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

Amprogal Veterinary, solution for administration in drinking water

2. Active ingredient

Amprolium hydrochloride 12% Inactive ingredients: see section "additional information"

3. What is the medicine intended for?

For prevention and treatment of coccidiosis disease in chickens. **Therapeutic group**: coccidiostats.

4. Contra-indications

Do not use in cases of known hypersensitivity to the active ingredient or to any of the inactive ingredients.

5. Side effects

If you noticed any serious side effects or other side effects that are not mentioned in this consumer leaflet, please inform your veterinarian.

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 (<u>www.health.gov.il</u>), which leads to an online form for reporting side effects. Alternatively you can use the following link: <u>https://sideeffects.health.gov.il</u>

6. Target animals

Broiler chickens

7. Dosage and route of administration

For administration in drinking water.

2 ml per one liter of water, for drinking consecutively for 2-3 days. After that the dosage can gradually be reduced to 1-1.5 ml per liter of water for 3-4 additional days, depending on the severity of the outbreak and the recommendations of the attending doctor.

8. How to use the product

When preparing the drinking water, the weight of the treated animals and their daily consumption of drinking water must be taken into account.

The consumption of drinking water may vary depending on the age, medical condition, breed and the husbandry of the animals.

The medicated drinking water should be the only source of drinking during the treatment, and the animals should have free access to them.

9. Withdrawal period: for slaughter for meat: 5 days.

10. Warnings

• <u>Special warnings regarding the use in the target animal:</u> Frequent and repeated use of antiprotozoal products from the same class or for a long period of time, increases the risk of developing drug resistance.

• <u>Special warnings concerning the safety of the person handling the product:</u>

People with known sensitivity to amprolium should avoid contact with these veterinary products.

The product must be handled carefully and inhaling or contact of the product with the skin or eyes, must be avoided.

Take special care when diluting the product in water:

- Wear a protective mask, gloves, overall and safety goggles.

- In case of contact with the skin and eyes, wash immediately with a large amount of water.

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

Laying:

No side effects have been described in laying birds

• Interactions with other drugs and other types of interactions: The product is an analog of thiamine. Its administration simultaneously with vitamin B complex could reduce its efficiency.

• Overdose:

Prolonged use may cause a decrease in the thiamine levels (if symptoms appear, thiamine should be administered).

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 the expiry date as appears on the bottle. The expiry date refers to the last day of the stated month.
- Storage conditions: Store below 25°C.
- Shelf life after dilution in drinking water: 24 hours.

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

Any residue of veterinary drugs or substances derived from veterinary products must be disposed of in accordance with the disposing instructions of the Ministry of the Environment.

13. Additional information

- In addition to the active ingredient, this medicine also contains: Purified Water, Propylene Glycol
- What does the medicine look like and what is the content of the package: clear light-yellow solution in a plastic bottle. Pack size: 1 L.

Manufacturer and License holder: BIOVAC LTD., 30 Hailan St., North industrial area, OR-AKIVA, 3060000

Revised in November 2022 according to the MOH's guidelines.

Registration number of the product in the National Drug Registry at the Ministry of Health : 083-33-92367