

PACKAGE LEAFLET FOR VETERINARY MEDICINAL PRODUCT

This medicine is dispensed with a veterinarian's prescription only
For veterinary use only

1. NAME OF THE MEDICINE, ITS FORM AND STRENGTH:

Gallifen Veterinary

Suspension for use in drinking water for chickens.

2. ACTIVE INGREDIENT AND OTHER INGREDIENTS

1 ml suspension contains:

Fenbendazole 200 mg

For the full list of excipients, see section 13 "Other Information".

3. WHAT IS THE MEDICINE INTENDED FOR

Treatment of chicken infected with *Heterakis gallinarum* (adult stages) or *Ascaridia galli* (adult stages).

4 . CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

5. ADVERSE REACTIONS

None known.

You can report side effects to the Ministry of Health by clicking on the link "Report side effects resulting from medicinal treatment" found on the homepage of the Ministry of Health website (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

If you notice any side effects, or you think that the medicine has not worked, please inform your veterinary surgeon.

6. TARGET SPECIES

Chickens

7. DOSAGE, ROUTE AND METHOD OF ADMINISTRATION

In drinking water use.

Shake well before use.

The dose is 1.0 mg fenbendazole per kg body weight per day (equivalent to 0.005 ml of the product). This dose has to be administered on 5 consecutive days.

Dose calculation:

The required daily amount of product is calculated from the total estimated body

weight (kg) of the entire group of chickens to be treated. Please use the following formula:

$\text{ml product/day} = \text{total estimated body weight (kg) of chickens to be treated} \times 0.005 \text{ ml}$

8. HOW TO USE THE MEDICINAL PRODUCT

To ensure administration of the correct dose, body weight should be determined as accurately as possible.

Before allowing animals to have access to the medicated water, the water delivery system should be drained, if possible, and flushed with the medicated water to ensure accuracy of dosing. This procedure may need to be performed on all treatment days.

The uptake of medicated water depends on age and clinical conditions of the birds, ambient temperature and light regime. In order to obtain the correct dosage concentration of the product should be adjusted accordingly.

Follow the instructions described below to prepare the medicated water. Use a sufficiently accurate commercially available measuring device.

For each treatment day the medicated water needs to be freshly prepared.

For use in medication tank:

Add the calculated amount of product to 40-80% of the daily water ration. Stir until content in the medication tank is visibly homogeneous. The medicated water appears hazy. No further stirring during administration is necessary.

For use in dosing pump:

Add the calculated amount of product to the unmedicated water in the stock suspension container of the dosing pump. The volume of unmedicated water in the stock suspension container has to be calculated taking as a basis the preset injection rate of the dosing pump and 40 to 80% of the chickens' daily water ration. Stir until content in the stock suspension container is visibly homogeneous. The medicated water appears hazy.

During treatment all animals must have unrestricted access to the medicated water as the sole source of drinking water.

During treatment, after complete consumption of the medicated water, animals must be allowed access to un-medicated drinking water as soon as possible.

Ensure that the total amount of medicated water offered is consumed.

9. WITHDRAWAL PERIODS

Meat and offal: 6 days.

Eggs: zero days.

10. SPECIAL WARNING(S)

Special warnings for target species:

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.

Under dosing, which may be due to underestimation of body weight,

misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Special precautions for use in animals:

The safety of the product at overdose has not been evaluated in chickens of less than 3 weeks of age.

Use of the product deviating from the instructions in the package leaflet may increase the risk of development of resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Embryotoxic effects cannot be excluded. Pregnant women must take extra precautions when handling this veterinary medicinal product.

This veterinary medicinal product may be toxic to humans after ingestion.

This product may cause eye irritation.

Contact with the skin and the eyes or accidental ingestion of the product should be avoided.

Do not smoke, eat or drink when handling the veterinary medicinal product.

In the event of accidental ingestion, rinse mouth with plenty of clean water and seek medical advice. In the event of accidental contact with the skin or eyes, rinse with plenty of clean water and seek medical advice.

Wash hands after use.

Pregnancy, lactation or lay:

Chicken: Can be used during lay. The safety of the veterinary medicinal product has not been established in male birds. Therefore use in male birds only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose

No adverse reactions have been observed at up to 5-fold of dose of 2 mg/kg body weight/day in broilers (aged approximately 3 weeks) No adverse reactions have been observed at up to 3-fold of dose of 2 mg/kg body weight/day in layers and breeders.

Incompatibilities:

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, as well as all other medicines, must be stored in a closed place out of the sight and reach of children and/or infants, in order to prevent poisoning.

Storage conditions: Store below 30°C.

Storage conditions after first opening: Below 25°C.

Product as packed for sales and after first opening: Do not freeze. Protect from frost.
Medicated water: Do not freeze.

Shelf life of the product after first opening in its original package: 3 months.

Shelf life after reconstitution in drinking water: 24 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after "EXP". The expiry date refers to the last day of that month.

12. INSTRUCTIONS FOR THE DISPOSAL OF THE MEDICINAL PRODUCT/ REMNANTS OF THE MEDICINAL PRODUCT AFTER USE

All remnants of a veterinary medicinal product, or any waste produced by use of a veterinary medicinal product, must be disposed of as poisonous waste. Do not dispose of via wastewater.

The product should not enter water courses as this may be dangerous for aquatic organisms.

13. FURTHER INFORMATION

- In addition to the active ingredients, this medicinal product also contains:
Water for injection, Povidone, Docusate sodium, Sodium benzoate 3.0 mg/ml, Hydrochloric acid

- What the medicine looks like and what the package contains:

White to almost white suspension packed in:

White cylindrical High Density Polyethylene (HDPE) bottle with white polypropylene (PP) screw tamper-evident closure of 125 ml and 1 litre; white rectangular HDPE bottle of 1 litre with vertically see-through bar and without graduated scale closed with white PP tamper-evident screw cap; white HDPE canisters with white HDPE ribbed tamperevident screw cap of 2.5 litres and 5 litres.

Not all pack sizes may be marketed.

Registration holder and importer:

G.W.Oracel International Ltd, Hahita 5, Moshav Sittriya 76834

Producer:

BIOVET Joint Stock Company

39, Petar Rakov St., Peshtera 4550, Bulgaria

Approved in: 07.2023

Registration number of the medicinal product in the Ministry of Health National Drug Registry:173-23-35803-00

