

1. Name, form, and strength of veterinary medicine

Kariflox 10% veterinary solution

2. Active ingredients and their concentration in a dosage unit

Each 1 ml contains: Enrofloxacin 100 mg

For a list of excipients in the product, see Section 13 "Additional information" for administration in drinking water.

3. What is the medicine intended for?

For treatment of infections susceptible to Enrofloxacin in broiler chickens and turkeys.

In broiler chickens

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida,
Avibacterium paragallinarum

In turkeys

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida

The product should be administered only after the susceptibility of the bacterium has been proven and it has been found that there is no alternative treatment (resistance to other products has been proven).

Therapeutic group: Fluoroquinolones

4. Contraindications

Do not use for prophylaxis.

Do not use in the case of known resistance/cross-resistance to quinolones in the animals intended for treatment.

Avoid treatment with this product if there is a known hypersensitivity to the active ingredient, quinolones, or the excipients.

5. Side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" 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 animals

Broiler chickens and turkeys

7. Method of administration and dosage for each target animal

In drinking water: 10 mg/kg per day in drinking water for 3-5 consecutive days, equivalent to 0.1 ml of the product for every kg of bodyweight per day. For 5 consecutive days in the case of mixed, progressive, and chronic infections. If there is no improvement within 2-3 days an alternative antibiotic treatment should be considered, based on susceptibility testing.

8. Method of use of the product

To adjust the dose, adjust the concentration to the actual consumption of drinking water per day. Be precise as possible regarding the animal's weight to avoid an underdose. Prepare a fresh solution each day and dispose of the remnants from the previous day. Consumption of drinking water with the medicinal product depends on the animal's clinical state and the season. Adjust the enrofloxacin concentration to

the conditions. Prepare the drinking water with the medicinal product every 24 hours. When the drinking water diluted with the product is the sole source of drinking water for the chickens, confirm that the drinking water with the product is fully consumed by checking the drinking water supply system. Before beginning treatment, empty the drinking water system and fill it with drinking water with the product. Use a precise and calibrated measurement instrument. The precise daily dose will be calculated based on the recommended dosage, the number and weight of the animals, according to the following formula:

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

9. Withdrawal period

Withdrawal period for slaughter: 7 days for broiler chickens and 13 days for turkeys.

Not for use in hens laying eggs for consumption.

10. Warnings

Special warnings regarding the use in target animal:

Treatment of mycoplasma infections may not eradicate the bacterium.

Special warnings regarding the safety of the use of the medicine in animals:

Official and antimicrobial policy should be considered when the product is given. The use of fluoroquinolones should be reserved for situations in which the susceptibility to other families of anti-microbials was weak or is expected to be weak.

When possible, the treatment with fluoroquinolones should be based on susceptibility tests.

Use of the product that is not in accordance with the indications given in the leaflet may increase the prevalence of resistance to fluoroquinolones and reduce the efficiency of treatment with the remaining quinolones due to the possibility of cross-resistance. Since the first use of enrofloxacin in chickens, a widespread reduction in the susceptibility of E. coli bacteria to fluoroquinolones and the appearance of resistant organisms have been observed.

Special warnings regarding the safety of people treating with the product:

People with known sensitivity to fluoroquinolones or to one of the product's ingredients should avoid contact with the product. Avoid contact with skin and eyes. Use gloves and avoid contact with the product while putting it in the drinking water. In case of contact wash immediately with a large amount of water. If effects such as skin sensitivity appear after exposure to the product, seek medical advice and show the product leaflet to the attending doctor. Swelling of the face, lips, or eyes as well as breathing difficulties are serious effects that require immediate medical treatment. Do not smoke, eat, or drink while using the product.

Pregnancy and breastfeeding: Do not use in hens laying eggs intended for human consumption.

Drug interactions and other types of interaction: Do not use this product with other bacteriostatic products such as macrolides, tetracyclines and phenols. Administration of the product together with products containing aluminum or magnesium may cause reduced absorption of the product.

Overdose: An overdose can cause diarrhea. Prolonged consumption of drinking water with the product such as on warm days may cause damage to cartilage.

Incompatibility: In the absence of compatibility studies, this product should not be mixed with other veterinary products.

11. Storage Instructions

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning.
- Do not use the medicine after the expiry date (Exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage instructions: Store at a temperature below 25°C.
- Shelf life after first opening the package: 3 months.
- Shelf life after reconstitution: 24 hours.

Note the withdrawal date on the package.

12. Instructions for disposing of the product / remaining product at the end of its use

Destroy all remnants of veterinary medicines or materials derived from veterinary products according to the Ministry of Environmental Protection's instructions for destruction.

13. Additional Information

- **In addition to the active ingredient the product also contains:**
Benzyl Alcohol (E1519), Potassium Hydroxide, purified water
- **What does the medicine look like and what is the content of the package:** a clear solution in vials of 250 ml, 1 liter, or 5 liters.
Not all package sizes may be marketed.
- **Manufacturer name and address:** Laboratorios Karizoo S.A, Barcelona, Spain.
- **Registration holder:** VETMARKET LTD., DERECH HACHORESH 23 , INDUSTRIAL PARK HEVEL MODIIN 7319900, P.O.B. 960, SHOHAM.
- Registration number of the product in the National Drug Registry at the Ministry of Health: 154-94-33668-00

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