Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:	
Fenbendazole	200 mg
Excipients:	
Sodium benzoate (E211)	3 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for use in drinking water.
White to almost white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens
Pheasants

4.2 Indications for use, specifying the target species

Treatment of chickens infected with *Heterakis gallinarum* (adult stages) or *Ascaridia galli* (adult stages).
Treatment of pheasants infected with *Heterakis gallinarum* (adult stages) (see section 4.7).

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

i. Special precautions for use in animals

The safety of the product at overdose has not been evaluated in chickens less than 8 weeks old and in pheasants less than 3 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.

ii. 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.

iii. Other precautions

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

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Chicken: Can be used during lay.

Pheasants: 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.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For use in drinking water.

Shake well before use.

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

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 uptake of medicated water depends on age and clinical conditions of the birds, ambient temperature and light regime. In order to obtain the correct dosage concentration of the product should be adjusted accordingly.

The dose is 1.0 mg fenbendazole per kg body weight per day (equivalent to 0.005 ml Gallifen suspension). This dose has to be administered on 5 consecutive days.

Dose calculation:
The required daily amount of 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:
ml product/day = total estimated body weight (kg) of chickens/pheasants to be treated x 0.005 ml

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 product to 40-80% of the daily water ration. For use in pheasants, add the calculated amount of 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 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 solely but unrestricted access to the medicated 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions have been observed at up to 5-fold overdose in broilers (aged approximately 8 weeks) and up to a 40-fold overdose in pheasants (aged approximately 3 weeks). No adverse reactions have been observed at up to 3-fold overdose (chickens) in layers and breeders.

4.11 Withdrawal period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazole derivatives - fenbendazole.
ATCvet Code: QP52AC13

5.1 Pharmacodynamic properties

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 is active and has a dose dependent activity on adult *Heterakis gallinarum* and *Ascarida galli* in chickens, and activity against adult *Heterakis gallinarum* in pheasants.

5.2 Pharmacokinetic particulars

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 (i.e. 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Docusate sodium
Povidone
Hydrochloric acid, concentrated (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

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.

6.4 Special precautions for storage

Product as packed for sales and after first opening: Do not freeze. Protect from frost.
Medicated water: Do not freeze.

6.5 Nature and composition of immediate 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.

Not all pack sizes may be marketed.

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

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.

7 MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA10782/030/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th March 2018

10 DATE OF REVISION OF THE TEXT

May 2019