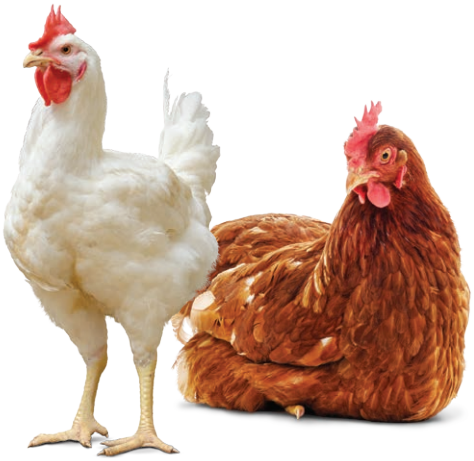
Gallifen®

200 mg fenbendazole/ ml
Suspension for use in drinking water for chickens



Easy deworming

HUVEPHARMA®
We add performance to your business

INTRODUCTION

Origin of the molecule

Fenbendazole is an anthelmintic belonging to the benzimidazole-carbamate group. The benzimidazoles were introduced into the animal health market primarily for the control of gastrointestinal nematodes. Their use quickly became widespread because they offered major advantages over previous medications in terms of:

- spectrum
- efficacy against immature stages
- safety for the host animal

They did not cause a set-back due to drug toxicity and it was possible to demonstrate the economic advantage of strategic treatment, even under conditions of mild parasitism.

Activity

Fenbendazole has a very broad spectrum anthelmintic activity against most prevalent worm infections:

- ***Ascaridia galli:*** the large roundworm is the most common and damaging worm.
- ***Heterakis gallinarum*** is a small roundworm that also plays a crucial role in the spread of the blackhead parasite *Histomonas*.

Pharmacodynamics

Fenbendazole acts by binding to beta-tubulin, thereby inhibiting the polymerisation of tubulin to microtubules and subsequently interfering with energy metabolism. The molecule is effective at killing all adult , larval stages and eggs of worm parasites.

Resistance

Resistance to fenbendazole is not widespread nor viewed to be a major problem.

Indications for use

Chickens

Gallifen® 200 mg fenbendazole/ ml suspension for use in drinking water for chickens is indicated for the treatment of chickens infected with *Ascaridia galli* and *Heterakis gallinarum*.

Formulation: Nanosuspension

Gallifen® 200 mg/ml suspension is developed by an innovative nanosuspension technology, ensuring all particles have a very small particle size in the nanometer range.

Benefits

- **Efficacy**
  - Homogenous suspension
    - Independent of water quality
    - In different kinds of administration systems for water medication
  - Higher bio-availability and stability
- **Safety**
  - No sedimentation
  - No obstructions
  - No risk of residues in pipelines
- **Convenience**
  - No additional steps needed
  - Very short preparation time

Gallifen® nanosuspension

Homogeneity
Small particles

Other suspensions

Disadvantages

-Predilution step
-Additional stirring

Precipitation
Bigger particles

- **Profit eaters**
  - Often subclinical infection
  - Egg production and hatchability ↘
  - Body weight gain ↘ and feed conversion rate ↗
  - Reduced immune response
  - Poor condition

- **Persistent re-infection**
  - Fast and massive excretion of sticky eggs
  - Eggs survive for more than 5 years in environment

