A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallifen 40 mg/g premix for medicated feeding stuff for chickens and pheasants
Fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:
Fenbendazole 40 mg

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

4. PACKAGE SIZE

1 kg
2 kg
5 kg
20 kg

5. TARGET SPECIES

Chickens.
Pheasants.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 8 days. Do not release pheasants for hunting for at least 8 days after the end of medication.

Eggs: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Exp:

Once opened use by….

Shelf-life after first opening: 3 months.

Shelf life after incorporation into meal or pelleted feed: 3 months.

11. SPECIAL STORAGE CONDITIONS

After first opening of the immediate packaging: Do not store above 25°C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 30282/4029

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Gallifen 40 mg/g premix for medicated feeding stuff for chickens and pheasants

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallifen 40 mg/g premix for medicated feeding stuff for chickens and pheasants.
Fenbendazole.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:

Fenbendazole 40 mg

Off-white to light yellow granules.

4. INDICATION(S)

Treatment of chickens infected with *Heterakis gallinarum* (L5 and adult stages) and *Ascaridia galli* (adult stages).
Treatment of pheasants infected with *Heterakis gallinarum* (adult stages).

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Chickens.
Pheasants.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use. In feed use.

9. ADVICE ON CORRECT ADMINISTRATION

The daily dose is 1 mg fenbendazole per kg b.w. per day administered in feed for 5 consecutive days.

For the preparation of medicated feed:

1 mg fenbendazole per kg bw per day corresponds to 0.025 g of the product per kg bw per day.

For the preparation of the medicated feed the body weight of the animals to be treated and their actual daily intake of feed should be taken into due account.

To provide the required amount of fenbendazole per kg medicated feed the premix has to be incorporated into the feed according to the following formula:

$$\frac{\text{0.025 g of the product per kg b.w. daily} \times \text{average body weight (kg) of the animals to be treated}}{\text{average daily feed intake per animal (kg)}} = \text{g of the product per kg feed}$$

For incorporation into dry feed at the registered mill:

A manufacturer who is approved to incorporate veterinary medicinal products, or premixtures containing such products, directly at any concentration, must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

To ensure adequate distribution of the product in the final feed it is recommended to premix the product at a ratio of 1:10 with feed ingredients before blending into the final feed.

If the premix is used for supplementation of pelleted feed, the pelleting temperature should not exceed 105 °C.

Not to be mixed in liquid feed.

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

The uptake of medicated feed depends on the clinical condition of the animals and environmental factors. The feed intake should be monitored regularly and the incorporation rate adjusted accordingly in order to guarantee an intake of 1 mg fenbendazole per kg bodyweight per day.

10. WITHDRAWAL PERIODS

Meat and offal: 8 days. Do not release pheasants for hunting for at least 8 days after the end of medication.

Eggs: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf life after first opening the container: 3 months.

Shelf life after incorporation into meal or pelleted feed: 3 months.

Veterinary medicinal product as packaged for sale: no special storage precautions. After first opening of the immediate packaging: do not store above 25°C.

Medicated feed (mash and pelleted): no special storage precautions.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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.

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).

Special precautions for use in animals:

The safety of the product at overdose has not been evaluated in chickens less than 8 weeks old.

Do not use in cases of *Capillaria* spp. infestations. 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 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.

Accidental ingestion of the product should be avoided.

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

This product may cause eye irritation and skin sensitisation.

Avoid contact with the eyes and skin.

When handling or mixing, care should be taken to avoid direct contact with the skin and eyes, and inhalation of dust, by wearing goggles, impervious gloves and a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.

Wash hands after use.

In case of skin and/or eye contact, immediately rinse with plenty of water

Pregnancy and lactation:
Can be used in chickens in lay.
The safety of the 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 undesirable effects have been observed in chickens (8-9 weeks of age) at up to 5 times the recommended dose.

Although not observed in other studies investigating the effects of overdosing, an increase in water intake vs. controls has been reported in laying hens treated with a dose exceeding 3X the recommended dose. An effect on water intake can therefore not be excluded when using this product in conditions of overdosing.

A small (<3%) but statistically significant difference in mean body weight of chicks from treated layers was observed in conditions of overdosing (3X the recommended dose for a duration exceeding 3X the recommended one in clinical conditions).

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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 fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2021

15. OTHER INFORMATION

The product is distributed in polyethylene-aluminium-paper /paper/paper bag of 20 kg, as well as in polyethylene/aluminium foil/polyethylene terephthalate zipper bags of 1, 2 and 5 kg.

Not all pack sizes may be marketed.

Approved: 16/12/21