PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Bag

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gallifen 40 mg/g premix for medicated feeding stuff

2. STATEMENT OF ACTIVE SUBSTANCES

Fenbendazole 40 mg/g

3. PACKAGE SIZE

1 kg
2 kg
5 kg
20 kg

4. TARGET SPECIES

Chickens and pheasants.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Chickens:
Meat and offal: 8 days.
Eggs: Zero days.

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate package: 3 months. Once opened use by….

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

9. SPECIAL STORAGE PRECAUTIONS

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

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 30282/3029 & 30282/5027

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each gram contains:

Active substance:
Fenbendazole 40 mg

Off-white to light yellow granules.

3. Target species

Chickens.
Pheasants.

4. Indications for use

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. Special warnings

Special warnings:
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 veterinary medicinal product, or lack of calibration of the dosing device (if any).

Special precautions for safe use in the target species:
The safety of the veterinary medicinal 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 veterinary medicinal product. In case of *Capillaria* infestation another appropriate anthelmintic veterinary medicinal product should be used. Use of the veterinary medicinal 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:

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

This veterinary medicinal product may cause eye irritation and skin sensitisation.

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

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.

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

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

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

Wash hands after use.

Special precautions for the protection of the environment:
The veterinary medicinal product should not be allowed to enter surface waters as it has harmful effects on aquatic organisms.

Laying birds:
Can be used in chickens in lay.
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.

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 veterinary medicinal 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).

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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

In feed use.

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

9. Advice on correct administration

For the preparation of medicated feed:

1 mg fenbendazole per kg bodyweight per day corresponds to 0.025 g of the veterinary medicinal product per kg bodyweight per day.

For the preparation of the medicated feed the bodyweight 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:

I 0.025 g of the veterinary medicinal product per kg bodyweight daily **II** X **III** average bodyweight (kg) of the animals to be treated **IV**

VI ---------- **VII** = **V** g of the veterinary medicinal product per kg feed

VIII average daily feed intake per animal (kg) **IX**

For incorporation into dry feed at the registered mill:

A manufacturer who is approved to incorporate veterinary medicinal products, or premixtures containing such veterinary medicinal 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 veterinary medicinal product in the final feed it is recommended to premix the veterinary medicinal 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, bodyweight 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

Chickens:
Meat and offal: 8 days.
Eggs: Zero days.

Pheasants:
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 immediate packaging: 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 precautions for disposal

Medicines should not be disposed of via wastewater.

This 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 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 30282/3029 & 30282/5027

Polyethylene-aluminium-paper/paper/paper bag of 20 kg and polyethylene/aluminium foil/polyethylene terephthalate zipper bags of 1, 2 and 5 kg.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
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

POM-V

Gavin Hall

Approved: 27 December 2024