# 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

Each ml contains:

**Active substance:**
Fenbendazole 200 mg

**Excipients:**

| Qualitative composition of excipients and other constituents | Quantitative composition if that information is essential for proper administration of the veterinary medicinal product |
|---|---|
| Sodium benzoate (E211) | 3 mg |
| Docusate sodium | |
| Povidone | |
| Hydrochloric acid, concentrated (for pH adjustment) | |
| Water for injections | |

White to almost white suspension.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs.

### 3.2 Indications for use for each target species

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

### 3.3 Contraindications

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

### 3.4 Special warnings

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).

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.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

None.

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 veterinary medicinal product may cause eye irritation.

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

Do not smoke, eat or drink when handling the veterinary medicinal product.

Personal protective equipment consisting of goggles and impervious gloves should be worn when handling the veterinary medicinal product.

In case of accidental ingestion, rinse mouth with plenty of clean water and seek medical advice immediately and show the package leaflet or the label to the physician. 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.

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.

## 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 also the package leaflet for respective contact details.

## 3.7 Use during pregnancy, lactation or lay

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

## 3.8 Interaction with other medicinal products and other forms of interaction

Exacerbation of paracetamol hepatotoxicity by fenbendazole cannot be excluded.

## 3.9 Administration routes and dosage

In drinking water use. Shake well before use.

To ensure a correct dosage, 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 veterinary medicinal product per kg body weight per day). This dose has to be administered on 2 consecutive days.

Dose calculation:
Based on the recommended dose and the number and weight of animals to be treated, the exact daily dose of the veterinary medicinal product should be calculated according to the following formula:

ml veterinary medicinal product/day = total estimated body weight (kg) of pigs to be treated x 0.0125 ml

The intake of medicated water depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of fenbendazole may need to be adjusted accordingly.

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 veterinary medicinal 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 veterinary medicinal 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.

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

No undesirable effects have been observed in pigs at up to 5 times the recommended dose.

### 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

Meat and offal: 4 days.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code:

QP52AC13

### 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 is active and has a dose dependent activity on the adult-, intestinal and migratory stages of *Ascaris suum.*

### 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 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.

## 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: 30 months
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dilution according to directions: 24 hours.

### 5.3 Special precautions for storage

Veterinary medicinal product as packaged for sale and after first opening: Do not freeze. Protect from frost.
Medicated water: Do not freeze.

### 5.4 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.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Medicines should not be disposed of via wastewater or household waste.

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 system applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerp
Belgium

## 7. MARKETING AUTHORISATION NUMBER

Vm 30282/3018

## 8. DATE OF FIRST AUTHORISATION

05 April 2018

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

December 2023

## 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).

Approved 04 May 2024