SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pigfen 40 mg/g granules for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g contains

Active substance:
Fenbendazole 40 mg

Excipients:
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Granules
Off-white to light yellow granules.

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) susceptible to fenbendazole.

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substance, other benzimidazoles or 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

Special precautions for use in animals

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.

Accidental ingestion of the product should be avoided.

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

This product may cause eye irritation and skin sensitisation.

Avoid contact with skin and/or eyes.

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

Wash hands after use.

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

The product can be safely administered to pregnant animals.

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.

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

Oral use.

The product is only intended for the treatment of individual pigs on farms where a small number of pigs are to receive treatment.

To be mixed with a small quantity (20%) of the daily feed ration and administered prior to offering the remaining feed.

The treated feed must be prepared daily just before administration to the animals.

Pigs to be treated should be separated and treated individually.

May be administered to pigs using the following dosage regimens:

- Single dose of 5 mg fenbendazole (corresponding to 125 mg of the product) per kg bodyweight (migrating larval, intestinal larval and adult stages);
- 0.72 mg fenbendazole (corresponding to 18 mg of the product) per kg bodyweight per day for 7 consecutive days (intestinal larval and adult stages);
- 0.36 mg fenbendazole (corresponding to 9 mg of the product) per kg bodyweight per day for 14 consecutive days (intestinal larval and adult stages).

Bodyweight should be determined as accurately as possible to avoid under-dosing.

For accurate dosing use a suitably calibrated measuring device.

Part-consumed feed must be disposed of with other waste feed and not given to other animals.

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

The product administered as a single 25 mg fenbendazole/kg dose for three consecutive days did not produce any clinically apparent adverse reactions in pigs.

4.11 Withdrawal period(s)

Meat and offal: 4 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazoles and related substances, 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 cytoskeleton, formation of the mitotic spindle and the uptake and intracellular transport of nutrients and metabolic products.

5.2 Pharmacokinetic particulars

Fenbendazole is only partly absorbed after oral administration and is then metabolised in the liver. Body clearance of fenbendazole in serum after intravenous administration to pigs at a dose rate of 1 mg/kg was 1.36 L/h/kg, volume of distribution at steady state was 3.35 L/kg and the mean residence time was 2.63 hours. After oral administration at a dose rate of 5 mg/kg the peak plasma concentration of fenbendazole was 0.07µg/ml, the T_{max} was 3.75 hours and the mean residence time was 15.15 hours. The bioavailability was 27.1 %. Oxfendazole was the major plasma metabolite i.e 2/3 of the total AUC.

Fenbendazole and its metabolites are distributed throughout the body and high concentrations can be found in the liver.

The elimination of fenbendazole and its metabolites occurs primarily via the faeces (>90%) and to a small extent in the urine and milk.

Fenbendazole is metabolised to its sulphoxide, then to sulphone and amines.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Pregelatinised starch

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

6.4 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.

6.5 Nature and composition of immediate packaging

Polyethylene/aluminium foil/polyethylene terephthalate zipper bags of 0.250 kg, 0.500 kg and 1 kg.

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

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 Antwerp
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 30282/4023

9. DATE OF FIRST AUTHORISATION

16 September 2015

10. DATE OF REVISION OF THE TEXT

June 2020

Approved: 04 June 2020