- **High infection rate in layers, breeders and pullets**

- **Faecal-oral infection route**

BREEDERS

PULLETS

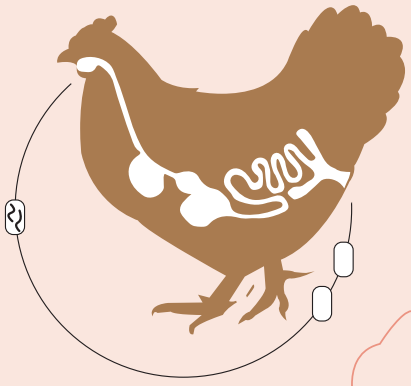
CAGE FREE HOUSED LAYING HENS

Aviary systems - barn egg production

Free range - Organic husbandry

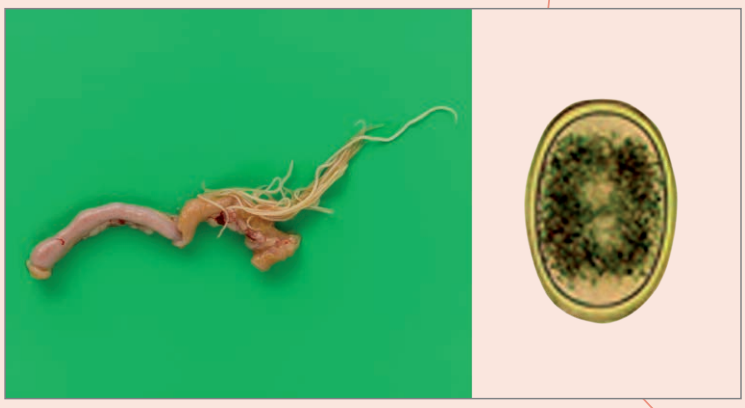
ASCARIDIA GALLI AND HETERAKIS GALLINARUM

- **Most prevalent worms**
- **Direct life cycle without intermediate host**



- **Diagnosis**
  - Necroscopy
  - Coproscopy

Ascaridia galli – Large roundworm



Prepatent period: 6 weeks
Adult stadia of 4-5 cm in small intestines

Heterakis gallinarum – Small roundworm

Prepatent period : 4 weeks
Adult stadia of 7-15 mm in caeca
Vector for *Histomonas meleagridis* (Blackhead disease)

Gallifen®

Contra-indications
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients

Special warnings for each 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 less than 8 weeks old. The efficacy of the veterinary medicinal product at the recommended dosage is not sufficient for the treatment of infections with *Capillaria spp.* The absence of *Capillaria spp.* infestation should be confirmed prior to use of the product. In case of *Capillaria* infestation another appropriate anthelmintic veterinary medicinal product should be used. Use of the product deviating from the instructions in the SPC may increase the risk of development of resistance.

Special precautions to be taken by the person administering the 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. Wear goggles and impervious gloves to avoid direct skin and eye contact with the product when handling or preparing medicated drinking water. 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.

Other precautions
The veterinary medicinal product should not be allowed to enter surface waters as it has harmful effects on aquatic organisms.

Adverse reactions (frequency and seriousness)
None known

Use during lay
Can be used during lay.

Interaction with other medicinal products and other forms of interaction
None known.

Major incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. The product should not enter water courses as this may be dangerous for aquatic organisms.

