

# Kariflox 10% veterinary solution

## Enrofloxacin

For veterinary use only • Requires a veterinarian's prescription

### 1. Name of veterinary product

Kariflox 10% veterinary solution

### 2. Product composition

Every 1 ml contains: Enrofloxacin 100 mg

For list of excipients in the product, see section 13- "Additional information".

### 3. Indication

For treatment of infections caused by bacteria susceptible to enrofloxacin in broiler chickens, only after the susceptibility of the bacteria has been proven and no alternative treatment exists (resistance to other products has been proven).

List of bacteria susceptible to enrofloxacin in chickens: *Mycoplasma gallisepticum*, *Mycoplasma synoviae*, *Avibacterium paragallinarum*, *Pasteurella multocida*, *Escherichia coli*.

**Therapeutic group:** Enrofloxacin is an anti-bacterial substance, of the fluoroquinolones group.

### 4. Contraindications

Do not use for prophylaxis.

Do not use when resistance/cross resistance to (fluoro)quinolones is known.

Do not use in the case of known hypersensitivity to the active substance, to other (fluoro)quinolones or to any of the excipients.

### 5. Side effects

Unknown.

If you notice severe effects or other effects that do not appear in this leaflet, refer to a veterinarian.

Side effects can be reported to the Ministry of Health using the online form for reporting side effects found on the home page of the Ministry of Health's website: [www.health.gov.il](http://www.health.gov.il)

Or via the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

### 6. Target species

Broiler chickens

### 7. Dosage and method of administration

Broiler chickens

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

Treatment duration is 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.

Administer via the drinking water. Always make sure that the entire required dose has been consumed. Prepare the medicated water fresh each day just before it is given to the animals. The medicine must be added to the drinking water throughout the treatment period, and no other water source should be available. Determine the bodyweight of the birds as accurately as possible in order to avoid under-dosing.

Use only fresh solutions, prepared every day before starting the treatment. Pumping systems should be checked regularly to assure proper medication. Empty the water system and fill it with medicated water before starting the treatment.

Calculate the daily quantity (ml) of Kariflox 10% Veterinary solution required for treatment period as follows:  
Total number of birds x Average body weight in kg x 0.1 = Total volume (ml) per day.

Kariflox 10% Veterinary solution may be administered directly into the water tank or via a water proportioner pump.

### 8. Withdrawal period

Broiler chickens: 7 days

Not authorized for use in chickens producing eggs.

### 9. Special storing conditions

Keep out of the reach of children.

Do not use this veterinary medicinal product after the expiry date (exp. date) stated on the package.

Store at a temperature below 25°C.

Shelf life after first opening the package: 3 months.

Shelf life after reconstitution: 24 hours

State the withdrawal date on the label.

### 10. Special warnings

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.

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.

Whenever possible, fluoroquinolones should only be used based on susceptibility testing.

Use of the product not according to instructions may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of treatment with other fluoroquinolones as result of the potential for cross-resistance.

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 cause damage of the articular cartilage.

No adverse clinical symptoms were observed in chickens treated with doses up to 10 times higher than the therapy dose.

In vitro, an antagonism was shown, when combining fluoroquinolones with bacteriostatic antimicrobial agents such as macrolides or tetracyclines and phenicols. The simultaneous administration of substances containing aluminum or magnesium may impair the absorption of enrofloxacin.

### User safety warnings:

- Those with known hypersensitivity to (fluoro) quinolones should avoid direct contact with the product.
- Avoid contact with the skin and eyes.
- Rinse any splashes from the skin or eyes immediately with water.
- Wash your hands and exposed skin after use.
- Do not eat, drink or smoke while using the medicine.

### 11. Special precautions for the disposal of unused product or waste material

Any unused veterinary medicinal product or waste materials derived from use of veterinary medicinal products should be regarded as toxic waste, and not disposed of via wastewater.

### 12. Date on which the package leaflet was approved

November 2015

### 13. Additional Information

#### List of excipients:

Benzyl Alcohol (E1519), Potassium Hydroxide, Purified water

Bottles of 250 ml, 1 or 5 liters.

Not all the pack sizes may be marketed.

#### Name and address of registration holder and manufacturer:

Registration holder: Udim, 57 Etzel St., Ramat Gan.  
Manufacturer: Laboratorios Karizoo S.A, Barcelona, Spain.

#### Drug registration number at the national medicines registry of the Ministry of Health:

154-94-33668-00

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