water before adding the required amount of product. The resulting mixture should be stirred.

11. WITHDRAWAL PERIOD

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

12. SPECIAL WARNINGS, IF NECESSARY

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

Special precautions for use in animals

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.

Before use, header tanks should be emptied, thoroughly cleaned and then filled with a known volume of clean water before adding the required amount of product. The resulting mixture should be stirred.

Before use, header tanks should be inspected at regular intervals for presence of dust, algae formation and sedimentation.

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 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.

If there is no clinical improvement within two to three days susceptibility testing should be repeated and therapy should be changed, if appropriate.

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

Wear impervious gloves when handling the product.
Direct contact with the skin should be avoided because of sensitisation, contact dermatitis and possible hypersensitivity reactions.
In the case of eye or skin contact, rinse the affected area with clean water and if irritation occurs, seek medical attention.Wash hands and exposed skin after use.
Do not eat, drink or smoke whilst using the product.
People with known hypersensitivity to fluoroquinolones should avoid contact with the product.

Interaction with other medicinal products and other forms of interaction

Concurrent use of enrofloxacin with other antimicrobials, tetracyclines and macrolide antibiotics, may result in antagonistic effects.
Absorption of enrofloxacin may be reduced if the product is administered together with substances containing magnesium or aluminium.
Do not combine enrofloxacin with steroidal anti-inflammatory products.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not exceed the recommended dose. In accidental overdose there is no antidote and treatment should be symptomatic.

Incompatibilities

Do not mix with any other veterinary medicinal product.
Increased influx of the air (admixing CO_2 from the air) into medicated drinking water may result in precipitation of enrofloxacin.
High concentrations of calcium and magnesium in the water system may result in precipitation of enrofloxacin during intermediate dilution in the dosage devices.

13. EXPIRY DATE

Expiry date
Once opened, use by …
Shelf life after first opening the container: 3 months.
Shelf life after dilution according to directions: 24 hours

14. SPECIAL STORAGE CONDITIONS

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

15. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

For animal treatment only
Keep out of the reach and sight of children
To be supplied only on veterinary prescription

Pack sizes: 250 mL, 1 L and 5 L

Date on which the package leaflet was last approved:

Marketing authorisation number:
Batch