EFFICACY OF GALLIFEN® ORAL SUSPENSION

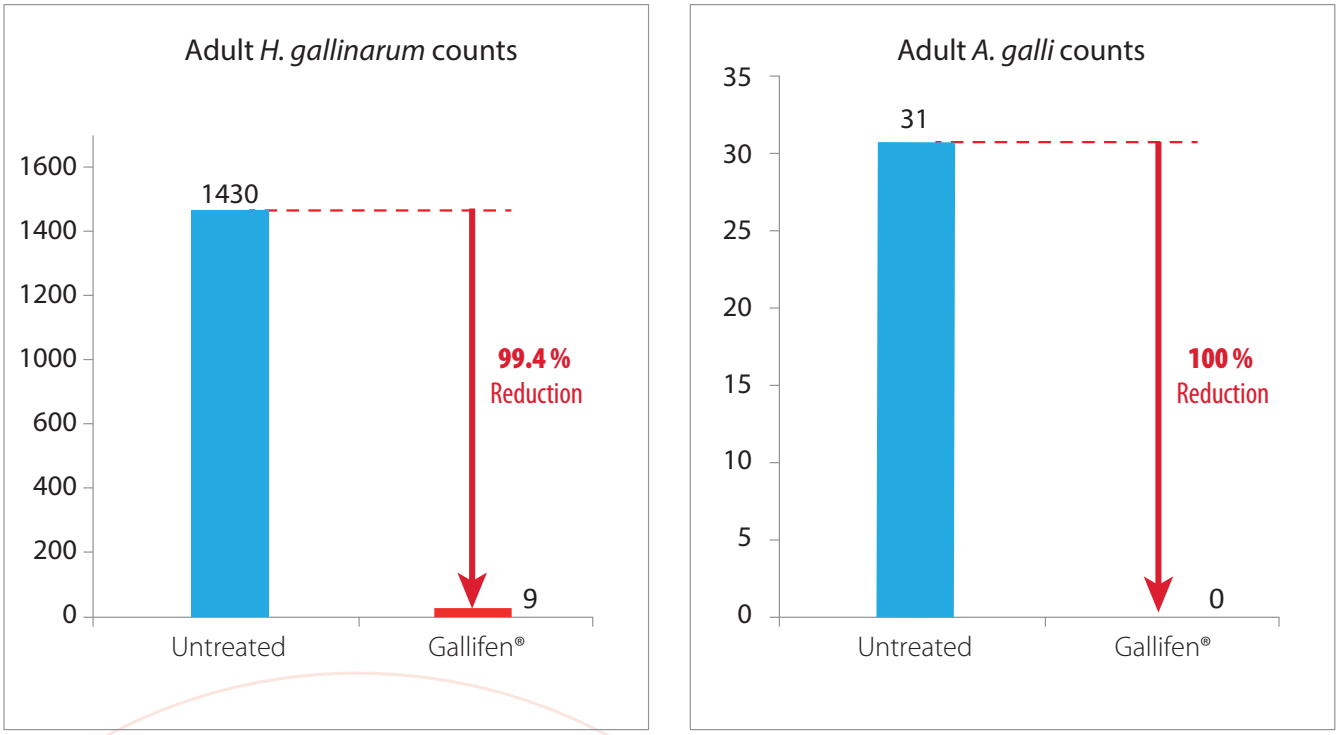


Fig.: Efficacy of a treatment with Gallifen® 200 mg/ml oral suspension against natural co-infections of Ascaridia galli and Heterakis gallinarum in layer chickens. Gallifen® was administered at 1 mg fenbendazole/ kg bodyweight/ day for 5 consecutive days. 5 Days after treatment, the total number of adult worms in treated layers were compared to an untreated control group (both groups: n=30). Internal data.

Deworming strategy:

- Repeated treatments every **6 weeks**
- Significant reduction of infection pressure
- Benefits
  1. Improved technical performances
  2. Improved general health status
  3. Reduction of transmission of other diseases
     - *Histomonas meleagridis*
     - *Salmonella*
     - Viruses

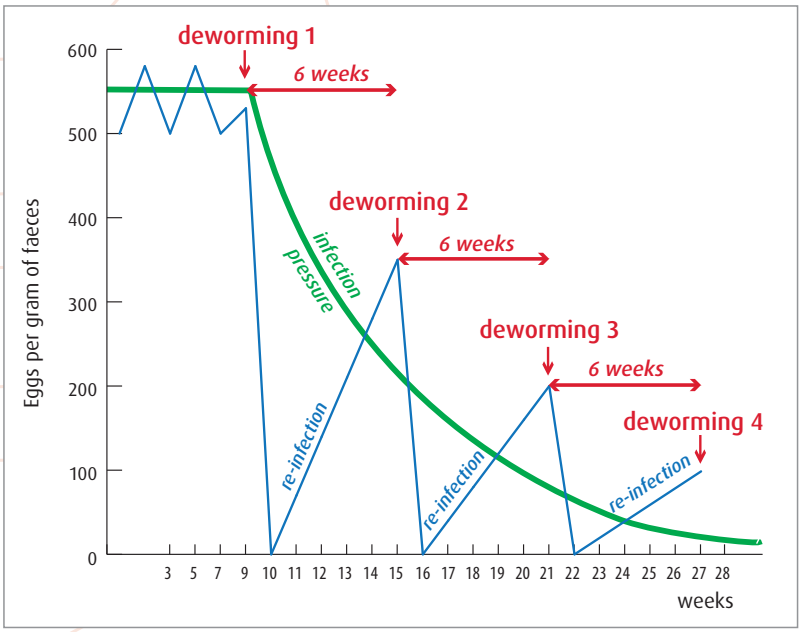


Fig.: Deworming strategy

DEWORMING STRATEGY: EVERY 6 WEEKS

Gallifen® 200 mg/ml suspension

Product specifications

- 1 ml contains 200 mg fenbendazole
- White to almost white suspension

Dosing

- For use in drinking water
- In medication tanks and dosing pumps
- Stir until visibly homogenous
- No further stirring during administration is necessary

Fenbendazole/ kg bodyweight		
Daily dose	1 mg	for 5 consecutive days
Total dose	5 mg	

Gallifen® oral suspension/ 1000 kg bodyweight		
Daily dose	5 ml	for 5 consecutive days
Total dose	25 ml	

Packaging	Total bodyweight
125 ml	5.000 kg
1 l	40.000 kg
2.5 l	100.000 kg
5 l	200.000 kg

Strategic deworming

Every 6 weeks

Withdrawal period

Eggs: **0 days**

Meat and offal: **6 days**

Shelf life and storage

- Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
- Shelf life after first opening the immediate packaging: 3 months.
- Shelf life of the medicated drinking water: 24 hours.

Protect product as packed for sale and after first opening from frost. Do not freeze medicated water.

Overdose

No adverse reactions have been observed at up to 5-fold overdose in broilers (aged approximately 8 weeks). No adverse reactions have been observed at up to 3-fold overdose in layers and breeders.

Packaging

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 with an LDPE insert closed with white PP tamper- evident screw cap with a LDPE sealing disk.White HDPE canisters with white HDPE ribbed tamper-evident screw cap of 2.5 litres and 5 litres.

*Used references can be obtained upon demand.
*Gallifen® suspension brochure follows the authorized EU SPC (available on request).
*Indications listed above are not necessarily authorized in all countries.
*Please consult the local label for exact indications and posology.
*Use medicines responsibly.
*POM-V
*VM 30282/4037

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