

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**
Doxygal Veterinary, powder for dissolution in drinking water
- 2. Active ingredient and quantity**
Doxycycline (as Hydrochloride) 100 %
- 3. What is the medicine intended for**
For treatment of infections caused by Mycoplasma Gallisepticum in Turkeys.
Therapeutic group: antibiotic belonging to Tetracycline group.
- 4. Contra-indications**
Do not use in cases of hypersensitivity to the active substance Doxycycline.
Do not use in animals with abnormal liver function.
- 5. Side effects**
Rarely, allergic reactions and sensitivity to light may appear.
Stop treatment if any side effect appear.
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:**
Turkeys
- 7. Dosage and administration**
Turkeys: 25 mg /kg body weight /day in drinking water for 5-7 consecutive days.
According to the recommended dosage, the number and weight of the treated animals- calculate the accurate daily amount of the product according to the following equation:

Mg of product/ kg body weight /day	x	Average body weight (kg) of treated animals	= Mg product/ litre of drinking water
Average daily consumption of water (litre) per animal			

Bodyweight should be determined as accurately as possible to ensure a correct dosage. The consumption of water with the medicine depends on the clinical condition of the animals. The medicine concentration in the drinking water should be adjusted to the water consumption to obtain the correct dosage.

It is recommended to use suitable and calibrated weighing equipment in case you use the medicine from incomplete packages. Add the daily amount to the drinking water in a way that will guarantee the entire medicine is consumed within 24 hours. It is recommended to prepare a concentrated pre-solution and dilute it until reaching the

required final (therapeutic) concentration.

The medicated water must be changed every 24 hours. The water with the medicine must be the only source of drinking water, throughout the treatment period. The medicated water should not be prepared or stored in a metal container.

8. How to use the product

To be used in drinking water, according to directions in section 7.

9. Withdrawal period-

Turkeys: 12 days for meat

Do not use in poultry that produce or are intended to produce eggs for human consumption.

10. Warnings

- Special warnings regarding the use of the medicine the target species
The uptake of medication by animals can be altered as a consequence of illness. In cases of insufficient uptake of drinking water, reach a veterinarian for advice. 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 regarding the safety of the use of the medicine in animals:
Inappropriate use of the product may increase the prevalence of bacteria resistant to tetracycline due to the potential for cross resistance.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local epidemiological information about susceptibility of the target bacteria.
Avoid administration in oxidised drinking equipment.
Do not use when tetracycline resistance has been detected in the flock due to the potential for cross resistance.
Due to the occurrence of resistant bacteria, bacteriological sampling and susceptibility testing for doxycycline are highly recommended.
As eradication of the target pathogens may not be achieved, medication should therefore be combined with good management practices, e.g. good hygiene, proper ventilation, no overstocking.
- Special warnings concerning the safety of the person administering the medicine:
During preparation and administration direct contact of the product with the skin, eyes and mucous membranes and inhalation of dust particles should be avoided. People with known hypersensitivity to Tetracyclines should avoid contact with the medicine.
Personal protective equipment including protective gloves (e.g., rubber or latex), safety glasses (goggles), and a suitable dust mask should be used when preparing the medicine.
Wash exposed skin after preparing the medicine. If by mistake the medicine splashes into the eye, wash the eye with plenty of water. Do not smoke, eat or drink while preparing the medicine.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Inflammation of the face, lips or eyes or respiratory difficulties are the most serious signs which require urgent medical attention.

- Use during laying period
Laboratory studies in rats and rabbits showed no evidence of a teratogenic effect, or toxicity to the fetus or the mother due to the administration of the medicine.
Do not use in birds in lay and within 4 weeks before the onset of the laying period.
- Interaction with other medicinal products and other forms of interaction
Do not administer concurrently with feed overloaded with polyvalent cations such as Ca^{2+} , Mg^{2+} , Zn^{2+} and Fe^{3+} because the formation of doxycycline complexes with these cations is possible. It is advised that the interval between administration of other products containing polyvalent cations and Doxygal administration should be 1-2 hours because they limit the absorption of tetracycline.
Do not administer together with antacids, kaolin or iron preparations.
Do not administer in conjunction with bactericidal antibiotics such as beta-lactams.
Doxycycline increases the action of anticoagulants.
- Overdose
During the target animal tolerance study, no adverse effect was observed even at the fivefold therapeutic dose administered for two times the recommended duration in either target animal species.
If suspected toxic reactions do occur due to extreme overdose, discontinue the medication and consult with the veterinarian.
- Incompatibility
Doxycycline may form insoluble complexes with divalent ions, especially iron or calcium, zinc and magnesium.

Do not mix with other veterinary products.

11. Storage instructions

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place outside the reach of children and/ or infants to prevent accidental poisoning.
- Do not use the medicine after its expiry date as it appears on the package. The expiry date refers to the last day of the stated month.
- Storage conditions: Store below 25°C.
Discard the medicated water not consumed after 24 hours.

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

Any veterinary medical product that was unused 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.
- What does the medicine look like and the content of the package -Yellow crystalline powder.
- Package sizes: A bag containing 500 grams, a jar containing 100 grams.
Not all package sizes may be marketed.

Manufacturer and License holder: BIOVAC LTD., HAILAN STR. 30, OR-AKIVA 3060000

Registration number of this medicine in the Ministry of Health State Medicine Registry:
081-21-92207-00

Approved on 5.2020