Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Pigfen 40 mg/g premix for medicated feeding stuff for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance
Fenbendazole 40 mg

Excipients

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
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.

Inappetent animals should be treated individually.

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.

This product may cause eye irritation.

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

Wash hands after use.

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

Do not eat or smoke during handling the premix or the medicated feed.

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

For oral administration. In-feed use.

The product is suitable for herd medication of pigs. Administer at a dose rate of 5 mg fenbendazole per kg bodyweight.

May be administered to pigs either as a single dose of 5 mg/kg (migrating larval, intestinal larval and adult stages) or by divided dose of 0.72 mg/kg over 7 days(intestinal larval and adult stages) or 0.36 mg/kg over 14 days (intestinal larval and adult stages)

Single dose treatment

Use the following formula to calculate how much product to add per tonne of feed:

$$\text{Kg Powder per tonne} = \frac{\text{Bodyweight (kg)}}{\text{(Daily feed intake (kg) x 8)}}$$

7 day treatment

The standard dose rate can be divided and administered in feed over 7 days. Use the following formula to calculate how much product to add per tonne of feed:

$$\text{Kg Powder per tonne} = \frac{\text{Bodyweight (kg)}}{\text{(Daily feed intake (kg) x 56)}}$$

14 day treatment

The standard dose rate can be divided and administered in feed over 14 days. Use the following formula to calculate how much product to add per tonne of feed:

$$\text{Kg Powder per tonne} = \frac{\text{Bodyweight (kg)}}{\text{(Daily feed intake (kg) x 112)}}$$

To avoid under dosing, all incorporation rate calculations as presented above should be based on the heaviest pig in the group.

For incorporation into dry feed at the registered mill.

A manufacturer who is approved to incorporate veterinary medicinal products, or premixtures containing such products, directly at any concentration, must be responsible mixing when incorporation is less than 2 kg per tonne for final feed.

To ensure adequate distribution of the product in the final feed it is recommended to premix the 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 85 °C .

Not to be mixed in liquid feed.

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

Pigfen administered as a single 25 mg fenbendazole/kg dose for three consecutive days did not produce any clinically apparent adverse reactions in pigs. In addition, it has been shown that administration of non-formulated fenbendazole at a dose of 2000 mg/kg for 14 consecutive days was well tolerated in pigs.

4.11 Withdrawal Period(s)

Meat and offal: 4 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 binding to beta-tubulin, thereby inhibiting the polymerisation of tubulin to microtubules and subsequently interfering with energy metabolism.

The anthelmintic affects both adult and immature stages of *Ascaris suum*.

5.2 Pharmacokinetic properties

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
Starch, pregelatinised

6.2 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: 3 years.
Shelf life after first opening the immediate packaging: 3 months.
Shelf life after incorporation into meal or pelleted feed: 3 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Multiple-layer paper bag with internal aluminium/polyethylene layer of 20 kg.
Polyethylene/aluminium foil/polyethylene terephthalate zipper bag of 1, 2 and 5 kg.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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(S)

VPA 10782/021/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th December 2016

10 DATE OF REVISION OF THE TEXT