ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE BOTTLE/CANISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallifen 200 mg/ml suspension for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Fenbendazole 200 mg/ml

3. PACKAGE SIZE

125 ml
1 L
2.5 L
5 L

4. TARGET SPECIES

Chickens and pheasants.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Suspension for use in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Chickens:
Meat and offal:
6 days for the dosage 1 and 2 mg fenbendazole/kg body weight/day
8 days for the dosage 3 mg fenbendazole/kg body weight/day
Eggs: zero days

Pheasants:
Meat and offal: 6 days
Do not release pheasants for hunting for at least 6 days after the end of medication.
Eggs: zero days

8. EXPIRY DATE

Exp.

Shelf life after first opening the immediate package: 3 months. Once opened use by….
Shelf life after dilution according to directions: 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Veterinary medicinal product as packed for sales and after first opening:
Do not freeze.
Protect from frost.

Medicated water:
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS

Vm 30282/3005

15. BATCH NUMBER

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Gallifen 200 mg/ml suspension for use in drinking water for chickens and pheasants

2. Composition

Each ml contains:

Active substance:
Fenbendazole 200 mg

Excipients:
Sodium benzoate 3 mg

White to almost white suspension for use in drinking water.

3. Target species

Chickens
Pheasants

4. Indications for use

Treatment of chickens infected with *Heterakis gallinarum* (adult stages), *Ascaridia galli* (adult stages), *Capillaria obsignata* (adult stages) or *Raillietina echinobothrida* (adult stages).
Treatment of pheasants infected with *Heterakis gallinarum* (adult stages).

5. Contraindications

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

6. Special warnings

Special warnings:
The veterinary medicinal product is to be used at the maximum recommended dose of 3 mg/kg/day for 10 consecutive days for the treatment of *Raillietina echinobothrida* which is encountered in free-ranging and traditionally reared poultry. Intensively reared broiler chickens are unlikely to be infected with *Raillietina echinobothrida*.

Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each flock.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a flock, maintenance of susceptible refugia is essential to reduce that risk.

Systematically applied interval-based treatment and treatment of a whole flock should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific flock should be sought from the responsible veterinarian.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test (FECRT). Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product at overdose has not been evaluated in chickens of less than 14 days of age and in pheasants of less than 3 weeks of age.

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 veterinary medicinal product may cause eye irritation.

Contact with the skin and the eyes or accidental ingestion of the veterinary medicinal 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.

Special precautions for the protection of the environment:
The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.

Due to the lack of an environmental risk assessment, do not use the veterinary medicinal product at 3 mg/kg/day for 10 days in intensively reared broilers (see also section ‘Special warnings’).

Laying birds:
See also section ‘Overdose’.
Chickens: can be used during lay.

Fertility:
Chickens: 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.

Pheasants: the safety of the veterinary medicinal product has not been evaluated in breeding pheasants. Therefore in these birds use 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 6.7-fold the maximum recommended dose of 3 mg/kg body weight/day over 30 days in broilers (aged approximately 14 days) and up to a 40-fold overdose in pheasants (aged approximately 3 weeks).
No adverse reactions have been observed in layers and breeders administered a dose rate of 4-fold the maximum recommended dose of 3 mg/kg body weight/day (i.e., 12 mg/kg body weight/day) over 30 days, however offspring viability (including reduced incubation survival, reduced fertility (fewer eggs hatched) and lower body weight of chicks) was adversely affected at this dose rate.
Increased frequency of physical abnormalities of eggs was observed at dose rates of 3- and 4-fold the maximum recommended dose of 3 mg/kg body weight/day administered over 30 days.
No adverse effects on offspring viability or egg physical characteristics were observed at 2-fold the maximum recommended dose of 3 mg/kg/day (chickens) over 30 days in layers and breeders.

Special restrictions for use and special conditions for use:
Not applicable.

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

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>.

8. Dosage for each species, routes and method of administration

In drinking water use.

Shake well before use.

Ascaridia galli and *Heterakis gallinarum:* The dose is 1.0 mg fenbendazole per kg body weight per day (equivalent to 0.005 ml of the veterinary medicinal product). This dose has to be administered on 5 consecutive days.
Capillaria obsignata: The dose is 2.0 mg fenbendazole per kg body weight per day (equivalent to 0.01 ml of the veterinary medicinal product). This dose has to be administered on 5 consecutive days.
Raillietina echinobothrida: The dose is 3.0 mg fenbendazole per kg body weight per day (equivalent to 0.015 ml of the veterinary medicinal product). This dose has to be administered on 10 consecutive days.

Dose calculation:
The required daily amount of veterinary medicinal product is calculated from the total estimated body weight (kg) of the entire group of chickens or pheasants to be treated. Please use the following formula:

Treatment of *Ascaridia galli* and *Heterakis gallinarum:*

ml veterinary medicinal product/day = total estimated body weight (kg) of chickens/pheasants to be treated x 0.005 ml

Treatment of *Capillaria obsignata*:

ml veterinary medicinal product/day = total estimated body weight (kg) of chickens to be treated x 0.01 ml

Treatment of *Raillietina echinobothrida*:

ml veterinary medicinal product/day = total estimated body weight (kg) of chickens to be treated x 0.015 ml

9. Advice on correct administration

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.
Accuracy of the dosing device should be thoroughly checked.

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 intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of fenbendazole may need to 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:
For use in chickens, add the calculated amount of veterinary medicinal product to 40-80% of the daily water ration. For use in pheasants, add the calculated amount of veterinary medicinal product to 40% 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 veterinary medicinal 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 or 40% of the pheasants' 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.

10. Withdrawal periods

Chickens:
Meat and offal:
6 days for the dosage 1 and 2 mg fenbendazole/kg body weight/day
8 days for the dosage 3 mg fenbendazole/kg body weight/day
Eggs: zero days

Pheasants:
Meat and offal: 6 days
Do not release pheasants for hunting for at least 6 days after the end of medication.
Eggs: zero days

11. Special storage precautions

Keep out of the sight and reach of children.

Veterinary medicinal product as packed for sales and first opening:
Do not freeze.
Protect from frost.

Medicated water:
Do not freeze.

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.

Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution according to directions: 24 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 30282/3005

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 tamper-evident screw cap of 2.5 litres and 5 litres.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

October 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

<+32 3 292 83 05 or +32 3 288 18 49>
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

<Local representatives and contact details to report suspected adverse reactions:>

17. Other information

Approved: 12 March 2024