

CONSUMER PACKAGE LEAFLET FOR A VETERINARY PREPARATION

The medicine is dispensed with a veterinarian's prescription only
For animal use only

1. NAME OF THE VETERINARY MEDICINE, ITS FORM AND STRENGTH:

Enrabic 10% Veterinary Solution for drinking water.

2. ACTIVE INGREDIENT:

Each 1 ml contains:
Enrofloxacin 100 mg
For a list of inactive ingredients see section 13 "Further Information".

3. WHAT IS THE MEDICINE INTENDED FOR?

Enrabic 10% Veterinary is intended for treatment of infectious diseases caused by the following bacteria that are sensitive to enrofloxacin in broilers and in turkeys:

Broilers:
Mycoplasma gallisepticum, *Mycoplasma synoviae*,
Avibacterium paragallinarum, *Pasteurella multocida*.

Turkeys:
Mycoplasma gallisepticum, *Mycoplasma synoviae*,
Pasteurella multocida.

The preparation should only be given after proof of bacterial susceptibility and after it is determined that an alternative treatment is not available (due to resistance to other antibiotics).

Therapeutic group:

Fluoroquinolones.

4. CONTRAINDICATIONS:

- Do not use for prophylaxis.
- Do not use in case of resistance or cross resistance to quinolones in animals for which the treatment is intended.
- Do not use in cases of known hypersensitivity to the active ingredient, to other quinolones or to the inactive ingredients.

5. SIDE EFFECTS:

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

Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

6. TARGET SPECIES:

Broilers and turkeys

7. METHOD OF ADMINISTRATION AND DOSAGE:

In drinking water: 10 mg/kg a day, for 3-5 consecutive days, which is equivalent to 0.1 ml of the preparation for each kg of body weight per day.

For 5 consecutive days in cases of mixed chronic and progressive infections.

If there is no clinical improvement within 2-3 days, alternative treatment should be considered based on susceptibility testing.

8. HOW TO USE THE PREPARATION:

To adjust the dose, the concentration should be adjusted to the actual daily water consumption. The animal's weight should be determined as accurately as possible in order to avoid underdosing. A fresh solution should be prepared every day and the remaining solution from the previous day should be disposed of. The consumption of the medicated drinking water depends on the animal's clinical condition and the season of the year. The concentration of enrofloxacin should be adjusted according to the conditions. The medicated drinking water should be prepared fresh every 24 hours, with the medicated water being the poultry's exclusive water source. Check that the medicated drinking water is consumed in its entirety by examining the drinking water supply system. Prior to the beginning of the treatment, empty the drinking water supply system and fill it with the medicated drinking water. Use an accurate and calibrated device.

The accurate daily dose should be calculated based on the recommended dosage, the number and weight of the animals using the following formula:

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

9. WITHDRAWAL PERIOD:

7 days for broilers and 13 days for turkeys.

Do not use in laying hens producing eggs for human consumption.

10. WARNINGS:

Special warnings regarding to the use in the target animal:

Treatment of mycoplasma infections may not eradicate the bacterium.

Special warnings regarding to the safety of use of the medicine in animals: Official and antimicrobial policy should be taken into account when administering the preparation. Treatment with fluoroquinolones should be reserved for situations in which treatment with other classes of antimicrobials have responded poorly or are expected to respond poorly. Treatment with fluoroquinolones should be based on susceptibility testing. Use of the product not according to the indication may increase the prevalence of resistance to fluoroquinolones and decrease the efficacy of treatment with other quinolones due to the possibility of cross resistance. Since the initial use of enrofloxacin in chickens, a widespread reduction in susceptibility of *E. coli* to fluoroquinolones and the emergence of resistant organisms have been observed.

Special warnings regarding to the safety of the person administering the preparation: People with known hypersensitivity to fluoroquinolones or to any of the preparation's ingredients should avoid contact with the preparation. Avoid contact with the skin and eyes. Use gloves and avoid contact with the preparation when adding it to the drinking water. In case of contact wash immediately with plenty of water. If effects such as skin sensitivity appear following exposure to the preparation, seek medical advice and show the preparation leaflet to the attending physician. Swelling of the face, lips or eyes, as well as breathing difficulties, are serious effects that require immediate medical attention. Do not smoke, eat or drink during use of the preparation.

Pregnancy and lactation of the treated animal: Do not use in laying hens producing eggs for human consumption.

Interactions with other medicines and other forms of interactions: Do not use this preparation with bacteriostatic preparations such as macrolides, tetracyclines and phenicols. The simultaneous administration of the preparation with those containing aluminum or magnesium can cause a reduction in the absorption of the medicine.

Overdose: Overdosing can cause diarrhea. The extended consumption of the medicated drinking water, for example, during hot days, may cause cartilage damage.

Incompatibilities: In the absence of compatibility studies, do not mix this preparation with other veterinary preparations.

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. Date) that appears on the label. The expiry date refers to the last day of that month.
- Storage conditions: Below 25°C.

12. INSTRUCTIONS REGARDING DISPOSAL OF THE PREPARATION/REMNANTS OF THE PREPARATION AFTER USE:

All remnants of a veterinary preparation, or any waste derived from use of a veterinary preparation, must be disposed of as toxic waste; do not discard into a wastewater drain.

13. FURTHER INFORMATION:

- In addition to the active ingredient, the medicine also contains:
Purified water, potassium hydroxide
- Package size: 1 liter.
- License holder and manufacturer: Abic Veterinary Products Ltd., P.O.B. 489, Bet Shemesh.

This leaflet was revised in January 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 082-18-92272