SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Curofen 50 mg/g oral powder for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:

Fenbendazole 50 mg

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder.
A white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

For the treatment of benzimidazole susceptible mature and immature (L_4) forms of the following nematodes of the gastrointestinal and respiratory tracts of pigs:

Hyostrongylus rubidus (red stomach worm)

Oesophagostomum spp. (nodular worms)

Ascaris suum (eelworm)
Trichuris suis (whipworm)
Metastrongylus apri (Lungworm)

4.3 Contraindications

Do not use in known cases of hypersensitivity to the active substance, other benzimidazoles 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.
- Underdosing, 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 veterinary medicinal product to animals

Embryotoxic effects cannot be excluded. Pregnant women must take extra precautions when handling this veterinary medicinal product

This product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to fenbendazole should avoid contact with the veterinary medicinal product.

Avoid skin contact when handling this product.
When handling or mixing, care should be taken to avoid direct contact with the skin and inhalation of any dust by wearing protective clothing, including impervious gloves and a face-mask. It is recommended to use either a disposable half-mask respirator conforming to European Standard EN 149 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.

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.

Other Precautions

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

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product can be used in pregnant or lactating sows.

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 by adding to small quantities of feed for immediate consumption by individual pigs.

Individual Treatment – single dose
The recommended therapeutic dose is 5 mg fenbendazole per kg bodyweight as a single dose individual treatment which is equivalent to 1g of product per 10kg bodyweight or 5g of product per 50 kg bodyweight or 20g of product per 200 kg bodyweight.

To ensure the correct dosage and to avoid possible under-dosing, the bodyweight and the amount of product to be administered should be determined as accurately as possible. To accurately measure the correct amount of product, a suitably calibrated weighing scale should be used.
The recommended amount of veterinary medicinal product should be added to a small quantity of the estimated daily amount of food for each individual animal in a bucket or a similar container and mixed thoroughly prior to being offered for immediate consumption.
Medicated feed should be freshly prepared before administration.
Part-consumed feed must be disposed of with other waste feed and not given to other animals.

Dosing table:

Pig Bodyweight (kg)	Amount (g) of product
50 kg	5g
100 kg	10g
150 kg	15g
200 kg	20g

For use in individual pigs on farms where only a small number of pigs are to receive the veterinary medicinal product. Larger groups should be treated with medicated feeding stuff manufactured using an appropriate anthelmintic premix.

Treatment for specific infections
For the treatment of *Trichuris suis*, it is recommended that the dosage is divided and administered over seven days.

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

None known.

4.11 Withdrawal period

Meat and offal: 6 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazole derivatives – fenbendazole.
ATCvet code: QP52AC13.

5.1 Pharmacodynamic properties

Fenbendazole is a broad spectrum anthelmintic from the benzimidazole-carbamate group. Benzimidazoles bind to nematode tubulin, a protein necessary for the formation and viability of microtubules. This occurs primarily in absorptive intestinal cells resulting in a complete absence of microtubules in the intestinal cells of the nematode, which means that these cells cannot absorb nutrients, a consequent reduction in glycogen and effective starvation of the parasites. Structural differences have been shown to exist between tubulin from mammalian and helminth sources, thus resulting in the preferential toxicity of fenbendazole to the helminth and not to the host. Fenbendazole may also inhibit energy production in helminths by inhibition of glucose uptake and glycogen breakdown.

5.2 Pharmacokinetic particulars

Fenbendazole is poorly soluble in water and consequently is poorly absorbed when administered orally. The main breakdown products are the sulphoxide (oxfendazole) and sulphone.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose monohydrate
Silica, colloidal anhydrous

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: 3 years
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Store in a dry place.
Store in the original container in order to protect from light.

6.5 Nature and composition of immediate packaging

200 g and 1kg bag composed of clear low density polyethylene (LDPE) laminated with metallised polyester.
1 kg bag composed of clear low density polyethylene (LDPE).

Package sizes:
5 x 200g LDPE laminated bags in a cardboard box
1 kg LDPE laminated bag
1 kg LDPE bag inside a white polypropylene container

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 fish and other aquatic organisms.

7. MARKETING AUTHORISATION HOLDER

Univet Ltd.
Tullyvin
Cootehill
Co. Cavan
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 05150/4004

9. DATE OF FIRST AUTHORISATION

04 December 2015

10. DATE OF REVISION OF THE TEXT

March 2021

Approved: 09/03/21