

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pigfen 200 mg/ml suspension for use in drinking water for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Fenbendazole 200 mg

Excipients:

Sodium benzoate 3 mg

For the full list of excipients, see section 6.

3. PHARMACEUTICAL FORM

Suspension for use in drinking water.

White to almost white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Treatment of pigs infected with *Ascaris suum* (adult, intestinal and migrating larval stages)

4.3 Contra-indications

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

4.4 Special warning 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

None

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

Administration of fenbendazole (500 mg/kg) to sows between days 8 and 33 of pregnancy produced no foetal effects. The safety of the product has not been established during lactation. Use according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Exacerbation of paracetamol hepatotoxicity by fenbendazole cannot be excluded.

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 dose is 2.5 mg fenbendazole per kg body weight per day (equivalent to 0.0125 ml Pigfen oral suspension per kg body weight per day). This dose has to be administered on 2 consecutive days.

Dose calculation:

The required daily amount of product is calculated from the total estimated body weight

(kg) of the entire group of pigs to be treated. Please use the following formula:

$$\text{ml product/day} = \frac{\text{total estimated body weight (kg) of pigs to be treated} \times 0.0125}{\text{ml}}$$

For each treatment day the medicated water needs to be freshly prepared. Follow the instructions described below to prepare the medicated water. Use a sufficiently accurate commercially available measuring device.

For use in medication tank:

Add the calculated amount of product to the volume of drinking water usually consumed by the animals over 6 hours. 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 into account the preset injection rate of the dosing pump and the volume of drinking water usually consumed by the animals over 6 hours. 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 undesirable effects have been observed in pigs at up to 5 times the recommended dose.

4.11 Withdrawal periods

Meat and offal: 4 days.

5. PHARMACOLOGICAL PROPERTIES

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 the adult-, intestinal and migratory stages of *Ascaris suum*.

5.2 Pharmacokinetic particulars

After oral administration fenbendazole is only partially absorbed. Following absorption, fenbendazole is rapidly metabolised in the liver mainly to its sulfoxide

(oxfendazole) and further to its sulphone (oxfendazole sulphone). In pigs oxfendazole is the main component detected in plasma, accounting for about 2/3 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 and to a small extent in the urine.

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 product or waste materials derived from the use of such products, if appropriate

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 N.V.
Uitbreidingstraat 80
2600 Antwerpen
Belgium

8. MARKETING AUTHORISATION NUMBER

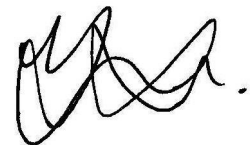
Vm 30282/4038

9. DATE OF FIRST AUTHORISATION

05 April 2018

10. DATE OF REVISION OF TEXT

July 2022

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 27 July 2022