

1. Name of the Veterinary Medicinal Product, Its Shape & Strength:
Syvaquinol 10% oral Veterinary

2. The Active Substances and Their Concentration per Each

Dosing Unit: Each 1 ml contains: 100 mg of Enrofloxacin
The list of excipients is available in Section 13. For use in drinking water.

3. What Is the Medicinal Product Intended for? SYVAQUINOL 10% is indicated for the treatment of infections susceptible to Enrofloxacin in fattening chickens and in turkeys.

In chickens:

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Avibacterium paragallinarum,
Pasteurella multocida

In turkeys:

Mycoplasma gallisepticum,
Mycoplasma synoviae,
Pasteurella multocida

The preparation may be used only in case of proven bacterial susceptibility after it is determined an alternative treatment is not available (proven resistance of other preparations).

Therapeutic group: Fluoroquinolones

4. Contraindications: Do not use for prophylaxis.

Do not use when resistance or cross-resistance to quinolones is known to occur in the animals for which the treatment is intended. In case of known hypersensitivity to the active substance, to other quinolones, or to the excipients, do not treat with this preparation.

5. Side Effects: Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects and Drug-related Adverse Events" on the homepage of the Ministry of Health website (www.health.gov.il), which redirects to an online form for reporting side effects, or by clicking on the link: <https://sideeffects.health.gov.il>

6. Target Species: Fattening chickens and turkeys.

7. Administration Route and Dose for Each Target Species:

In drinking water: 10 mg/kg a day in drinking water for 3-5 consecutive days, which equals 0.1 ml of the preparation for each kg of bodyweight per 24 hours. Over a period of 5 consecutive days in case of mixed infections, progressive infections, or chronic infections. If a clinical improvement is not achieved within 2-3 days, alternative antibiotic treatment should be considered based on susceptibility testing.

8. Way of Using the Preparation: To determine the correct dose, the concentration should be adjusted depending on the actual daily water consumption. The animal's bodyweight should be determined as accurately as possible 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. The concentration of Enrofloxacin should be adjusted according to the actual conditions. The medicated drinking water should be prepared every 24 hours when the medicated water is 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 start of the treatment, empty the drinking-water supply system and fill it with the medicated drinking water. Use an accurate and calibrated measurement device. The accurate daily dose should be calculated based on the recommended dose as well as the number of animals and their weight using the following formula:

10 mg/kg/day x average animal weight (kg) = ml of the preparation
100 mg/ml x average daily water consumption = for every liter of
(liters per 24 hours)

9. Withdrawal Period Dosing Unit: Withdrawal period before slaughter: 7 days for fattening chickens and 13 days for turkeys.
Do not use in laying hens producing eggs for human consumption.

10. Warnings:

Special Warnings Regarding Use in the Target Species:

Treatment of mycoplasma infections might not eliminate the bacterium.

Special Warnings Regarding the Safe Use of the Medicinal Product in

The format of this insert was determined by the Israel Ministry of Health and its content was examined and approved by the Ministry.
Package Insert for a Veterinary Preparation | This medicine is only marketed 5 Liter
subject to a veterinarian's prescription | For use only in animals

Animals: Official and antimicrobial policies should be considered when administering the preparation. Treatment with fluoroquinolones should be reserved for situations in which treatment with other classes of antimicrobials resulted in a poor response or is expected to result in a poor response. Whenever possible, treatment with fluoroquinolones should only be used based on susceptibility testing. Use of the product not according to the indications listed in the insert may increase the prevalence of bacterial resistance to fluoroquinolones and decrease the efficacy of treatment with other quinolones due to potential cross-resistance. Since the initial use of Enrofloxacin in chickens, a widespread reduction in the susceptibility of *E. coli* to fluoroquinolones and the emergence of resistant organisms have been diagnosed.

Special Warnings Regarding 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 the 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 symptoms such as skin sensitivity appear following exposure to the preparation, seek medical advice and show the insert to your attending physician. Swelling of the face, lips, or eyes as well as breathing difficulties are serious symptoms that require immediate medical treatment. Do not smoke, eat, or drink during use of the preparation.

Pregnancy and Lactation: Do not use in laying hens producing eggs for human consumption.

Drug Interactions and Other Forms of Interaction: Do not use this preparation with bacteriostatic preparations, such as macrolides, tetracyclines, and phenolics. The simultaneous administration of this preparation with preparations containing aluminum or magnesium can impair the absorption of Enrofloxacin.

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

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

11. Storage Instructions:

- Prevent poisoning! This medicinal product and any other medicinal product should be kept in a closed place out of the reach of children and/or babies to prevent poisoning.
- Prevent poisoning! This medicinal product and any other medicinal product should be kept in a closed place out of the reach of children
- Storage conditions: store in a cool and dry place protected from light under 25°C.

12. Instructions Pertaining to the Disposal of the Preparation/Remaining Quantity of the Preparation Once Its Use Is Over:

Any remaining quantity of the veterinary medicinal product or waste materials derived from such a veterinary medicinal product should be disposed of according to the disposal instructions set forth by the Ministry of Environmental Protection.

13. Additional Information:

- In addition to the active substance, the preparation also contains: Benzyl alcohol, Potassium hydroxide, Purified water.
- What the medicinal product looks like and what the package content is: A clear solution in 1-liter and 5-liter HDPE containers.
- Drug Registration Number: 083-29-92349-00
- Name of the Manufacturer: Syva Laboratories, Leon, Spain
- Name of the Registration Holder: M.P.VET Ltd., POB 7004, Petah Tikva 49170

A medical prescription will only be valid after approval is obtained from a government physician who specializes in poultry diseases