

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

Oxygal Veterinary
Powder for dissolution in drinking water

2. Active ingredients and their quantity in a dosage unit

Oxytetracycline HCl 50%

For the list of the inactive ingredients in the product, see section 13 "Additional Information"

3. What is the medicine intended for?

For treatment of diseases caused by riketsia arlichia mycoplasma clamidia plasmodium glinesium spirocheta and other bacteria sensitive to tetracyclines in turkey.

For treatment and prevention of diseases caused by gram positive and gram negative bacteria sensitive to oxytetracycline in carp fish.

For the treatment of diseases caused by microorganisms susceptible to oxytetracycline in broilers.

Therapeutic group:

An antimicrobial product from the tetracyclines group

4. Contraindications

Do not use in cases of hypersensitivity to the active ingredient or any other substance from the tetracyclines group.

Do not use in cases of known resistance to tetracyclines.

In fish - do not use together with growth promoters or other antibiotics.

5. Side effects

Very rare effects (less than one animal in 10,000 animals treated) – gastro-intestinal disorder, allergy and photosensitivity.

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

Broilers

Turkeys

Carp fish

7. Dosage

Broilers: 40-60 grams per 100 liters of drinking water for 3-5 days as the only drinking source.

Fresh preparation every 12 hours.

Turkeys: 100 grams per 100 liters of drinking water for 3-5 days.

Fish: 150 grams of product per 1 tone live weight of fish by mixing in food, for 10 days.

8. How to use the product

Turkeys and Broilers - administer by dissolving in drinking water. Dissolve the powder in a small amount of drinking water and only then add water up to the final amount.

For fish, to be mixed with food.

9. Withdrawal period

Broilers: 7 days

Turkeys: 7 days

Carp fish: 20 days in 20°C temperature (400° days)

10. Warnings

- Special warnings regarding the use of this medicine in the treatment of poultry

Use of the product should be based on susceptibility testing of bacteria isolates from the animal. If not possible, therapy should be based on local epidemiological information about susceptibility of the target bacteria.

Use of the product deviating from the instructions given in the leaflet may increase the prevalence of bacteria resistant to the oxytetracycline and may decrease the effectiveness of treatment with tetracyclines, due to the potential for cross-resistance.

Prolonged or repeated use should be avoided as these practises can enforce development and spread of the bacterial resistance. This is particularly likely in enterobacteria and Salmonella spp., many of which are already resistant.

As eradication of the target pathogens may not be achieved, medication should be combined with good management practices, e.g., good hygiene, proper ventilation, no overstocking.

Extensive resistance to oxytetracycline has been recognized in poultry isolates of strains from E. Coli, Salmonella spp., Campylobacter spp. and Enterococcus spp.

The product should only be used where culture and sensitivity testing have demonstrated that it is likely to be effective.

- Special warnings regarding the safety of the person administering the product

People with known hypersensitivity to tetracyclines should avoid contact with the product.

Avoid inhaling dust when handling the product until complete solubilization in water.

Use in a well-ventilated area away from draughts.

Avoid contact with skin and eyes.

Therefore, use gloves, a protective mask, protective glasses and wear protective clothing when handling this product.

In case of accidental eye or skin contact, rinse the affected area with large amounts of clean water. If irritation occurs, refer immediately to a physician and show the physician this leaflet.

Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands and skin that was in contact with the product immediately after handling the product.

Do not smoke, eat or drink while handling the product.

- Incompatibilities

In fish, do not administer the product together with calcium products, certain growth promoters and bactericidal antibiotics.

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 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: below 25°C.

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

Any residue of a veterinary medical product or any waste obtained from the use of a veterinary medical product should be disposed of as toxic waste, do not throw into the sewage system.

13. Additional Information

- In addition to the active ingredient, the product contains Citric acid
- Package sizes: 250 gram, 1 kg, 5 kg.

Manufacturer and License holder: Biovac Ltd., 30 Hailan St., North Industrial Area, Or Akiva, 3060000

Registration number of this medicine in the Ministry of Health State Medicine Registry:
080-93-92200-00

Revised on 10.2023 in accordance with the guidelines of the Ministry of Health