SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Fenbendazole 40 mg

Excipients:

Qualitative composition of excipients and other constituents
Maize starch
Starch, pregelatinised

Off-white to light yellow granules.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and pheasants.

3.2 Indications for use for each target species

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).

3.3 Contraindications

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

3.4 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).

3.5 Special precautions for use

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 fenbendazole may be dangerous for fish and other aquatic organisms.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

Can be used in chickens in lay.

Fertility:

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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

In feed use.

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

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:

$$\frac{\text{0.025 g of the veterinary medicinal product per kg bodyweight daily} \times \text{average bodyweight (kg) of the animals to be treated}}{\text{average daily feed intake per animal (kg)}} = \text{g of the veterinary medicinal product per kg feed}$$

For incorporation into dry feed at the registered mill:

A manufacturer who is approved to incorporate veterinary medicinal products, or premixtures containing such 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 studies investigating the effects of overdosing in other classes of the target species, an increase in water intake compared with controls has been reported in laying hens treated with a dose exceeding 3X the recommended dose.

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).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AC13

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4.2 Pharmacodynamics

Fenbendazole is an anthelmintic belonging to the benzimidazole-carbamate group. It acts by interfering with the energy metabolism of the nematode.

Fenbendazole inhibits the polymerisation of tubulin to microtubules. This interferes with essential structural and functional properties of the cells of helminths, such as formation of the cytoskeleton, formation of the mitotic spindle and the uptake and intracellular transport of nutrients and metabolic products. Fenbendazole has activity against *Ascaridia galli* (adult stage) and *Heterakis gallinarum* (L5 and adult stages) in chickens and against *H. gallinarum* (adult stage) in pheasants.

4.3 Pharmacokinetics

After oral administration fenbendazole is only partially absorbed. Following absorption, fenbendazole is rapidly metabolised in the liver mainly to its sulphoxide (oxfendazole) and further to its sulphone (oxfendazole sulphone). In chickens oxfendazole sulfone is the main component detected in plasma, accounting for about 3/4 of the total AUC (ie the sum of the AUC for fenbendazole, oxfendazole and oxfendazole sulphone). Fenbendazole and its metabolites are distributed throughout the body, reaching highest concentrations in the liver.

The elimination of fenbendazole and its metabolites occurs primarily via the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 3 months.

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

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

Polyethylene-aluminium-paper/paper/paper bag of 20 kg.

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

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBERS

Vm 30282/3029 & 30282/5027

8. DATE OF FIRST AUTHORISATION

24 January 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 27 December 2024