

Consumer leaflet for a Veterinary Product

This medicine is marketed according to a veterinarian's prescription only.
For animal use only

1. Name of the veterinary medicine, form and strength

TYLOGAL POWDER VETERINARY, soluble powder for dissolution in drinking water, containing TYLOSIN (AS TARTRATE salt) 90.9% W/W

2. Active ingredient and quantity in a single dose

TYLOSIN (AS TARTRATE) 90.9 %W/W
Equivalent to 100% tylosin tartrate

3. What is the medicine intended for

Chickens:

- Treatment and prevention of chronic respiratory diseases (CRD) caused by *Mycoplasma gallisepticum* and *Mycoplasma synoviae* when the disease has been established in the flock.
- Treatment and prevention of necrotic enteritis caused by *Clostridium perfringens* when the disease has been established in the flock.

Turkeys:

Treatment and prevention of infectious sinusitis caused by *Mycoplasma gallisepticum* when the disease has been established in the flock.

Therapeutic group: Antibiotic of the macrolide group.

4. Contra-indications

Do not use in in case of known hypersensitivity to tylosin or other macrolides.
Do not use in cases of known resistance to tylosin or cross-resistance to other macrolides.
Do not use in animals vaccinated with tylosin-sensitive vaccines either at the same time or within 1 week previously.
Do not use in animals with hepatic disorders.

5. Side effects

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 animals: Chickens, turkeys

7. Dosage and administration

Administration through the drinking water.

1.1 gram of the product corresponds to 1 gram of tylosin. The

Dosages:

Turkeys:

75 – 100 mg tylosin per kg BW per day (corresponding to 82.5 – 110 mg of the product per

kg BW) for 3 – 5 days.

Chickens:

For the treatment of chronic respiratory disease:

75 – 100 mg tylosin per kg BW per day (corresponding to 82.5 – 110 mg of the product per kg BW) for 3 – 5 days.

For the treatment of necrotic enteritis:

20 mg tylosin per kg BW per day (corresponding to 22 mg of the product) for 3 days.

For the preparation of the medicated water the body weight of the animals to be treated and their actual daily water consumption should be taken into due account. Consumption may vary depending on factors like age, state of health, breed, husbandry system. To provide the required amount of active substance in mg per liter drinking water, the following calculation should be made:

$$\frac{\text{..... mg tylosin per kg bodyweight per day} \times \text{Average bodyweight (kg) of the animals to be treated}}{\text{Average amount of drinking water / animal (liter)}} = \text{.....mg tylosin / liter of drinking water}$$

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period.

Should there be no clear response to treatment within 3 days the treatment approach should be reconsidered. After the end of the medication period the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance which might support development of resistance.

Medicated water should be replaced every 24 hours.

If individual animals show signs of a serious infection such as a reduced water or feed intake, then they should be treated individually, such as by injection.

8. How to use the product

For administration in drinking water according to the instructions in paragraph 7.

9. Withdrawal period

Turkeys (meat and offal): 2 days

Chickens (meat and offal): 1 day

Eggs: Zero days

10. Warnings

- Special warnings for use of the medicine in target animals

Due to likely variability (time, geographical) in susceptibility of bacteria to tylosin, bacteriological sampling and susceptibility testing are recommended. Under-dosing or treating for an insufficient length of time are considered to promote the development of resistance in bacteria and should be avoided.

- Special warnings for safe use of the medicine in animals
Animals with acute infections may have a reduced water and feed consumption and should be treated with a suitable injectable veterinary medicinal product first.
Do not leave or dispose of water containing tylosin tartrate where it may be accessible to either animals not under treatment or wildlife.

- Special warnings regarding the safety for the person administering the veterinary medicinal product to animals

Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa. Allergic reactions to these substances may occasionally be serious and therefore direct contact should be avoided. To avoid exposure during preparation of the medicated drinking water, wear overalls, safety glasses, impervious gloves and wear either a disposable half mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143.

Wash hands after use.

In the event of accidental skin contact, wash thoroughly with soap and water. In case of accidental eye contact, flush the eyes with plenty of clean, running water.

Do not handle the product if you are allergic to ingredients in the product. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

- Interaction with other medicinal products and other forms of interaction
Lincosamides and aminoglycoside antibiotics antagonise the activity of tylosin.
- Overdose
There is no evidence of tylosin toxicity in chickens or turkeys, when administered orally at up to three times the recommended dose.
- Incompatibility
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach of children and/or infants to prevent accidental poisoning.
- Do not use the medicine after its expiration date (exp. date) as it appears on the package. The expiration date refers to the last day of the stated month.
- Storage conditions: Store below 25°C.

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

Any unused veterinary medical product or any substance remaining after using the veterinary medical product must be disposed of as toxic waste; do not throw into the sewage system.

13. Additional information

- This medicine does not contain other ingredients in addition to the active ingredient.
- How does the medicine look like and what is the content of the package – laminate bag containing white to yellowish powder.
- Pack sizes 110 g, 330 g, 550 g, 1100 g. Not all pack sizes may be marketed.

Manufacturer and License holder: BIOVAC LTD. , POB 300, OR-AKIVA 30600

This leaflet has been checked and approved by the Ministry of Health in: 01/2019

Registration number of this medicine in the Ministry of Health State Medicine Registry: 082-34-92289