PACKAGE LEAFLET FOR A VETERINARY PRODUCT

This medicine is marketed according to a veterinarian's prescription only

For animal use only

1. **Name of veterinary medicine, form and strength:**
   Lanflox 100 mg/mL veterinary, solution for administration in drinking water
2. **Active ingredients** and their concentration in a dose unit: each mL contains: Enrofloxacin 100 mg
   For the list of excipients, please see section 13.
3. **What is the medicine intended for:** Treatment of infections caused by the following bacteria susceptible to enrofloxacin:
   Broilers: Mycoplasma gallisepticum, Mycoplasma synoviae,Avibacterium paragallinarum, Pasteurella multocida.
   Turkey: Mycoplasma gallisepticum, Mycoplasma synoviae, Pasteurella multocida.
   Enrofloxacin should be used only after sensitivity of the bacteria has been confirmed and there is no alternative therapy (due to resistance to other antibiotics).
   Therapeutic group: fluoroquinolones.
4. **Contraindications:** Not to be used for prevention. Do not use in the event of known resistance or cross-resistance to quinolones in animals that are candidates for treatment. If there is known hypersensitivity to the active substance, to other quinolones or to any of the excipients, avoid treatment with this product.
5. **Side effects** can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Repot" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link: https://sideeffects.health.gov.il/
6. **Target species:** Broilers and turkeys.
7. **Dosage and administration for each target species:** <u>In drinking water:</u>
   10 mg/kg per day in drinking water for 3 - 5 consecutive days, equivalent to 0.1 ml of the product per 1 kg body weight per day. Administer for 5 consecutive days in the event of mixed, progressive and chronic infections. If no improvement is achieved after 2 - 3 days, an alternative antibiotic treatment should be considered based on a sensitivity test.
8. **How to use the product:** For dose adjustment, the concentration should be adjusted to the actual drinking water consumption in one day. The animal's body weight should be determined as accurately as possible in order to avoid underdosing. Fresh solution should be prepared daily and remains from the preceding day should be disposed of. The consumption of drinking water including the medicinal product depends on the clinical condition of the animal and on the season of the year. The concentration of enrofloxacin must be adjusted accordingly. Drinking water with the medicinal product must be prepared every 24 hours. The drinking water containing the medicinal product should be the poultry's sole drinking source. Make sure that the drinking water containing the product is consumed in its entirety by checking the drinking water supply system. Prior to initiating treatment, the drinking water system must be emptied and filled with drinking water containing the product. An exact and

calibrated measuring device should be used. The accurate daily dose should be calculated based on the recommended dosage, the number of animals and their body weight, according to the following formula:

$$\frac{\text{10 mg/kg/day x average body weight of animals (kg)}}{\text{100 mg/ml x average daily water consumption (liter per day)}} = \text{ml product per liter drinking water}$$

9. **Withdrawal time:** 7 days before slaughter for broilers, and 13 days before slaughter for turkeys. Not for use in hens laying eggs for human consumption.
10. **Warnings**

Special warnings regarding use of the medicine in the target species
The treatment of mycoplasma infections may not be sufficient to eradicate the pathogen.
Special warnings regarding the safe use of the medicine in animals
Official and anti-microbial policy should be taken into account when applying the product. Treatment with fluoroquinolones should be reserved for situations in which a weak response was achieved or is expected to occur following treatment with other families of anti-microbial agents.
Whenever possible, treatment with fluoroquinolones should be based on sensitivity tests. Using the product not in accordance with the indication specified in the package leaflet may increase the incidence of fluoroquinolone resistance and reduce the efficacy of other quinolones due to possible cross-resistance. Since the beginning of treatment with enrofloxacin in chickens, a vast decrease in the sensitivity of E. coli to fluoroquinolones was observed, as well as emergence of resistant species.
Special warnings regarding the safety of the person administering the product:
People with known sensitivity to fluoroquinolones or to any of the product ingredients should avoid contact with the product. Avoid contact with skin and eyes. Use gloves and avoid contact with the product during its addition to drinking water. In the event of contact, rinse immediately with large amount of water. If reactions such as cutaneous sensitivity appear after exposure to the product, seek for medical advice and show the product leaflet to the attending physician. Swelling of the face, lips or eyes as well as breathing difficulties are severe reactions requiring immediate medical treatment.
Do not smoke, eat or drink while using the product.
Pregnancy and lactation: Not to be used in hens laying eggs for human consumption.
Interactions with other medicines and other types of interaction: do not use this product together with bacteriostatic drugs, such as macrolides, tetracyclines and phenicols. Administering the product together with products including aluminum or magnesium can cause decreased absorption of the product.
Overdose: Overdose can cause diarrhea. Long term consumption of the medicated drinking water, for example in hot days, might cause damage to the cartilage.
Incompatibility: Due to lack of compatibility studies, this product should not be mixed with other veterinary products.

11. Storage instructions

- Avoid poisoning! Keep this medicine and any other medicine in a closed place out of the reach and sight of children and/or infants to avoid poisoning.
- Do not use this medicine after the expiry date indicated on the package. The expiry date refers to the last day of the month indicated.
- Storage conditions: below 25^{o}C
- Shelf life after first opening of the package: 3 months.
- Shelf life after reconstitution: 24 hours

12. Instructions regarding the disposal of the product/remaining product after its use

Any unused veterinary medical product or any substances originated from using veterinary medical products must be disposed of in accordance with the guidelines of the Ministry of Environmental Protection.

13. Additional information

In addition to the active ingredient, the medicine also includes:
Benzyl alcohol, Potassium hydroxide, Purified water

- How does the medicine look like and what is the content of the package – clear solution.
- Package sizes: 1 liter or 5 liter bottles. Not all package sizes may be marketed.

Registration holder: Romat Ltd., 39/104 Ha'maapilim Street, Herzliya
Manufactured for (rights holder): Vetpharma Animal Health, S.L., Les Corts, 23 08028 –Barcelona, Spain
Manufacturer/production site: Laboratorios Karizoo, S.A., Polígono Industrial La Borda, Mas Pujades, 11-12, 08140 – CALDES DE MONTBUI (Barcelona), Spain
Registration number of the product in the National Drug Registry at the Ministry of Health: 159-83-35085-00
A doctor's prescription will be valid only after certification by the governmental physician for poultry diseases.
Revised in 12/ 2020.
This leaflet of 12/2020 is in the format determined by the Ministry of Health and its content corresponds to the leaflet of the original product, which was checked and approved by the Ministry of Health in January 2020.